Site Imaging Manual
ACRIN 6702

A MULTI-CENTER STUDY EVALUATING THE UTILITY OF DIFFUSION WEIGHTED IMAGING FOR DETECTION AND DIAGNOSIS OF BREAST CANCER

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Letter of Introduction

Dear Imaging Staff,

This Site Imaging Manual contains the image acquisition instructions for the ACRIN 6702 Trial: “A Multi-Center Study Evaluating the Utility of Diffusion Weighted Imaging for Detection and Diagnosis of Breast Cancer.”

To successfully meet the study objectives, it is critical that the DWI image datasets are acquired according to the imaging protocol detailed in this manual.

Quality Control (QC) review of the images will be performed by the ACR Imaging Core Laboratory. This review will be performed in a timely fashion, as part of ACRIN standard operating procedures. If any protocol deviations or technical issues are identified during the review, an ACR Core Lab Imaging Technologist will contact your site to provide feedback expeditiously. This will allow your site to make any necessary adjustments early in the conduct of the study.

The ACRIN 6702 Imaging Team wishes to thank you in advance for your diligence in adhering to the procedures described in this manual to ensure the integrity of the image data collected for the study. Please do not hesitate to contact the ACRIN 6702 Imaging Technologist (see contact information below) if you have any questions.

Sincerely,

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**ACRIN 6702 Study Schema**

1. Woman scheduled for clinical breast MRI
2. Undergoes breast MRI with DCE and DWI
3. If BI-RADS 3, 4, or 5 lesion based only on DCE-MRI, participant is enrolled and continues on study
4. Imaging data transferred to ACRIN (including site ADC calculation)
5. Centralized ADC calculation by ACRIN Core Laboratory
6. Lesion biopsied and/or 1 year of follow-up assessments
7. ROC Analysis (benign vs. malignant)

- Participant consents to study
- Central vs. Site ADC comparisons

**Malignant**

**Benign**
1.0 Imaging Requirements

<table>
<thead>
<tr>
<th>Protocol Specific Application (PSA)</th>
<th>Submission of this document verifies that a site has the necessary personnel, equipment, and referral base to carry out the requirements specific to the ACRIN 6702 protocol</th>
</tr>
</thead>
</table>
| General Requirements               | • 1.5T or 3T whole body MRI scanner  
• Site must utilize a dedicated breast radiofrequency coil  
• Site must acquire pre-contrast DWI as standard of care |
| TRIAD Installation                | TRIAD 4 will be the sole means of image transfer to the ACR Core Laboratory. TRIAD 4 should be installed prior to study participant enrollment to ensure prompt secure, electronic submission of imaging. |
| DWI Qualification                  | Submit prior to ACRIN 6702 study enrollment (for each scanner):  
• DWI Phantom Qualification Exam  
• (2) DWI and DCE-MRI In Vivo Test Scans  
(acquired per the ACRIN 6702 standardized imaging protocol)  
*Scanners that are currently qualified for ACRIN 6698 will not need to re-qualify for ACRIN 6702* |
| Standardized DWI Phantom Biannual Re-qualification | DWI phantom re-qualification performed every 6 months |
| Standardized DWI Phantom Re-qualification for Maintenance | The qualification phantoms must be rescanned prior to any subsequent participant scan if there are any substantive changes in scanner hardware, software, or coil during the trial. |

