ACRIN 6698

Diffusion-weighted MRI Biomarkers for Assessment of Breast Cancer Response to Neoadjuvant Treatment: An I-SPY 2 Trial Substudy

CRF Set
**ACRIN Study 6698**

**PLACE LABEL HERE**

**Registration/Eligibility Checklist**

**Institution__________________**

**Institution No.__________**

**Participant Initials__________**

**Case No.__________**

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**DEMOGRAPHICS**

**Instructions:** The 6698 registration form (A0) is used to register cases to the 6698 trial and confirm study eligibility status. This information is submitted to ACRIN via the website: www.acrin.org.

1. **Name of institutional person registering this case**
2. **Was the eligibility check list completed?**
   - O 1 No
   - O 2 Yes
3. **Is the participant eligible for this study?**
   - O 1 No
   - O 2 Yes
4. **Date the study-specific consent form was signed (mm-dd-yyyy)**
   - (Must be prior to study entry) __-__-__
5. **Participant’s Initials (last, first) (L, F)**
6. **Verifying physician (Site PI)**
7. **Date of birth (mm-dd-yyyy) __-__-__**
8. **Ethnicity**
   - O 1 Hispanic or Latino
   - O 2 Not Hispanic or Latino
   - O 9 Unknown
9. **Gender**
   - O 1 Male
   - O 2 Female
10. **Participant's country of residence (if other, complete Q12a)**
    - O 1 United States
    - O 2 Canada
    - O 3 Other
    - O 9 Unknown
    - Q12a. Other country, specify (completed if Q12 is coded “other”) ____________
11. **Zip Code (5 digit code, US residents)**
12. **Participant's insurance status**
   - O 0 Other
   - O 1 Private Insurance
   - O 2 Medicare
   - O 3 Medicare and Private Insurance
   - O 4 Medicaid
   - O 5 Medicaid and Medicare
   - O 6 Military or Veteran’s Administration
   - O 7 Self Pay
   - O 8 No means of payment
   - O 9 Unknown/Decline to answer
13. **Will any component of the participant’s care be given at a military or VA facility?**
   - O 1 No
   - O 2 Yes
   - O 9 Unknown
14. **Calendar base date [Date of registration] (Date of ISPY-2 Registration) (mm-dd-yyyy) __-__-__**
15. **Race (check all that apply)**
   - O American Indian or Alaskan Native
   - O Asian
   - O Black or African American
   - O Native Hawaiian or other Pacific Islander
   - O White
   - O Unknown
16. **ISPY2 Participant ID #**

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ACRIN 6698
Diffusion-weighted MRI Biomarkers for Assessment of Breast Cancer Response to Neoadjuvant Treatment: An I-SPY 2 Trial Substudy
Registration/Eligibility Checklist

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

ACRIN Study 6698

Institution ________________  Institution No. ________________
Participant Initials ___________  Case No. ________________

Comments: ____________________________________________

_________________________________________________________________________

_________________________________________________________________________

_________________________________________________________________________

_________________________________________________________________________

_________________________________________________________________________

[30]

Initials of person(s) completing this form  Date Form Completed (mm-dd-yyyy)

[31]  [32]
Part I. MR Visit
1. Time point: [1] Visit 2 (baseline imaging)
2. Imaging completed? [2] Yes, Date of imaging:
   [_____ - _____ - ______ ] mm-dd-yyyy [3]
   [No, reason:] [4]
   - Equipment failure
   - Patient refusal
   - Medical contraindication
   - Injection site complications
   - Claustrophobia
   - Other, specify

Part II. Steroid use and Renal Function Test
   3a. If yes, provide details below:

<table>
<thead>
<tr>
<th>Steroid Name</th>
<th>Steroid Dose Per Day</th>
<th>Start Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>[Unit: [9] mg]</td>
<td></td>
</tr>
<tr>
<td></td>
<td>[Dose [8] mg/mL]</td>
<td></td>
</tr>
<tr>
<td></td>
<td>[other, specify]</td>
<td></td>
</tr>
</tbody>
</table>

4. Did the participant have a serum creatinine level within 4 weeks of this imaging visit? [12]
   [Yes, Date of Labs: [13] mm-dd-yyyy]
   [No]
   eGFR: [_____ - _____ - _____] ml/min/1.73m² [81]
   [other, specify]

