ACRIN 6702

Diffusion Weighted Imaging for Detection and Diagnosis of Breast Cancer

CRF Set
Subject: Subject
Page: CT Image Transmittal Worksheet

<table>
<thead>
<tr>
<th>Date of imaging</th>
<th>Date of imaging submission</th>
<th>Mode of image submission</th>
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</thead>
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<table>
<thead>
<tr>
<th>#PET data sets submitted</th>
<th>Select all that apply</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
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</tr>
</tbody>
</table>

Add a new Log line

**COMMENTS**

- Name of Technologist
- Technologist phone number
- Technologist email

**Printable Version Icon Key**

**IMPORTANT REQUIREMENT:** This form must be signed by the Radiologist to confirm that DCE-MRI was reviewed before DWI.

Date of MRI scan

Reader Name

Total number of BI-RADS 3, 4, and 5 MRI-detected lesions that were not previously biopsied.

| # | Lesion number | Breast | Quadrant | Clock position | Distance from the nipple (mm) | MRI finding type | ML Size | SI Size | AP Size | Shape | Margin | Internal enhancement | NME Enhancement | Internal enhancement patterns | T2 Signal | Initial kinetics | Delayed kinetics | BI-RADS | Recommendation | Type of additional imaging recommended |
| 1 | Data | Data | Data | Data | Data | Data | Data | Data | Data | Data | Data | Data | Data | Data | Data | Data | Data | Data | Data | Data | Data | Data | Data |

Add a new row line

Count Rows

Count Rows 6

Count rows 7

Printable Version Icon Key

<table>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>...</td>
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</tbody>
</table>

**Add a new Log line**

- **Patient Initials (LFM)?**
- **Patient's Date of Birth?**
- **Ethnicity?**
- **Gender of a Person?**
- **Country of Residence?**
- **ZIP Code?**
- **Method of Payment?**

**Printable Version · Icon Key**

Subject: Subject
Page: DWI Central Assessment

Date of MRI scan

Total number of MRI-detected lesions that are BI-RADS 3, 4, or 5 based on DCE-MRI:

DWI quality score:

In which breast was normal fibroglandular tissue measured?

Reason normal fibroglandular tissue was not measured:

Provide the normal tissue ADC values

Normal ADC b=0, 100, 600, 800:

Normal ADC b=0, 800:

Normal ADC b=0, 600:

Normal ADC b=0, 100:

Normal ADC b=100, 600, 800:

Normal ADC b=100, 600:

Normal ADC b=100, 800:
Enter one log line for each study lesion with suspicion level of BI-RADS 3, 4 or 5 based on DCE-MRI

<table>
<thead>
<tr>
<th>#</th>
<th>Lesion number</th>
<th>Breast</th>
<th>Quadrant</th>
<th>Clock position</th>
<th>Is the lesion visible on DWI?</th>
<th>ADC b=0, 100, 600, 800</th>
<th>ADC b=100, 600</th>
<th>ADC b=100, 800</th>
</tr>
</thead>
<tbody>
<tr>
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Add a new Log line

[Printable Version] [Icon Key]
Subject: **Subject**  
Page: **DWI Local Assessment**

Was ADC map calculated with all b-values? □

- No
- Yes

Provide the b-value combination used to calculate ADC map?
- ADC b=0.600
- ADC b=0.800
- ADC b=100,600,800
- Other

Enter one log line for each previously unbiopsied lesion with suspicion level of BI-RADS 3, 4 or 5 based on DCE-MRI

<table>
<thead>
<tr>
<th>#</th>
<th>Lesion Number</th>
<th>Breast</th>
<th>Quadrant</th>
<th>Clock position</th>
<th>ADC</th>
<th>Did reviewing DWI cause a change in BI-RADS or recommendation for this lesion?</th>
<th>What is the post DWI BI-RADS assessment?</th>
<th>What is the post DWI recommendation?</th>
<th>Post DWI type of additional imaging recommended</th>
</tr>
</thead>
<tbody>
<tr>
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<td>Data</td>
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Add a new Log line

Printable Version | Icon Key

CRF Draft 2781 - Page Generated: 16 Mar 2015 17:00:53 Greenwich Standard Time
Subject: Subject
Page: Eligibility Checklist

FORM_OID

Date the informed consent was signed

Was the informed consent obtained from the patient?

Has the participant received chemotherapy in the last 6 months?

Does the patient have at least one MRI-detected lesion, which has not been previously biopsied, categorized as either BI-RADS 3, 4, or 5 based on DCE-MRI only (without reference to DWI)?

Did the participant complete a breast MRI examination with DWI that meets protocol criteria?

