ACRIN 6698

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

CRF Set

A0

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

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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 _____ [1]

2. Was the eligibility check list completed? [2] O 1 No O 2 Yes

3. Is the participant eligible for this study? [3] O 1 No O 2 Yes

4. Date the study-specific consent form was signed (mm-dd-yyyy) **(Must be prior to study entry)** ___-___-___ [4]

5. Participant's Initials *(last, first) (L, F)* _____ [5]

6. Verifying physician (Site PI) _____ [6]

8. Date of birth *(mm-dd-yyyy)* ___-___-___ [8]

9. Ethnicity [9] O 1 Hispanic or Latino O 2 Not Hispanic or Latino O 9 Unknown

11. Gender [11] O 1 Male O 2 Female

12. Participant's country of residence **(if other, complete Q12a)** [12]

O 1 United States O 3 Other
O 2 Canada O 9 Unknown

12a. Other country, specify (completed if Q12 is coded **"other"**) _____ [18]

13. Zip Code **(5 digit code, US residents)** _____ [13]

14. Participant's insurance status [14]

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

15. Will any component of the participant's care be given at a military or VA facility? [15]

O 1 No O 2 Yes O 9 Unknown

16. Calendar base date [Date of registration] **(Date of ISPY-2 Registration)** *(mm-dd-yyyy)* ___-___-___ [16]

Date of registration **(ACRIN Registration Date)** *(mm-dd-yyyy)* ___-___-___ [17]

17. Race (check all that apply)

18. ☐ American Indian or Alaskan Native [19]
19. ☐ Asian [20]
20. ☐ Black or African American [21]
21. ☐ Native Hawaiian or other Pacific Islander [22]
22. ☐ White [23]
23. ☐ Unknown [24]

24. ISPY2 Participant ID # _____ [28]

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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

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Comments: _____

_____

_____

_____ [30]

_____ [31]
Initials of person(s) completing this form

_____-_____-_____ [32]
Date Form Completed (mm-dd-yyyy)

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MR

ACRIN 6684

Tumor Hypoxia in Glioblastoma using FMISO MRI/MRS Assessment

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

ACRIN Study 6684

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Part I. MR Visit

1. **Time point:** [1] O **Visit 2** *(baseline imaging)*

2. **Imaging completed?** [2] O **Yes, Date of imaging:**

_____-_____-_____ *mm-dd-yyyy* [3]

O **No, reason:** [4]
- O Equipment failure
- O Patient refusal
- O Medical contraindiction
- O Injection site complications
- O Claustrophobia
- O Other, specify _____ [5]

Part II. Steroid use and Renal Function Test

3. **Was the participant taking any steroids at the time of the MRI?** [6] O **Yes** O **No**

3a. If yes, provide details below:

Steroid Name	Steroid Dose Per Day	Start Date
[7] _____ ☐ Name unknown [78]	_____ Dose [8] Unit: [9] O mg O mg/mL O mcg O other, specify _____ [10]	[11] _____-_____-_____ *mm-dd-yyyy* ☐ Date unknown [79]

4. **Did the participant have a serum creatinine level within 4 weeks of this imaging visit?** [12]

O **Yes, Date of Labs** _____-_____-_____ *mm-dd-yyyy* [13] O **No**

eGFR: _____ _____ _____ . _____ [80] O ml/min/1.173m^2 [81]

O other, specify _____ [82]

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] O 1.5 Tesla O 3.0 Tesla

7. **Manufacturer/vendor the exam acquired on?** [20] O GE O Philips O Siemens

7a. Model name / number _____ [77]

8. **Has the scanner used for this study been qualified by ACRIN?** [21] O Yes O No, reason: _____ [22]

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MR **ACRIN 6684**

Tumor Hypoxia in Glioblastoma using FMISO MRI/MRS Assessment

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

ACRIN Study **6684**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Part IV. Sequences Acquired

Sequence	Performed? *(check one)*
T1 weighted pre-contrast [24]	O **Yes** O **No**, *reason* [25] O Equipment failure O Claustrophobia O Other, specify _____ [26]
T2 weighted pre-contrast [27]	O **Yes** O **No**, *reason* [28] O Equipment failure O Claustrophobia O Other, specify _____ [29]
FLAIR [30]	O **Yes** O **No**, *reason* [31] O Equipment failure O Claustrophobia O Other, specify _____ [32]
BOLD [33]	O **Yes**, provide: **Initial room air mean O_2 saturation** _____ % [34] ☐ Unknown [35] **O_2 flow rate** _____ **L/min** [36] ☐ Unknown [37] **Mean O_2 saturation during hyperoxia** _____ % [38] ☐ Unknown [39] O **No**, *reason* [40] O Equipment failure O Claustrophobia O Other, specify _____ [41]
T1 Mapping [42]	O **Yes** O **No**, *reason* [43] O Equipment failure O Claustrophobia O Other, specify _____ [44]