5. Subject weight (at time of scan): [_____ - _____ - _____] kg [17]
   Unknown / not done [18]

Part III. Scanner
6. What magnet strength was the exam acquired on? [19] 1.5 Tesla [20] 3.0 Tesla
   7a. Model name / number
8. Has the scanner used for this study been qualified by ACRIN? [21] Yes [22] No, reason:
### Part IV. Sequences Acquired

<table>
<thead>
<tr>
<th>Sequence</th>
<th>Performed? (check one)</th>
</tr>
</thead>
<tbody>
<tr>
<td>T1 weighted pre-contrast</td>
<td>○ Yes ○ No, reason</td>
</tr>
<tr>
<td></td>
<td>○ Equipment failure ○ Claustophobia ○ Other, specify</td>
</tr>
<tr>
<td>T2 weighted pre-contrast</td>
<td>○ Yes ○ No, reason</td>
</tr>
<tr>
<td></td>
<td>○ Equipment failure ○ Claustophobia ○ Other, specify</td>
</tr>
<tr>
<td>FLAIR</td>
<td>○ Yes ○ No, reason</td>
</tr>
<tr>
<td></td>
<td>○ Equipment failure ○ Claustophobia ○ Other, specify</td>
</tr>
<tr>
<td>BOLD</td>
<td>○ Yes, provide: Initial room air mean O₂ saturation %</td>
</tr>
<tr>
<td></td>
<td>○ No, reason</td>
</tr>
<tr>
<td></td>
<td>○ Equipment failure ○ Claustophobia ○ Other, specify</td>
</tr>
<tr>
<td></td>
<td>○ O₂ flow rate L/min Unknown</td>
</tr>
<tr>
<td></td>
<td>○ Unknown</td>
</tr>
<tr>
<td></td>
<td>○ Mean O₂ saturation during hyperoxia % Unknown</td>
</tr>
<tr>
<td></td>
<td>○ Unknown</td>
</tr>
<tr>
<td>T1 Mapping</td>
<td>○ Yes ○ No, reason</td>
</tr>
<tr>
<td></td>
<td>○ Equipment failure ○ Claustophobia ○ Other, specify</td>
</tr>
</tbody>
</table>

10. Was contrast given? ○ Yes, Dose ○ mL ○ No ○ other, cc/sec ○ Unknown ○ Prohance ○ Optimark ○ Other, specify

<table>
<thead>
<tr>
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<th>Performed? (check one)</th>
</tr>
</thead>
<tbody>
<tr>
<td>DCE</td>
<td>○ Yes ○ No, reason</td>
</tr>
<tr>
<td></td>
<td>○ Equipment failure ○ Claustophobia ○ Other, specify</td>
</tr>
<tr>
<td>Diffusion-weighted/diffusion tensor</td>
<td>○ Yes ○ No, reason</td>
</tr>
<tr>
<td></td>
<td>○ Equipment failure ○ Claustophobia ○ Other, specify</td>
</tr>
</tbody>
</table>

11. Was 2nd injection performed? ○ Yes, Dose ○ mL ○ No ○ other, cc/sec ○ Unknown ○ Other, specify

<table>
<thead>
<tr>
<th>Sequence</th>
<th>Performed? (check one)</th>
</tr>
</thead>
<tbody>
<tr>
<td>DSC</td>
<td>○ Yes ○ No, reason</td>
</tr>
<tr>
<td></td>
<td>○ Equipment failure ○ Claustophobia ○ Other, specify</td>
</tr>
<tr>
<td>Post T1 3D</td>
<td>○ Yes ○ No, reason</td>
</tr>
<tr>
<td></td>
<td>○ Equipment failure ○ Claustophobia ○ Other, specify</td>
</tr>
<tr>
<td>Post T1 SE</td>
<td>○ Yes ○ No, reason</td>
</tr>
<tr>
<td></td>
<td>○ Equipment failure ○ Claustophobia ○ Other, specify</td>
</tr>
<tr>
<td>CSI MR Spectroscopy</td>
<td>○ Yes, provide: ○ No, reason</td>
</tr>
<tr>
<td>O 3D</td>
<td>○ Equipment failure ○ Claustophobia ○ Other, specify</td>
</tr>
<tr>
<td>or O 2D</td>
<td>○ Best FWHM %</td>
</tr>
</tbody>
</table>