2.0 Study Overview

This is a single arm multi-institution study with the primary objective of determining whether quantitative DWI can decrease the biopsy rate of conventional breast DCE-MRI. The study design incorporates observational analysis of DWI in women undergoing breast MRI. ADC values will be measured for breast lesions identified on DCE-MRI (BI-RADS 3, 4, or 5) to evaluate the ability to distinguish benign and malignant lesions based on ADC. We plan to recruit 100 women with breast lesions (BI-RADS 3, 4, or 5) identified by conventional breast DCE-MRI requiring either biopsy, surgical excision or short-interval imaging follow-up. We anticipate
accrual for the study will take 12 months, with approximately 10 participating ACRIN-approved sites that acquire DWI in their standard clinical MRI protocol. Site qualification for study participation will require passing quality control (QC) requirements as specified in this manual. At participating sites, all potentially-eligible participants will be informed of the study and, if interested, will be consented prior to undergoing clinical breast MRI to include a DWI scan. Sites will use a standardized acquisition sequence per the study protocol. At the time of interpretation, the site radiologists will record a BI-RADS assessment to determine study eligibility prior to reviewing DWI. Those with lesions identified on MRI as BI-RADS 3, 4, or 5 will be enrolled in the study. Participants who do not have lesions assessed as BI-RADS 3, 4, or 5 will not be enrolled in the study. Sites will measure the lesion ADC values, and all images, measures, and associated clinical and pathological data will be sent to the ACR Imaging Core Laboratory. All enrolled participants will be followed at 30 days, 6 months, and 12 months post-MRI. In addition, participants with study lesions not biopsy-proven to be malignant (including biopsied benign and non-biopsied lesions), follow-up at 12 months post-MRI will be required to verify benign outcome. ACRIN will perform a centralized read of DWI to measure lesion ADC and normal breast tissue ADC values, with researchers blinded to lesion outcomes and site ADC measurements. Data analysis will then be performed to compare ADC values in benign and malignant lesions and address the study objectives.

### 3.0 Scanner Qualification

Participation in ACRIN 6702 requires that all sites adhere to a standardized MRI imaging protocol. The use of standard imaging guidelines is an essential component of clinical trials in which imaging plays a central role in the research endpoints. This is of particular importance in multicenter trials where equipment, personnel, and imaging acquisition protocols can vary significantly. Thus, the use of standardized imaging guidelines helps control the inter- and intra-site variability inherent in multicenter imaging trials.

To participate in the ACRIN 6702 trial, each site must qualify by first scanning the DWI ice water phantom based on ACRIN 6702 phantom scanning protocol (see Appendix I for instructions). Phantom scanning provides an opportunity to evaluate compliance with sample imaging acquisition protocols prior to participant recruitment and actual trial-specific protocols. In addition to the phantom scan, each site will be required to submit at least (2) DCE-MRI and DWI in vivo test scans.

These qualification examinations will be reviewed by the ACR Imaging Core Lab for both protocol compliance and image quality; approval of the qualification exams is required prior to ACRIN 6702 site activation. Suboptimal image quality and/or imaging not performed per the trial-standardized protocol can result in exclusion of the imaging exam(s) and/or the
entire case from analysis. Therefore, routine QC and adherence to the ACRIN 6702 image acquisition protocol are of great importance. Sites will be asked re-qualify biannually using the phantom and if there should be any substantive changes in hardware or software to the scanner during the conduct of the trial.

3.1 **DWI Phantom Scanning**

Prior to participant enrollment, a DWI phantom qualification scan must be run. Upon receipt of the ACRIN 6702 Protocol-Specific Application (PSA), a pair of DWI phantoms will be delivered to the site for system qualification. The phantoms consist of a pair of 1.5 liter white plastic containers with a sealed 75ml tube pre-filled with distilled water. The design of this phantom allows for the measurement of apparent diffusion coefficient (ADC) values of a known temperature-controlled fluid to confirm proper MRI system performance in acquisition of diffusion weighted (DW) imaging. Upon completion and approval of the DWI phantom qualification imaging, sites are asked to keep the ice-water phantom in the event that there is a need for DWI phantom re-qualification.

Please see Appendix I for detailed DWI phantom qualification scan parameters and instructions.

3.2 **DWI and DCE-MRI In Vivo Test Scans**

After receiving ACRIN-approval of the DWI phantom scan, (2) *in vivo* DWI and DCE-MRI test scans are required for each scanner to be approved for study imaging.

The DWI test scans should be acquired per the trial specific acquisition protocol parameters provided in Appendix II of this Imaging Manual.

The DCE-MRI portion of the test scan should be acquired according to the ACR Breast MRI guidelines found on the ACR Breast MRI Accreditation website. [http://www.acr.org/~/media/ACR/Documents/Accreditation/BreastMRI/Requirements.pdf](http://www.acr.org/~/media/ACR/Documents/Accreditation/BreastMRI/Requirements.pdf)
3.3 Qualification Review

All phantom and in vivo qualification exams will be evaluated for image quality (e.g. artifacts, distortion, and signal-to-noise) and compliance with the standardized acquisition protocol. An ACR Imaging Core Lab Technologist will notify the site of the results of the qualification review via e-mail. E-mail documentation will include your site’s Study Coordinator (SC), site PI, and lead technologist to inform the site team whether the qualifying exams have been approved or not. If the qualifying exams are not approved, required corrections for rescanning will be included in the e-mail.