10. Was contrast given? [45] O **Yes, Dose** [46] _____ O mL [83] O **No** O other, _____ [84]

Rate of injection: _____ cc/sec [47]

Contrast Brand: [48] O Magnevist O Optimark O Prohance O Omniscan O Dotarem O Other, specify _____ [49]

Sequence	Performed? *(check one)*
DCE [50]	O **Yes** O **No**, *reason* [51] O Equipment failure O Claustrophobia O Other, specify _____ [52]
Diffusion-weighted/diffusion tensor [53]	O **Yes** O **No**, *reason* [54] O Equipment failure O Claustrophobia O Other, specify _____ [55]

11. Was 2nd injection performed? [56] O **Yes, Dose** [57] _____ O mL [85] O **No** O other, _____ [86]

Rate of injection: _____ cc/sec [58]

Sequence	Performed? *(check one)*
DSC [59]	O **Yes** O **No**, *reason* [60] O Equipment failure O Claustrophobia O Other, specify _____ [61]
Post T1 3D [62]	O **Yes** O **No**, *reason* [63] O Equipment failure O Claustrophobia O Other, specify _____ [64]
Post T1 SE [65]	O **Yes** O **No**, *reason* [66] O Equipment failure O Claustrophobia O Other, specify _____ [67]
CSI MR Spectroscopy [68] **or** O **3D** O **2D** [75]	O **Yes, provide:** O **No**, *reason* [69] O Equipment failure O Claustrophobia **Best FWHM** ____ ____ [76] O Other, specify _____ [70]

12. Were any AE's reported? [71] O **Yes**, *record and report AE per protocol* O **No**

_____ [72] Initials of Technologist

_____ [73] Initials of person(s) completing this form

_____-_____-_____ [74] Date form completed *(mm-dd-yyyy)*

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IA

ACRIN 6698/ ISPY 2

Pre-Study Mammography Abstraction Form

ACRIN Study 6698
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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

Instructions: This form is completed by the research associate. The IA data is abstracted from the pre-study mammography report, if available. Sites are not expected to re-read the mammography image. 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, ATTN: 6698 Data Management, 1818 Market Street, St. 1600, Philadelphia, PA 19103. All dates are reported as mm/dd/yyyy. All responses are required unless otherwise noted.

General Imaging Information

1. Clinical trial timepoint [1]
- O Pre-treatment

2. Date of Mammography:

_____-_____-_____ *(mm-dd-yyyy)* [3]

3. Was a Mammogram performed prior to protocol treatment or within 3 months of enrollment? [2]
- O No *(initial and date form)*
- O Yes

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

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

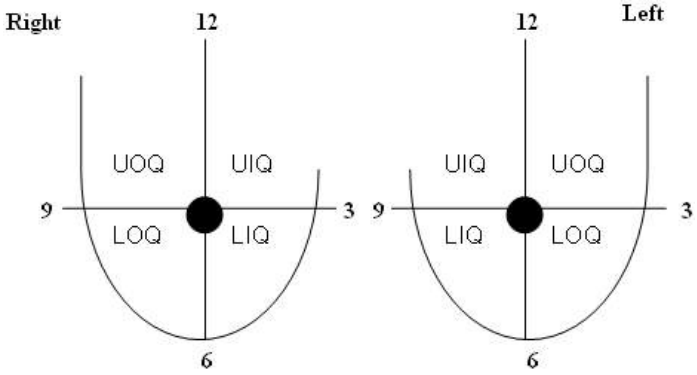
Index Lesion Assessment

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

7. Index Lesion Type *(Select all that apply)*
- ☐ Mass *(Complete Q8-9)* [7]
- ☐ Calcifications *(Complete Q10)* [8]
- ☐ Architectural distortion [9]
- ☐ Asymmetry [10]
- ☐ Not reported [11]

7a. Index lesion lateralization [12]
- O Right breast
- O Left breast
- O Not reported

7b. Index lesion quadrant [13]
- O Upper Inner (UIQ)
- O Upper outer (UOQ)
- O Lower inner (LIQ)
- O Lower outer (LOQ)
- O Not reported



