ACRIN 6657 Extension

Contrast-Enhanced Breast MRI and MRS for Evaluation of Patients Undergoing Neoadjuvant Treatment for Locally Advanced Breast Cancer

Case Report Form Set

American College of Radiology Imaging Network
Forms Index

ACRIN Study 6657

Form Version		Version Date

Visit 1: Pre-Registration / Baseline Visit - Within 4 weeks prior to start of neoadjuvant treatment

A0	Registration Eligibility Checklist	05-11-09
N1	Mammography Interpretation Form (within 3 months before or 2 weeks after entry MRI/MRS but before treatment start)	12-07-07
T1	MRI-1 Baseline/Pretreatment Form	12-11-07
U1	Ultrasound Interpretation Form	09-10-07
V1	MRS-1 Baseline/Pretreatment Form	12-15-08

Additional Visit (For 30 consented patient's ONLY): Within 72 hours post Baseline and prior to type 1 chemotherapy

TA	MRI-1.1 Additional Baseline / Pretreatment Reproducibility Form	11-29-07
VA	MRS-1.1 Additional Baseline / Pretreatment Reproducibility Form	01-09-09

Visit 2: MRI/MRS within 20-28 or 48-96 hours post Baseline MRI/MRS

T2	MRI-2 Treatment Form	11-29-07
V2	MRS-2 Treatment Form	11-19-08

Visit 3: MRI/MRS after Type 1 Chemotherapy

T3	MRI-3 MRI Inter-Regimen Treatment Form	11-29-07
V3	MRS-3 Inter-Regimen Treatment Form	01-09-09

Visit 4: Within 3-4 weeks after final chemotherapy treatment and 1-2 weeks prior to Surgery

N4	Mammography Interpretation Form	12-07-07
T4	MRI-4 Pre-Surgery Form	11-29-07
U4	Ultrasound Interpretation Form	10-08-07
V4	MRS-4 Pre-Surgery Form	01-09-09
S4	Surgical Pathology Form *(Post-Surgery)*	10-08-07

Form Version	Version Date

Supplemental MRI Form: Continued reporting of lesions not seen on Baseline (MRI-1)

TS	Supplemental MRI Form	10-12-07

Additional Forms

AE	ACRIN Adverse Event Form	01-21-10
PR	Protocol Variation Form	03-21-03
DS	End of Study Form	10-16-07
GCM	General Communication Memo	

Enter the data through the Data Center on the ACRIN website. All data should be entered within two weeks of the procedure. Any questions related to these forms should be directed to the contact personnel located on the 6657 website.

Form Revision Notices

Form Revision Notice

Study: ACRIN 6657

From: ACRIN Data Management

Date: February 15, 2010

RE: ACRIN Adverse Event (AE) Form Revision Notice

Form Title:

- (AE) Adverse Event Form

The form was:

- Revised on: 01/21/2010
- Posted to the ACRIN study website on: 01/15/2010
- Posted to the online web entry system: 02/12/2010
- Distributed and effective: 02/15/2010

Description of revisions:

1. **AE Description:**
   - Limited to 200 characters
   - Element # 2 has been inactivated
   - Reference the AE form completion instructions for further details

2. **AE Short Name CTCAE v3.0/MedDRA (online look-up) :**
   - Updated to AE Short Name (online look-up)
   - CTCAE: Common Terminology Criteria for Adverse Events
   - CTCAE version 4.0 will be used for this study.
   - Reference attached CTCAE v4.0.

3. **AdEERS submitted:**
   - AdEERS: Adverse Event Expedited Reporting System
   - Updated to “Expedited Report Submitted”

4. **Investigator’s Signature:**
   - Labeled for “external use only”: for use by the site investigator.

All prior versions of blank forms in your department should be discarded. For questions, please contact your ACRIN [6657] Data Manager at ACRIN Headquarters.

Form Revision Notice

Study: ACRIN 6657

From: ACRIN Data Management Department

Date: May 11, 2009

RE: ACRIN 6657 A0 Forms Notice

Form Title: A0 - Registration Form

The following form revision(s) were:

- Revised on: 5/11/2009
- Posted to the ACRIN study website on: 5/11/2009
- Posted to the online web entry system: 5/11/2009
- Distributed and effective: 5/11/2009

Instructions on Page 1:

Description of revision:

Added to instructions: "Please retain source documents with patients age, weight, serum creatinine level, and date of draw in patient file."