3.4 Changes to Qualified Scanner(s) and/or Breast Coil

Changes in the scanner or breast coil used to image ACRIN 6702 study patients should be reported immediately to the ACR Imaging Core Lab. The addition of a new scanner or breast coil for study imaging will require full scanner qualification. Software and/or hardware upgrades to already qualified scanners will be reviewed by the ACR Imaging Core Lab to determine whether additional QC testing will be required. In either case, use of a new scanner/breast coil or software/hardware upgrades, sites should consult the ACR Imaging Core Lab prior to scanning study participants.

3.5 Bi-annual Phantom Re-qualification

For each qualified scanner, sites are required to conduct DWI phantom retest every 6 months using the same phantom and testing procedures used for the initial qualification testing. The purpose of bi-annual phantom re-qualification is to provide a standardized, quantitative process to confirm ongoing MRI system performance in acquisition of diffusion weighted (DW) images of the breast.

ACRIN will identify a testing schedule for each site based on the approval date of the initial site qualification testing.

3.6 Qualifying Exam Submission

All qualifying image submissions will be submitted via TRIAD 4. Please refer to section 9.1 of this manual for TRIAD 4 submission details.

NOTE:

Scanners that are currently qualified for ACRIN 6698 will not need to re-qualify for ACRIN 6702

4.0 Participant Eligibility

4.1 Inclusion Criteria

- Willing and able to provide written informed consent
• 18 years of age or older
• Successful completion of breast MR examination with DWI required by protocol
• Undiagnosed breast lesion (BI-RADS 3, 4, or 5) identified on MRI; The BI-RADS assessment must refer to a focal finding within the breast (i.e. mass, non-mass, or focus) as opposed to diffuse processes (e.g. background parenchymal enhancement, skin thickening) or lesions outside the subcutaneous breast (e.g. axillary lymph nodes, focal skin lesions, osseous lesions, etc.)

4.2 Exclusion Criteria
• Patients with current or recent history (6 months prior to the MRI) of chemotherapy for cancer
• Neoadjuvant chemotherapy between MRI and confirmation of lesion outcome (study lesions must be biopsied prior to undergoing any chemotherapy)
• Pregnant (if a female is of childbearing potential - defined as a pre-menopausal female capable of becoming pregnant - confirmation of pregnancy status per the site’s standard of practice should be done prior to MRI)
• Unwilling or not suitable to undergo MRI or use the contrast agent gadolinium. Sites will comply with their institutional standard policies and procedures for performance and assessment of conducting MRI and the use of gadolinium in their patients

5.0 Participant Screening

Sites will recruit potential participants scheduled for a clinical breast MRI examination including both DWI and DCE scans. These participants should be consented for potential participation in the trial. Only participants with lesions deemed probably benign (BI-RADS 3) or malignant (BI-RADS 4 or 5) by conventional MRI will qualify for the study. After the potential participant has been deemed eligible, confirmed by conventional MR images (without DWI), sites will register the participant to the trial in Medidata Rave. Participants who do not have MRI-detected lesions assessed as BI-RADS 3, 4, or 5 are not eligible and will not be registered. Sites will comply with their institution’s IRB requirements in maintaining a screening log including the number of consented potential participants and reasons for not enrolling them into the trial.

Each site will maintain all documentation of the screening and eligibility assessments, as well as documentation for all clinical procedures, as related to the trial and study-related procedures for source verification.
6.0 Participant Preparation

- Prepare participant according to local standard practice, including any pre-treatment for severe claustrophobia or anxiety, testing renal functioning, and/or testing for pregnancy.
- Patient should be scanned in a dedicated breast radiofrequency coil in the prone position
- An in-dwelling IV catheter should be placed in preparation for a single dose contrast agent injection (FDA-approved gadolinium-based contrast agent)

7.0 Recommended Breast MRI Sequences

Each submitted breast MRI study must meet the ACR Breast Accreditation technical parameter requirements.

Refer to: [http://www.acr.org/~/media/ACR/Documents/Accreditation/BreastMRI/Requirements.pdf](http://www.acr.org/~/media/ACR/Documents/Accreditation/BreastMRI/Requirements.pdf) for detailed recommended acquisition parameters.