Mass

8. Mass Shape [14]
- O Round
- O Oval
- O Lobular
- O Irregular
- O Not reported

9. Mass Margins *(select one)* [15]
- O Circumscribed
- O Microlobulated
- O Obscured
- O Indistinct
- O Spiculated
- O Not reported

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IA

ACRIN 6698/ ISPY 2

Mammography Local Interpretation Form

ACRIN Study 6698

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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

Calcifications

10. Calcification pattern [16]

- O Typically benign *Complete Q10a)*
- O Indeterminate *(Complete Q10b & c)*
- O Not reported *(Skip to Q12)*

10a. Benign Calcification Characteristics [17]

- O Skin calcifications
- O Vascular calcifications
- O Coarse ("Popcorn-like")
- O Large rod-like (secretory)
- O Lucent centered
- O Eggshell or rim
- O Milk of calcium
- O Suture
- O Dystrophic
- O Not reported

10b. Morphology of Indeterminate Calcifications [18]

- O Round or punctate
- O Amorphous or indistinct
- O Coarse heterogeneous
- O Pleomorphic or heterogeneous (granular)
- O Fine, linear, branching (casting)
- O Not reported

10c. Distribution of Indeterminate Calcifications [19]

- O Diffuse/scattered
- O Regional
- O Grouped/clustered
- O Linear
- O Segmental
- O Not reported

Index Lesion Features

11. Associated Features *(select all that apply)*

- ☐ Skin thickening [23]
- ☐ Solitary dilated duct [24]
- ☐ Multiple dilated ducts [25]
- ☐ None [26]

Additional Interpretation Questions

12. Were any additional lesions besides the index lesion seen? [20]

- O No
- O Yes
- O Not reported

13. 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** [21]

14. Is axillary lymphadenopathy present? [22]

- O No
- O Yes
- O Not reported

15. BI-RADS score

15a. Right breast [27]

- O 1 Negative
- O 2 Benign
- O 3 Probably benign
- O 4 Suspicious
- O 5 Highly suggestive of malignancy
- O 6 Biopsy-proven malignancy

15b. Left breast [28]

- O 1 Negative
- O 2 Benign
- O 3 Probably benign
- O 4 Suspicious
- O 5 Highly suggestive of malignancy
- O 6 Biopsy-proven malignancy

Comments: _____

_____

_____

_____ [29]

_____ [30]

Initials of person responsible for data

_____-_____-_____ [31]

Date form completed (mm-dd-yyyy)

_____ [32]

Initials of person entering data onto the web

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IT

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 √ 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

ACRIN Site Number: ____

ACRIN Case Number: ____

ISPY-2 Case Number: _____

Patient DOB: __-__-19__

Study Date: __-__-20__

Patient Initials (L, F): __-__

Image Submission:

☐ DWI MRI ☐ DCE MRI

☐ Axial T2 FS FSE ☐ Axial STIR ☐ DWI retest

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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M4

ACRIN 6698/ ISPY 2
MRI Local Interpretation Form

ACRIN Study 6698
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

If this is a revised or corrected form, please √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 [1]
- O Pre-treatment
- O Early treatment
- O Inter-regimen
- O Pre-surgery

2. Date of MRI: _____-_____-_____ *(mm-dd-yyyy)* [2]

3. Reader ID |_|_|_|_|_|_|_| [3]

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

4a. Reason uninterpretable *[mark all that apply]*
- ☐ Motion [5]
- ☐ Artifacts [6]
- ☐ Contrast Media [7]
- ☐ DICOM Header [8]
- ☐ Lost Images [9]
- ☐ Poor S/N [10]
- ☐ Incomplete anatomic coverage [11]
- ☐ Other, [12] specify _____ [13]