12. Were any AE’s reported? ○ Yes, record and report AE per protocol ○ No

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### General Imaging Information

1. **Clinical trial timepoint**
   - Pre-treatment

2. **Date of Mammography**
   - _____-_____-______ (mm-dd-yyyy)

3. **Was a Mammogram performed prior to protocol treatment or within 3 months of enrollment?**
   - No (initial and date form)
   - Yes

4. **Is a mammography report available?**
   - No (initial and date form)
   - Yes

5. **Density of Breast Parenchyma**
   - Almost entirely fat
   - Scattered fibroglandular densities
   - Heterogeneously dense
   - Extremely dense
   - Not reported

### Index Lesion Assessment

6. **Was the index lesion identified on Mammography?**
   - No (skip to Q12)
   - Yes

7. **Index Lesion Type (Select all that apply)**
   - Mass (Complete Q8-9)
   - Calcifications (Complete Q10)
   - Architectural distortion
   - Asymmetry
   - Not reported

8. **Mass Shape**
   - Round
   - Oval
   - Lobular
   - Irregular
   - Not reported

9. **Mass Margins (select one)**
   - Circumscribed
   - Microlobulated
   - Obscured
   - Indistinct
   - Spiculated
   - Not reported

### Index Lesion Quadrant

- Upper Inner (UIQ)
- Upper outer (UOQ)
- Lower inner (LIQ)
- Lower outer (LOQ)

### 7a. Index lesion laterization

- Right breast
- Left breast
- Not reported
ACRIN Study 6698
PLACE LABEL HERE
Institution __________________ Institution No. __________
Participant Initials ____________ Case No. __________

Calcifications

10. Calcification pattern
   [16]
   ○ Typically benign (Complete Q10a)
   ○ Indeterminate (Complete Q10b & c)
   ○ Not reported (Skip to Q12)

10a. Benign Calcification Characteristics [17]
   ○ Skin calcifications
   ○ Vascular calcifications
   ○ Coarse (“Popcorn-like”)
   ○ Large rod-like (secretory)
   ○ Lucent centered
   ○ Eggshell or rim
   ○ Milk of calcium
   ○ Suture
   ○ Dystrophic
   ○ Not reported

10b. Morphology of Indeterminate Calcifications [18]
   ○ Round or punctate
   ○ Amorphous or indistinct
   ○ Coarse heterogeneous
   ○ Pleomorphic or heterogeneous (granular)
   ○ Fine, linear, branching (casting)
   ○ Not reported

10c. Distribution of Indeterminate Calcifications [19]
   ○ Diffuse/scattered
   ○ Regional
   ○ Grouped/clumped
   ○ Linear
   ○ Segmental
   ○ Not reported

Index Lesion Features

11. Associated Features (select all that apply)
   [20]
   □ Skin thickening
   □ Solitary dilated duct
   □ Multiple dilated ducts
   □ None

Additional Interpretation Questions

12. Were any additional lesions besides the index lesion seen?
    [20]
    ○ No
    ○ Yes
    ○ Not reported

13. Longest Diameter of FullExtent of Disease
   (Longest diameter spanning all disease present, including both invasive and DCIS foci, even if there is normal tissue intervening.)
   ___________________ mm [21]

14. Is axillary lymphadenopathy present?
   [22]
   ○ No
   ○ Yes
   ○ Not reported

15. BI-RADS score

   15a. Right breast [27]
      ○ 1 Negative
      ○ 2 Benign
      ○ 3 Probably benign
      ○ 4 Suspicious
      ○ 5 Highly suggestive of malignancy
      ○ 6 Biopsy-proven malignancy

   15b. Left breast [28]
      ○ 1 Negative
      ○ 2 Benign
      ○ 3 Probably benign
      ○ 4 Suspicious
      ○ 5 Highly suggestive of malignancy
      ○ 6 Biopsy-proven malignancy

Comments: ________________________________

__________________________ [29]
Initials of person responsible for data

__________________________ [30]
Initials of person entering data onto the web

Date form completed (mm-dd-yyyy) __________________________ [31]
**ACRIN 6698**  
**Imaging Transmittal Worksheet (ITW)**  
**DWI MRI Biomarkers for Assessment of Breast Cancer Response to Neoadjuvant treatment (I-SPY2)**