At a minimum, the following sequences should be acquired:

- Localization scan
- T2-weighted sequence with fat saturation performed before contrast
- Protocol specific multi-b value DWI acquisition (prior to injection)
- Multi-phase contrast-enhanced T1-weighted series:
  - T1-weighted sequence performed once pre-contrast and multiple times post-injection using identical sequence parameters

8.0 Protocol Specific DWI Acquisition

The DWI scan must be acquired prior to the DCE sequence using a diffusion-weighted spin echo-echo planar imaging (DW SE-EPI) sequence. Please refer to Appendix II of this manual for detailed parameter recommendations.

- Axial orientation
- Diffusion gradients applied in three orthogonal directions to measure isotropic ADC
- Parallel imaging (reduction factor > 2)
- Fat suppression utilizing the optimal technique (SPAIR, STIR, etc.) for the MRI scanner being used
- Minimum of 4 b-values: 0, 100, 600 and 800 s/mm²
- Acquire the maximum number of slices that can be acquired during a single acquisition (typically 24-30 slices); coverage should be adjusted to keep the scan
within a single acquisition to minimize scan time and motion artifacts. Total scan duration for the DWI multi-b value sequence should be on the order of 5 minutes.

9.0 Data Submission

9.1 Submission of Image Data to ACR Core Lab

ACRIN 6702 imaging should be submitted to the ACR Imaging Core Lab via TRIAD 4 within 48 hours of acquisition. TRIAD® is ACR’s proprietary image exchange application that will be used as the sole method of data transfer to the ACR Clinical Research Center Core Laboratory for this trial. ACRIN will provide installation on one or several computers of choice within the institutional “firewall” and on the institutional network; internet access is 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 de-identifies, encrypts, and performs a lossless compression of the images before they are transferred to the ACRIN image archive in Philadelphia.

Please refer to Appendix III for detailed TRIAD 4 registration and installation procedures. For more information, contact: TRIAD-support@phila.acr.org or call 215-940-8820.

9.2 De-identification of Image Data

Sites are urged not to employ the use of other de-identification software before uploading the images to TRIAD 4, as these applications are typically not developed for research purposes and may remove data pertinent to the research. TRIAD 4 removes patient information and replaces it with site and study-specific identifiers provided by and at the site. The implementation of TRIAD 4 anonymization is based on DICOM Supplement 142: Clinical Trial De-Identification Profiles, ftp://medical.nema.org/medical/dicom/final/sup142_ft.pdf.

9.3 Image Transmittal Worksheet (ITW)

All imaging should be submitted within 48 hours after acquisition and should include an Image Transmittal Worksheet (ITW). An Image Transmittal Worksheet (ITW) is used during the exam QC review to verify a complete transfer of images has been submitted to the ACR Imaging Core Lab. The ITW is completed in the Medidata/Rave data management system and upon the completion of this form, an email will be automatically generated to the ACR Imaging Core Lab Technologist to notify an image submission has taken place.
10.0 Site Image Review Procedures

10.1 Site DWI Image Review

The DWI sequence should be reviewed at the site for protocol compliance and image quality. This assessment will include:

- Proper acquisition parameters, including FOV, matrix, phase direction, slice thickness, and use of fat saturation
- Proper anatomic prescription to include entire breast and axilla
- Proper number and choice of B values
- Acceptable signal-to-noise ratio
- Absence of severe artifacts that would render the series clinically non-diagnostic

10.2 Site Lesion ADC measurement

ADC measures will be performed for each study lesion by ROI by the site radiologist. An ROI will be drawn over the largest solid tumor region on DWI, with tumor size and location determined from corresponding DCE-MRI images. Areas of necrotic, cystic, or adipose tissue will be avoided by referencing to T1- and T2-weighted images and ADC maps in defining the ROIs. **A screen capture will be saved in each case to illustrate ROI placement for reporting.**
11.0 ACR Core Laboratory Image Quality Control Procedures

11.1 ACR Core Laboratory Quality Control Review

Upon receipt of the images at the ACR Imaging Core Lab, an initial QC review will be conducted by a qualified Core Lab Imaging Technologist. The Core Lab Imaging Technologist will check for missing images/sequences, appropriate image anonymization, complete anatomical coverage of the breast and axilla, adherence of all sequences to imaging protocol, and absence of image artifact.