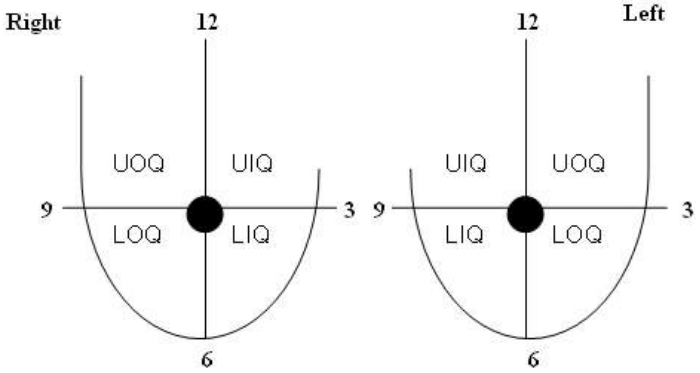
Index Lesion Assessment

5. Was an index lesion identified on MRI? [14]
- O No (skip to Q16)
- O Yes

6. Index Lesion Type [15]
- O Mass *(complete Q7-9)*
- O Non-mass enhancement *(complete Q10-11)*

6a. Index lesion lateralization [16]
- O Right breast
- O Left breast

6b. Index lesion quadrant [17]
- O Upper Inner (UIQ)
- O Upper outer (UOQ)
- O Lower inner (LIQ)
- O Lower outer (LOQ)



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M4

ACRIN 6698/ ISPY 2
MRI Local Interpretation Form

ACRIN Study 6698
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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

Mass

7. Shape [18]
- O Round
- O Oval
- O Lobular
- O Irregular

8. Margin [19]
- O Smooth
- O Irregular
- O Spiculated

9. Mass enhancement [20]
- O Homogeneous
- O Heterogeneous
- O Rim enhancement
- O Dark internal septation
- O Central enhancement

Non-Mass Enhancement

10. Distribution Modifiers [21]
- O Focal Area
- O Linear
- O Ductal
- O Segmental
- O Regional
- O Multiple regions
- O Diffuse

11. Internal Enhancement [22]
- O Homogeneous
- O Heterogeneous
- O Stippled, punctate
- O Clumped
- O Reticular, dendritic

Index lesion kinetic curve assessment

12. Initial Rise [23]
- O Slow
- O Medium
- O Rapid

13. Delayed Phase [24]
- O Persistent
- O Plateau
- O Washout

Additional Interpretation Questions

14. Were any additional lesions besides the index lesion seen? [25]
- 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** [26]

16. Other Findings *(select all that apply)*
- ☐ None apply [27]
- ☐ Nipple retraction [28]
- ☐ Nipple invasion [29]
- ☐ Pre-contrast high ductal signal [30]
- ☐ Skin thickening (focal) [31]
- ☐ Skin thickening (diffuse) [32]
- ☐ Skin invasion [33]
- ☐ Edema [34]
- ☐ Lymphadenopathy [35]
- ☐ Pectoralis muscle invasion [36]
- ☐ Chest wall invasion [37]
- ☐ Hematoma/blood [38]
- ☐ Abnormal signal void [39]
- ☐ Cysts [40]

Comments: _____

_____

_____ [41]

_____ [42]
Initials of person(s) completing this form

_____-_____-_____ [43]
Date form completed *(mm-dd-yyyy)*

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MC

ACRIN 6698/ ISPY 2
MRI Imaging Core Lab Modules

Imaging Characteristics Assessment Form

ACRIN Study 6698
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

1. Data Set [1]

- O 3 plane localizer
- O T2-FS axial
- O Stir axial
- O DWI axial
- O DCE 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	Image Degradation				Action *(CTMS only)*				Comments
	Within Normal limits	Minor	Severe	N/A	Queried	Date of Query	Date of Query Resolution	PR Required?	
Patient positioning	○	○	○	○ [2]	☐ [3]	[4]	[5]	☐ [6]	[7]
Coil placement	○	○	○	○ [8]	☐ [9]	[10]	[11]	☐ [12]	[13]
Consistency of arm positioning/ wrap	○	○	○	○ [14]	☐ [15]	[16]	[17]	☐ [18]	[19]
Acquisition/reconstruction artifacts	○	○	○	○ [20]	☐ [21]	[22]	[23]	☐ [24]	[25]
Signal to Noise Ratio	○	○	○	○ [26]	☐ [27]	[28]	[29]	☐ [30]	[31]
Voluntary/ involuntary Patient Motion	○	○	○	○ [32]	☐ [33]	[34]	[35]	☐ [36]	[37]
Anatomic coverage	○	○	○	○ [38]	☐ [39]	[40]	[41]	☐ [42]	[43]
Contrast enhancement	○	○	○	○ [44]	☐ [45]	[46]	[47]	☐ [48]	[49]

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ACRIN 6698/ ISPY 2
MRI Imaging Core Lab Modules

Imaging Characteristics Assessment Form

ACRIN Study 6698
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Image Acquisition Verification	Image Degradation				Action *(CTMS only)*				Comments
	Within Normal limits	Minor	Severe	N/A	Queried	Date of Query	Date of Query Resolution	PR Required?	
Image resolution	○	○	○	○ [50]	☐ [51]	[52]	[53]	☐ [54]	[55]
Temporal resolution	○	○	○	○ [56]	☐ [57]	[58]	[59]	☐ [60]	[61]
Study specific acquisition parameters followed	○	○	○	○ [62]	☐ [63]	[64]	[65]	☐ [66]	[67]
Consistent acquisition parameters across reporting periods	○	○	○	○ [68]	☐ [69]	[70]	[71]	☐ [72]	[73]

Overall Assessment: [74] 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.