If this is a revised or corrected form, please **check** box. □

**Instructions**: Imaging exams should be submitted to the ACRIN-Image Management Center within 48 hours of imaging visit. A completed, signed Image Transmittal Worksheet MUST accompany all imaging exams submitted to ACRIN for each time-point. For exams submitted via the internet, complete this worksheet, and email to imagearchive@acr.org or fax to 215-923-1737. For exams submitted via media, complete this worksheet and include with the media shipment. Please affix a label to the jacket of the media to include: study name, site name, and case no., date of exam, time point, and type of imaging.

For further information or questions contact the Image Management Center at ACRIN.

### Section I: Image Data Demographics

<table>
<thead>
<tr>
<th>Field</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACRIN Site Number:</td>
<td>[ ]</td>
</tr>
<tr>
<td>ACRIN Case Number:</td>
<td>[ ]</td>
</tr>
<tr>
<td>ISPY-2 Case Number:</td>
<td>[ ]</td>
</tr>
<tr>
<td>Patient DOB:</td>
<td>[ ] 19</td>
</tr>
<tr>
<td>Study Date:</td>
<td>[ ] 20</td>
</tr>
<tr>
<td>Patient Initials (L, F):</td>
<td>[ ]</td>
</tr>
<tr>
<td>Image Submission:</td>
<td>□ DWI MRI □ DCE MRI □ Axial T2 FS FSE □ Axial STIR □ DWI retest</td>
</tr>
</tbody>
</table>

### Section II: Time point being submitted

- Pre-treatment
- Inter-regimen
- Early treatment
- Pre-Surgery

### Section III: Mode of Image Submission

- Shipped on CD (enclosed) * □  
- Electronic Transfer via TRIAD □

* Please contact Image Management Center before submitting images on CD.

Institution Comments:

Form Completed By: [ ]  
Phone: [ ]

Email: [ ]  
Date: [ ] 20

ACRIN Image Management Center  
ACRIN 6698  
American College of Radiology  
1818 Market Street, Suite 1600  
Philadelphia, PA 19103

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Version 1.0  
6698 IT  
11-07-12  
1 of 1
If this is a revised or corrected form, please check the box.

Instructions: This form is to be completed by the Radiologist for each timepoint specified in the protocol. The completed form is submitted to ACRIN via the web site www.acrin.org and the corresponding reports are mailed to American College of Radiology, ACRIN Data Management/6698, 1818 Market Street, St. 1600, Philadelphia, PA 19103. All dates are reported as MM/DD/YYYY. All responses are required unless otherwise noted. All images are to be transmitted to ACRIN as detailed in the study protocol.

General Imaging Information

1. Clinical trial timepoint
   - Pre-treatment
   - Early treatment
   - Inter-regimen
   - Pre-surgery

2. Date of MRI: __________-________-________ (mm-dd-yyyy)

3. Reader ID ____________

4. Image quality
   - Adequate
   - Suboptimal (complete Q4a then continue with form)
   - Uninterpretable (complete Q4a then initial and date form)

4a. Reason uninterpretable [mark all that apply]
   - Motion
   - Artifacts
   - Contrast Media
   - DICOM Header
   - Lost Images
   - Poor S/N
   - Incomplete anatomic coverage
   - Other, specify

Index Lesion Assessment

5. Was an index lesion identified on MRI?
   - No (skip to Q16)
   - Yes

6. Index Lesion Type
   - Mass (complete Q7-9)
   - Non-mass enhancement (complete Q10-11)

6a. Index lesion laterализation
   - Right breast
   - Left breast

6b. Index lesion quadrant
   - Upper Inner (UIQ)
   - Upper outer (UOQ)
   - Lower Inner (LIQ)
   - Lower outer (LOQ)

Right: 12
   - UIQ
   - LOQ

Left: 12
   - UIQ
   - LOQ

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### Mass

7. **Shape**
   - O Round
   - O Oval
   - O Lobular
   - O Irregular

8. **Margin**
   - O Smooth
   - O Irregular
   - O Spiculated

9. **Mass enhancement**
   - O Homogeneous
   - O Heterogeneous
   - O Rim enhancement
     - O Dark internal septation
     - O Central enhancement