In cases where image sets are judged to be suboptimal ("technically inadequate"), the trial PI will be informed, and a replacement participant will be accrued from participating institution.

11.2 Image Data Queries

If it is found during the QC review that the submitted exam has missing data or does not follow the protocol guidelines, detailed in this manual, the Medidata/Rave data management system will generate an auto-query. Sites are expected to resolve data queries expeditiously. Queries not resolved within 7 business days will be sent to the ACRIN 6702 trial team for additional follow-up.

12.0 Imaging Forms

There are 3 imaging forms that must be completed and submitted via the Medidata/Rave eCRF system for each DCE/ DWI exam.

- MRI Image Transmittal Worksheet (ITW)
- DCE-MRI Assessment Form
- DWI Assessment form

It is recommended that each of the above forms be made available, in hard copy format, for the Imaging Technologists and Clinicians to be completed during image acquisition and interpretation when the requested information on these forms is most readily available.
Appendix I

DWI Phantom Test Instructions
DWI PHANTOM TEST INSTRUCTIONS

Objective:

Measure apparent diffusion coefficient (ADC) values of a known temperature-controlled fluid to confirm proper MRI system performance in acquisition of diffusion weighted (DW) images of the breast.

DWI Ice Water Phantom Preparation Procedure:

Once prepared, ice water phantoms require approximately 1 hour to reach thermal equilibrium. Please plan on filling the phantoms well in advance of scanning. Once at thermal equilibrium, phantoms will be usable for several hours. Do not dispose of foam insulation sleeves and zip-lock plastic bags shipped with each phantom.

1. Each phantom consists of a 1.5 liter white plastic container with a sealed 75 ml tube pre-filled with distilled water. Leave the 75 ml tubes sealed and affixed within each container. For phantom preparation, temporarily remove containers from the foam insulation sleeves and zip-lock bags.

2. You will need a source of ice cubes or ice chips and a sink basin. The volume of ice cubes/chips required is approximately twice the volume of the white containers. Fill each white container to the top with ice cubes/chips then add cold tap water and fill to the top – the colder the water, the better. Loosely cap each phantom for an initial “cool down period” of approximately 10 minutes.

3. Depending on how cold your tap water is, much of the ice will melt relatively quickly. Therefore after 10 minutes, re-open each container and add more ice to replace the melted ice. Fill ice to the top allowing displaced water to overflow into the sink. The objective is to have ice cubes to the full depth of the phantom and the interstitial space filled with water and minimal air (Figure 1). Screw cap on tightly, dry off each phantom and inspect for leaks.

4. Put each phantom into a foam insulation sleeve with the container top at the open end of the sleeve and seal each phantom in a zip-lock bag. Set the phantoms aside for an additional 50 minutes to allow the central tubes to come to thermal equilibrium with the surrounding ice water. As long as there is adequate ice in the phantom, temperature will be controlled to near 0°C thereby holding water within the tubes at a known diffusion coefficient. The phantoms should be usable for several hours within the insulation sleeves. If desired, you can store phantoms in a refrigerator (not a freezer) to extend the usable time.

Figure 1: MRI of DWI phantom contents
5. After scanning, simply empty the ice water down the drain but leave the central tubes filled and sealed for use at a later date by following the same procedure.

**DWI Ice Water Phantom Scan Procedure:**

Start a “New Patient/Exam” using same dedicated breast coil and patient entry convention normally used for bilateral diagnostic breast MRI exams (e.g., “Feet first, Prone”). Keep phantoms in their zip-lock bags and insulation sleeves during the scan procedure to keep condensate off of MRI system components. Center the phantoms in each of left and right breast coil wells with phantom caps facing up (toward “patient’s posterior”). Wedge the phantoms using patient support pads to hold the phantoms firmly in place with the water tubes approximately vertical (i.e., parallel to Ant/Post axis) as shown in Figure 2. Precise alignment is not required, although the phantoms should be positioned similar to left and right breasts of a typical patient.

![Figure 2: Positioning of DWI ice water phantoms](image)

**Overview of Series Required for DWI QC Phantom Scanning:**

1. Three-plane scout/survey
2. Axial 3D bilateral axial T1-weighted spoiled gradient echo without fat-suppression
3. Bilateral axial DWI using single-shot echo-planar-imaging (EPI) at b-values=0, 100, 600, 800s/mm². A set of DWI containing all 4 b-values is called one “pass”.
4. “Copy-&-Paste” the DWI series and repeat to acquire a total of four passes in immediate succession in four consecutive series. Avoid changing scanner pre-scan/hardware settings between these consecutive series.