_____ Initials of person completing the form

_____-_____-_____ Date form completed (mm-dd-yyyy)

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S2

ACRIN 6698

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 √ box. ☐

ACRIN Study 6698

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

DEMOGRAPHICS

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.

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 _____ [9]

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]

_____ [12]
Initials of person(s) entering data onto web

_____-_____-_____ *(mm-dd-yyyy)* [13]
Date form completed

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TM

ACRIN 6698/ ISPY 2

MRI Technical Assessment Form

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

ACRIN Study 6698
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Instructions: This form is to be completed by the Technologist 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. Participant consent for a retest DWI is required at Pre-treatment and/or Early treatment clinical timepoints.

General Imaging Information

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

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

3. Date of MRI: _____-_____-_____ *(mm-dd-yyyy)* [5]

4. Subject weight ___ ___ ___ . ___ kg [6]
- ☐ Unknown [7]

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

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

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

5a. T2 series #: _____ [28]

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

Pre-contrast DW-MRI (axial)

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

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

8. Shim method? [12]
- O Auto Shim
- O Volume Shim
- O Image-based shim
- O Other, specify _____ [13]
- O 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]
- O No *(complete Q10a)*
- O 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]
- O No
- O Yes

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

12. Was T2 weighted retest imaging performed? [53]
- O No *(skip to Q13)*
- O 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]
- O No *(complete Q14a)*
- O 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]
- O No *(skip to Q27 and complete PR form)*
- O Yes

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TM

ACRIN 6698/ ISPY 2

MRI Technical Assessment Form

ACRIN Study 6698
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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

16. Pre-contrast DCE image series #: _____ [33]

17. Brand of contrast agent injected *(check only one)* [34]
- O Magnevist
- O Omniscan
- O ProHance
- O Other, specify _____ [35]

17a. Was the contrast administered according to protocol? (dose: 0.1mm/kg body weight, rate: 2cc/sec, flush: 20cc)? [60]
- O No *(complete PR form)*
- O Yes

18. Time of injection *(military time)* ____ ____ : ____ ____ [36]

18a. Was the DCE-MRI started within 5 seconds of start of injection? [37]
- O No *(specify reason in comments)*
- O Yes

19. Rate of injection ___.___ **cc/sec** [38]

20. Volume of contrast injection _____ **cc** [39]

21. Volume of saline flush _____ **cc** [40]

22. Site of injection [41]
- O Right hand
- O Right arm
- O Left hand
- O Left arm
- O Other, specify _____ [42]
- O Unknown

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 25:59 instead of 00:01 or 01:59) are **not** commonly used.

0000 = 12 am midnight	0800 = 8 am	1600 = 4 pm	2400 = 12 am midnight
0100 = 1 am	0900 = 9 am	1700 = 5 pm	
0200 = 2 am	1000 = 10 am	1800 = 6 pm	
0300 = 3 am	1100 = 11 am	1900 = 7 pm	
0400 = 4 am	1200 = 12 pm noon	2000 = 8 pm	
0500 = 5 am	1300 = 1 pm	2100 = 9 pm	
0600 = 6 am	1400 = 2 pm	2200 = 10 pm	
0700 = 7 am	1500 = 3 pm	2300 = 11 pm	

25. Were post-contrast DCE images acquired in the same series as pre-contrast? [69]
- O No, complete Q25a
- O 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 _____ [61]
Post-contrast series 2 _____ [62]
Post-contrast series 3 _____ [63]
Post-contrast series 4 _____ [64]
Post-contrast series 5 _____ [65]
Post-contrast series 6 _____ [66]
Post-contrast series 7 _____ [67]
Post-contrast series 8 _____ [68]

26. Was the duration of each phase between 80-100 seconds? [45]
- O No *(complete Q26a and PR form)*
- O Yes

26a. Single phase duration:

_____ **sec** [46]

Adverse Events

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

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

Comments: _____

_____

_____ [49]

_____ [50]
Initials of person responsible for data

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

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

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