### Non-Mass Enhancement

10. **Distribution Modifiers**
    - O Focal Area
    - O Linear
    - O Ductal
    - O Segmental
    - O Regional
    - O Multiple regions
    - O Diffuse

11. **Internal Enhancement**
    - O Homogeneous
    - O Heterogeneous
    - O Stippled, punctate
    - O Clumped
    - O Reticular, dendritic

### Index lesion kinetic curve assessment

12. **Initial Rise**
    - O Slow
    - O Medium
    - O Rapid

### Additional Interpretation Questions

13. **Delayed Phase**
    - O Persistent
    - O Plateau
    - O Washout

14. **Were any additional lesions besides the index lesion seen?**
    - O No
    - O Yes

15. **Longest Diameter of Full Extent of Disease**
    (Longest diameter spanning all disease present, including both invasive and DCIS foci, even if there is normal tissue intervening:)
    
    _________ mm

16. **Other Findings** (select all that apply)
    - O None
    - O Nipple retraction
    - O Nipple invasion
    - O Pre-contrast high ductal signal
    - O Skin thickening (focal)
    - O Skin thickening (diffuse)
    - O Skin invasion
    - O Edema
    - O Lymphadenopathy
    - O Pectoralis muscle invasion
    - O Chest wall invasion
    - O Hematoma/blood
    - O Abnormal signal void
    - O Cysts

### Comments:

...[41]

...[42]

Initials of person(s) completing this form

...[43]

Date form completed (mm-dd-yyyy)
# ACRIN 6698 / ISPY 2 MRI Imaging Core Lab Modules

## Imaging Characteristics Assessment Form

**MC**

**Version 0.2**

1. **Data Set**
   - O 3 plane localizer
   - O DWI axial
   - O T2-FS axial
   - O DCE axial
   - O Stir axial

**Normal Limits** – The noted Imaging Characteristic was acquired per protocol within the limits of normal variation.

**Minor** – The noted Imaging Characteristic causes a minor degradation of the image reducing the ability to view the vital structures or a minor deviation from what is outlined in the protocol, which generally affects the quality of the image in a small or localized manner.

**Severe** – The noted Imaging Characteristic causes a severe degradation of the image resulting in an inability to accurately view the vital structures or a major deviation from what is outlined in the protocol, which severely limits the overall quality and usefulness of the image.

### Image Acquisition Verification

<table>
<thead>
<tr>
<th>Image Acquisition Verification</th>
<th>Image Degradation</th>
<th>Action (CTMS only)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Within Normal limits</td>
<td>Minor</td>
<td>Su     e</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Queried</td>
<td>Date of Query</td>
</tr>
<tr>
<td>Coil placement</td>
<td></td>
<td>[8]</td>
<td>[9]</td>
</tr>
<tr>
<td>Consistency of arm positioning/ wrap</td>
<td></td>
<td>[14]</td>
<td>[15]</td>
</tr>
<tr>
<td>Acquisition/reconstruction artifacts</td>
<td></td>
<td>[20]</td>
<td>[21]</td>
</tr>
<tr>
<td>Signal to Noise Ratio</td>
<td></td>
<td>[26]</td>
<td>[27]</td>
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<td>Voluntary/ involuntary Patient Motion</td>
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<td>Contrast enhancement</td>
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<th>Comments</th>
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<td>Within Normal limits</td>
<td>Minor</td>
<td>Severe</td>
</tr>
<tr>
<td>Image resolution</td>
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<tr>
<td>Temporal resolution</td>
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<tr>
<td>Study specific acquisition parameters followed</td>
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<td></td>
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</tr>
<tr>
<td>Consistent acquisition parameters across reporting periods</td>
<td></td>
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</tr>
</tbody>
</table>

**Overall Assessment:**

- O Study compliant
- O Not study compliant

**Comment:** An email will be sent to the Imaging Analyst when "Minor", "Severe", and overall assessment = "Not study compliant" are selected within the Imaging Characteristics Assessment Module. Action(s) of the Imaging Analyst would be driven by the protocol.
Diffusion-weighted MRI Biomarkers for Assessment of Breast Cancer Response to Neoadjuvant Treatment: An I-SPY 2 Trial Substudy

Treatment Registration

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

**Instructions:** The 6698 treatment registration form (S2) must be used to confirm randomization to ISPY-2 treatment. This information is submitted to ACRIN via the website: www.acrin.org following the participants consent to treatment.