**Details of Required Series:**

1. Three-plane scout/survey: Use site-preferred breast survey sequence as used for graphic prescription of subsequent series.

2. Axial 3D bilateral T1-weighted spoiled gradient echo without fat-suppression:
   
   \[ \text{FOV} = 320 \text{mm (R/L phase)} \times 320 \text{mm (A/P frequency)} \] at 256 x 256 matrix.
   
   Acquire 2mm slice thickness interpolated to 1mm. Acquire sufficient slices to cover 120mm in the superior/inferior direction. TR=4-10ms, TE=min, flip angle 10°, single average, acquisition time <3min.

3. Axial single-shot isotropic diffusion weighted single SE, echo planar imaging (EPI) by parameter settings listed in Table 1. **One DWI “pass” should contain all 4 b-values.** Copy and paste the DWI series so that 4 consecutive passes are acquired in separate series. Total scan time for DWI is approximately 4 passes x 3min/pass = 12min.

**Table 1. DWI Ice Water Phantom Scan Parameters**

<table>
<thead>
<tr>
<th>Field Strength</th>
<th>1.5T or 3T</th>
<th>DWI Sequence</th>
<th>Single-Shot SE EPI</th>
<th>Single Echo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Receiver Coil</td>
<td>Bilateral Breast</td>
<td>TR (ms)</td>
<td>&gt;8000</td>
<td></td>
</tr>
<tr>
<td>FOV (mm)</td>
<td>320 x 320</td>
<td>TE (ms)</td>
<td>75-100</td>
<td></td>
</tr>
<tr>
<td>Acquisition Matrix</td>
<td>160 x 160 (a)</td>
<td>Half-scan, Partial-Fourier, Frac-NEX</td>
<td>No (a)</td>
<td></td>
</tr>
<tr>
<td>Reconstruction Matrix</td>
<td>256 x 256 (b)</td>
<td>Number of Gradient Directions (c)</td>
<td>3 orthogonal axes</td>
<td></td>
</tr>
<tr>
<td>Orientation</td>
<td>Bilateral Axial; Frequency A/P; Foldover Phase R/L</td>
<td>Freq Enc Bandwidth per Acq Pixel (Hz) (d)</td>
<td>1000 to 2600</td>
<td></td>
</tr>
<tr>
<td># of Slices</td>
<td>30</td>
<td>Parallel Imaging Factor (eg. SENSE)</td>
<td>2 (on 1.5T) 3 (on 3T)</td>
<td></td>
</tr>
<tr>
<td>Slice Thickness (mm)</td>
<td>4</td>
<td>b-values (s/mm²) (e)</td>
<td>0, 100, 600, 800</td>
<td></td>
</tr>
<tr>
<td>Gap (mm)</td>
<td>0</td>
<td># Signal Averages</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Image Filtering (eg.SCIC or CLEAR)</td>
<td>Off</td>
<td>Fat Suppression (f)</td>
<td>On</td>
<td></td>
</tr>
</tbody>
</table>

a. Some systems may require “half-scan”, “partial-Fourier”, or “fractional-NEX” in DWI scans. It is preferred to acquire the full phase-encode matrix = 160 by setting half-scan/ partial-Fourier/Fractional-NEX to “No” or at least as close to 1 as possible.

b. Interpolate image matrix to 256 x 256. Some systems may do this automatically.
c. Acquire DWI along three orthogonal axes so that “isotropic” or “trace” diffusion weighted images are generated for each slice and b-value. “Tetrahedral” or “Gradient Overplus” diffusion encoding schemes are allowed wherein combinations of X, Y and Z gradients are applied simultaneously for each orthogonal DWI axis. Individual diffusion axes DW images are not required. Only the b=0 and DWI trace images at each b-value are required.

d. Frequency encoding bandwidth may not be under full operator control. If possible use “maximum bandwidth”, or equivalently “minimum fat shift per pixel”, or set within 1000 to 2600 Hz/pixel range.

e. Use site-preferred spectral fat suppression technique. Do NOT use the Inversion-Recovery fat suppression technique “STIR” for DWI Phantom scans.