Is the participant scheduled to begin neoadjuvant chemotherapy before pathologic confirmation of lesion outcome?
Subject: Subject
Page: End of Study

Date of disposition

Provide reason for study disposition by selecting one of the following

- Protocol defined follow up completed
- Participant lost to follow up
- Participant refused follow up/withdrew
- Death
- Adverse Event/Side Effects/Complications
- Disease progression
- Study terminated by sponsor
- Protocol violation-did not meet eligibility
- Protocol violation-technical problems
- Protocol violation-related to study visits
- Protocol violation-related to imaging
- Protocol violation-related to randomization
- Other, specify

Date of Death

Cause of Death

- Disease progression
- Other, specify

Printable Version  Icon Key
Subject: **Subject**  
Page: **Follow up-IImaging**

Was imaging of the breast performed since last study visit or follow-up time point?

- No
- Yes

Select the reason imaging was not done

- Not indicated
- Participant missed appointment
- Participant unable to be located
- Participant refused
- Referring physician's choice
- Participant's death
- Other

Enter one log line for each lesion described for each imaging procedure done since last study visit.

<table>
<thead>
<tr>
<th>#</th>
<th>Lesion number</th>
<th>Breast</th>
<th>Quadrant</th>
<th>Clock position</th>
<th>Date of imaging</th>
<th>Type of imaging performed</th>
<th>BI-RADS Assessment</th>
<th>Follow up recommendation</th>
<th>Type of additional imaging recommended</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Data</td>
<td>Data</td>
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Add a new Log line

- 27 Days
- 33 Days
- 155 Days
- 211 Days
- 338 Days
- 394 Days

Printable Version  Icon Key
**INSTRUCTIONS:** Complete one log line for each lesion reported on the DCE-MRI form. For lesions that underwent pathological sampling, add a separate log line for each procedure, repeating the lesion number.

<table>
<thead>
<tr>
<th>#</th>
<th>Lesion number</th>
<th>Breast</th>
<th>Quadrant</th>
<th>Clock position</th>
<th>Distance from the nipple</th>
<th>Was a biopsy or surgery performed on this lesion that has not previously been reported to ACRIN?</th>
<th>Reason tissue sampling was not done?</th>
<th>Date of sampling</th>
<th>Type of procedure</th>
<th>Type of image guidance used for tissue sampling</th>
<th>Procedure findings</th>
</tr>
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<tr>
<td>1</td>
<td>Data</td>
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- 27 Days
- 33 Days
- 155 Days
- 211 Days
- 338 Days
- 394 Days
Subject: Subject
Page: Follow up-Participant Status

Was follow-up information obtained for this time-point?  
○ No  ○ Yes

Reason follow-up information was not obtained: 
- Unable to contact participant's treating physician
- Unable to contact participant's family member or participant proxy
- Unable to review participant's medical record
- Unable to contact the participant

Source of information used to obtain participant data for this form:
- Site physician
- Outside physician/hospital
- Family
- Medical record
- Cancer registry
- Participant

What was the method of contact?  
○ Office visit  ○ Telephone  ○ Mail

Date the data was obtained

Participant vital status
- Alive  ○ Dead  ○ Unknown  ○ Unspecified

Date participant last known to be alive
Date of death

- 27 Days
- 33 Days
- 155 Days
- 211 Days
- 228 Days
- 394 Days

Printable Version   Icon Key
Subject: Subject
Page: Lost to Follow-Up

FORM_OID

Patient Lost to Follow-Up
Was the study participant unable to be contacted for follow-up per defined criteria?
○ No  ○ Yes

Date of last contact

#     Methods of Contact | Date of most recent attempt
1     Data               | Data

Add a new Log line

Study Participant Found
Was a study participant previously deemed lost to follow-up able to be contacted?
○ No  ○ Yes

Date most recent contact

Lost to Follow-Up Internal Review
Study participant lost to follow-up approved?
○ No  ○ Yes

Date of Approval

Printable Version  Icon Key
Subject: Mammography Image Transmittal Worksheet

Date of imaging

Date of imaging submission

Mode of image submission

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Add a new Log line

**COMMENTS**

Name of Technologist

Technologist phone number

Technologist email

Printable Version  Icon Key

Clinical indication for MRI (Check all that apply):

- Evaluate extent of disease for known breast cancer
- Further evaluation of lesion detected on other imaging
- Further evaluation of palpable lesion
- Short interval follow-up MRI
- Screening due to personal history of breast cancer
- Screening due to genetic risk or family history of breast cancer
- Evaluate implant integrity
- Known malignant axillary adenopathy, unknown primary
- Other

Specify Indication

Printable Version  Icon Key
Subject: Subject
Page: Other Image Transmittal Worksheet

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**COMMENTS**

Name of Technologist

Technologist phone number

Technologist email

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Page: PET Image Transmittal Worksheet

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