**DEMOGRAPHICS**

1. Was patient randomized to treatment? [2]
   - O 1 No
   - O 2 Yes

1a. If no, reason why not [14]
   - O 1 Decided not to have neoadjuvant chemotherapy
   - O 2 Decided not to be treated with a novel agent
   - O 3 Patient found to be ineligible for the study
   - O 4 Patient found to be ineligible because they are MammaPrint Low, ER Positive, HER2 Negative
   - O 5 Patient found to be ineligible because inability to complete MammaPrint Test
   - O 6 Patient found to be ineligible because they did not meet other eligibility criteria
   - O 7 Patient found to be ineligible because patient could not complete MRI
   - O 8 Participant found to be ineligible because patient could not complete core biopsy
   - O 88 Other, specify

2. ISPY2 Participant ID # [6]

3. Was the eligibility check list completed for treatment? [10]
   - O 1 No
   - O 2 Yes

4. Treatment consent date ___-___-___ (mm-dd-yyyy) [11]

Initials of person(s) entering data onto web [12] Date form completed [13]

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Version 1.2 ACRIN 6698 S2 09-04-13 1 of 1
General Imaging Information

1. Clinical trial timepoint [1]
   - Pre-treatment
   - Early treatment
   - Inter-regimen
   - Pre-surgery

2. Was MRI performed at this visit? [2]
   - No (complete PR, initial and date form)
   - Yes

3. Date of MRI: ______-____-____ (mm-dd-yyyy) [5]

4. Subject weight _________: _________ kg [6]
   - Unknown [7]

   4a. Source of weight [8]
       - Measured day of scan
       - Provided by patient

Pre-contrast T2-weighted FSE or STIR (axial or sagittal)

5. Was T2 imaging performed? [27]
   - No (skip to Q6 and complete PR form)
   - Yes

   5a. T2 series #: __________________________ [28]

   5b. T2 start time (military time) ______ : ______ [29]

Pre-contrast DW-MRI (axial)

6. Was DWI performed? [9]
   - No (skip to Q15 and complete PR form)
   - Yes

7. Fat suppression method: [10]
   - FatSat
   - SPIR
   - SPAIR
   - Other, specify __________________________ [11]
   - Unknown

   - Auto Shim
   - Volume Shim
   - Image-based shim
   - Other, specify __________________________ [13]
   - Unknown

9. DWI start time (military time) ______ : ______ [14]

   9a. DWI series scan duration
       ______ : ______ (min:sec) [56]

10. Were all b-values performed in a single series? [15]
    - No (complete Q10a)
    - Yes, series #: __________________________ [16]

10a. b-value (s/mm²)
    - 0, 100
    - 0, 600
    - 0, 800

   DWI Series # [17] [18] [19]

Pre-contrast DW-MRI Retest (axial)

11. Did the participant consent to a retest DWI? [57]
    - No
    - Yes

   11a. Was a retest DWI performed? [20]
       - No (skip to Q15 and complete PR form)
       - Yes

12. Was T2 weighted retest imaging performed? [53]
    - No (skip to Q13)
    - Yes

12a. T2 series #: __________________________ [54]

12b. T2 start time (military time) ______ : ______ [55]

13. Retest DWI start time (military time) ______ : ______ [21]

14. Were all b-values performed in a single series? [22]
    - No (complete Q14a)
    - Yes, series #: __________________________ [23]

14a. b-value (s/mm²)
    - 0, 100
    - 0, 600
    - 0, 800

   DWI Series # [24] [25] [26]

DCE-MRI [axial]

15. Was DCE performed? [30]
    - No (skip to Q27 and complete PR form)
    - Yes
16. Pre-contrast DCE image series #: ________________ [33]

17. Brand of contrast agent injected (check only one) [34]
   ○ Magnevist
   ○ Omniscan
   ○ ProHance
   ○ Other, specify ____________________________ [35]

17a. Was the contrast administered according to protocol? (dose: 0.1mm/kg body weight, rate: 2cc/sec, flush: 20cc)? [36]
   ○ No (complete PR form)
   ○ Yes