ADC Map Generation:

Generate ADC maps for all slices using software tools available on the scanner. The ADC map should be derived from the full set of b-values = 0, 100, 600, 800. If possible, take a “screenshot” of a region-of-interest (ROI) drawn in a central tube region showing ROI size/location and resultant statistics. The screenshots should be simply saved within the phantom examination for transfer to ACRIN as DICOM images. Site certification and QC calculations will be performed on ADC maps generated at ACRIN core lab, however, the screenshots are helpful to confirm proper image scaling and equivalence in ADC calculation routines.

Image Submission:

Do not de-identify DWI phantom images before uploading to TRIAD 4. Submit all DWI phantom images, including screen-shots, to the ACR Imaging Core Laboratory via TRIAD 4 under the ACRIN 6702 study. It is important to note that all images must be in DICOM format.
Appendix II

DWI Acquisition Parameters
### Table 1. DWI Acquisition Parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>DWI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sequence type</td>
<td>DW SE-EPI</td>
</tr>
<tr>
<td>2D or 3D sequence</td>
<td>2D</td>
</tr>
<tr>
<td>Fat-suppression</td>
<td>Active fat-sat</td>
</tr>
<tr>
<td>Slice orientation</td>
<td>Axial</td>
</tr>
<tr>
<td>Laterality</td>
<td>Bilateral</td>
</tr>
<tr>
<td>Phase direction</td>
<td>A/P (R/L optional)</td>
</tr>
<tr>
<td>In-plane resolution</td>
<td>1.5 – 2.0 mm</td>
</tr>
<tr>
<td>FOV</td>
<td>36cm (optional)*</td>
</tr>
<tr>
<td>Matrix (acquired)</td>
<td>See Table 2</td>
</tr>
<tr>
<td>Reconstruction Matrix</td>
<td>256 x 256</td>
</tr>
<tr>
<td>Slice thickness (acquired)</td>
<td>4 mm</td>
</tr>
<tr>
<td>Slice Gap</td>
<td>No gap</td>
</tr>
<tr>
<td>TR</td>
<td>≥ 4,000 ms</td>
</tr>
<tr>
<td>TE</td>
<td>Minimum (50-100ms)</td>
</tr>
<tr>
<td>Bandwidth (Water-Fat shift)</td>
<td>Max (Water-Fat shift = Min)</td>
</tr>
<tr>
<td>Flip Angle</td>
<td>90 degrees</td>
</tr>
<tr>
<td>b values</td>
<td>0, 100, 600, 800 s/mm²</td>
</tr>
<tr>
<td>Number of Gradient Directions</td>
<td>3 orthogonal axes</td>
</tr>
<tr>
<td>Parallel imaging factor</td>
<td>≥ 2</td>
</tr>
<tr>
<td>Number of excitations/averages</td>
<td>≥ 2</td>
</tr>
<tr>
<td>Sequence acquisition time</td>
<td>Approx. 5 minutes</td>
</tr>
</tbody>
</table>

*Set FOV based on body habitus to include both breasts and axilla and to avoid wrap artifacts

### Table 2. FOV and Matrix Settings

- **On systems where Acquired Voxel Size is entered, set in-plane voxel size between 1.5 – 2.0 mm**

<table>
<thead>
<tr>
<th>FOV (mm)</th>
<th>Acquisition Matrix</th>
</tr>
</thead>
<tbody>
<tr>
<td>260 to 280</td>
<td>140 to 173</td>
</tr>
<tr>
<td>281 to 300</td>
<td>150 to 187</td>
</tr>
<tr>
<td>301 to 320</td>
<td>160 to 201</td>
</tr>
<tr>
<td>321 to 340</td>
<td>170 to 214</td>
</tr>
<tr>
<td>341 to 360</td>
<td>180 to 227</td>
</tr>
<tr>
<td>361 to 380</td>
<td>190 to 241</td>
</tr>
<tr>
<td>381 to 400</td>
<td>200 to 254</td>
</tr>
<tr>
<td>401 to 420</td>
<td>210 to 267</td>
</tr>
<tr>
<td>421 to 440</td>
<td>220 to 281</td>
</tr>
</tbody>
</table>

- **On systems where Acquired Matrix is entered, use guide below to achieve appropriate in-plane resolution:**