18. Time of injection (military time) __ : __ : __ __ __ [37]

18a. Was the DCE-MRI started within 5 seconds of start of injection? [38]
   ○ No (specify reason in comments)
   ○ Yes

19. Rate of injection ___ ___ ___ cc/sec [39]

20. Volume of contrast injection ___ ___ ___ cc [40]

21. Volume of saline flush ___ ___ ___ cc [41]

22. Site of injection [42]
   ○ Right hand
   ○ Right arm
   ○ Left hand
   ○ Left arm
   ○ Other, specify ____________________________

23. IV gauge: ________________ [43]

24. Total number of post-contrast DCE phases:
   ________________ [44]

Military Time conversion: In a 24-hour time clock, both 00:00 and 24:00 represent midnight - 24:00 of the previous day is the same time as 00:00 of the next day. The day begins at midnight, 00:00, and the last minute of the day is 23:59. The notation 24:00 mainly serves to refer to the exact end of a day. Time-of-day notations beyond 24:00 (such as 24:01 or 25:00 instead of 00:01 or 01:00) are not commonly used.

<table>
<thead>
<tr>
<th>Military Time</th>
<th>24-hour Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>0000 = 12 am midnight</td>
<td>00:00</td>
</tr>
<tr>
<td>0100 = 1 am</td>
<td>01:00</td>
</tr>
<tr>
<td>0200 = 2 am</td>
<td>02:00</td>
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<tr>
<td>0300 = 3 am</td>
<td>03:00</td>
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<tr>
<td>0400 = 4 am</td>
<td>04:00</td>
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<tr>
<td>0500 = 5 am</td>
<td>05:00</td>
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<tr>
<td>0600 = 6 am</td>
<td>06:00</td>
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<tr>
<td>0700 = 7 am</td>
<td>07:00</td>
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<tr>
<td>0800 = 8 am</td>
<td>08:00</td>
</tr>
<tr>
<td>0900 = 9 am</td>
<td>09:00</td>
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<tr>
<td>1000 = 10 am</td>
<td>10:00</td>
</tr>
<tr>
<td>1100 = 11 am</td>
<td>11:00</td>
</tr>
<tr>
<td>1200 = 12 pm noon</td>
<td>12:00</td>
</tr>
<tr>
<td>1300 = 1 pm</td>
<td>13:00</td>
</tr>
<tr>
<td>1400 = 2 pm</td>
<td>14:00</td>
</tr>
<tr>
<td>1500 = 3 pm</td>
<td>15:00</td>
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<tr>
<td>1600 = 4 pm</td>
<td>16:00</td>
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<tr>
<td>2100 = 9 pm</td>
<td>21:00</td>
</tr>
<tr>
<td>2200 = 10 pm</td>
<td>22:00</td>
</tr>
<tr>
<td>2300 = 11 pm</td>
<td>23:00</td>
</tr>
</tbody>
</table>

25. Were post-contrast DCE images acquired in the same series as pre-contrast? [45]
   ○ No, complete Q25a
   ○ Yes

25a. Series number(s) for all post-contrast DCE images. (Do NOT include derived images e.g. subtractions. If all post-contrast scans were in a single series then ONLY “Post-contrast series 1” gets an entry)
   - Post-contrast series 1
   - Post-contrast series 2
   - Post-contrast series 3
   - Post-contrast series 4
   - Post-contrast series 5
   - Post-contrast series 6
   - Post-contrast series 7
   - Post-contrast series 8

26. Was the duration of each phase between 80-100 seconds? [46]
   ○ No (complete Q26a and PR form)
   ○ Yes

26a. Single phase duration: ________________ sec

Adverse Events

27. Any adverse events related to imaging to report for this timepoint? [47]
   ○ No (initial and date form)
   ○ Yes (complete Q27a and reference the protocol section titled Adverse Events)

27a. Does the event meet the criteria of a serious adverse event? [48]
   ○ No
   ○ Yes (reference the protocol section titled Adverse Events)

Comments: ________________________________ [49]

Initials of person responsible for data ________________ [50]

Initials of person entering data onto the web ________________ [51]

Date form completed (mm-dd-yyyy) ________________________________ [52]