Question #: 15

Description of revision: Added "(Y/N)" for response clarification (1 No, 2 Yes).

Question #: 22

Description of revision:

Previous question:

Is the participant receiving neoadjuvant chemotherapy consisting of an anthracycline based regimen alone or followed by a taxane?

New question:

Is the participant receiving neoadjuvant chemotherapy consisting of a taxane based regimen only or followed by anthracycline?

Question #: 25

Description of revision:

Previous question:

25. Was the participant's serum creatinine clearance > 30 mL/min within 28 days prior to registration?

    Indicate the actual serum Creatinine result

New question:

25. Was the participant's serum creatinine clearance > 30 mL/min within 28 days prior to or up to day registration?

    Calculated serum creatinine clearance

All prior versions of blank forms in your department should be discarded. For questions, please contact your ACRIN Data Manager at ACRIN Headquarters.

Form Revision Notice

Study: ACRIN 6657

From: ACRIN Data Management Department

Date: February 3, 2009

RE: ACRIN 6657 V1, VA, V2, V3, and V4 Forms Revision Notice

Form Title: V1 MRS Form:

The following form revision(s) were made to each of the above forms:

- Revised on: 12/15/08
- Posted to the ACRIN study website on: 2/3/09
- Posted to the online web entry system: 2/3/09
- Distributed and effective: 2/3/09

Question #: 2

Description of revision:

Previous instructions were:

Indicate treatment time window

New instructions are:

Question #2 deleted from form.

All prior versions of blank forms in your department should be discarded. For questions, please contact your ACRIN Data Manager at ACRIN Headquarters.

Form Title: V2 MRS Form:

The following form revision(s) were made to each of the above forms:

- Revised on: 11/19/08
- Posted to the ACRIN study website on: 2/3/09
- Posted to the online web entry system: 2/3/09
- Distributed and effective: 2/3/09

Question #: 2

Description of revision:

Previous instructions were:

Indicate treatment time window

New instructions are:

Indicate actual treatment time window
(This must reflect the actual time window that the participant was scanned; not the treatment window assigned at registration)

Form Title: VA, V3, and V4 MRS Forms:

The following form revision(s) were made to each of the above forms:

- Revised on: 1/9/09
- Posted to the ACRIN study website on: 2/3/09
- Posted to the online web entry system: 2/3/09
- Distributed and effective: 2/3/09

Question #: 2

Description of revision:

Previous instructions were:

Indicate treatment time window

New instructions are:

Question #2 deleted from form.

All prior versions of blank forms in your department should be discarded. For questions, please contact your ACRIN Data Manager at ACRIN Headquarters.

Form Revision Notice

Study: ACRIN 6657

From: ACRIN Data Management Department

Date: November 4, 2008

RE: ACRIN 6657 A0 and AE Forms Notice

Form Title: A0 - Registration Form

The following form revision(s) were:

- Revised on: 9/12/2008
- Posted to the ACRIN study website on: 11/4/2008
- Posted to the online web entry system: 11/4/2008
- Distributed and effective: 11/4/2008

Question #: 25

Description of revision:

Previous question: None

New question:

25. Was the participant's serum creatinine clearance > 30 mL/min within 28 days prior to registration?

    Indicate the actual serum Creatinine result

All prior versions of blank forms in your department should be discarded. For questions, please contact your ACRIN Data Manager at ACRIN Headquarters.

Form Title: AE – Adverse Events Form

The following form revision(s) were:

- Revised on: 6/4/2008
- Posted to the ACRIN study website on: 6/19/2008
- Posted to the online web entry system: 8/9/2008
- Distributed and effective: 11/4/2008

Description of revision:

Previous AE forms: Several Adverse Events were reported on the AE form.

Revised AE form: Only one Adverse Event will be captured on the revised AE form.

All prior versions of blank forms in your department should be discarded. For questions, please contact your ACRIN Data Manager at ACRIN Headquarters.

FORM REVISION NOTICE

STUDY: ACRIN 6657

FROM: ACRIN Data Management Department

DATE: April 23, 2008

RE: **ACRIN 6657 V3 Forms Notice - Effective 4/23/2008**

Please find the attached copy of the 6657 V3 Form that will be used for the extension phase of the trial. The V3 form must be used when submitting data for the Inter-regimen MRS.

- **The form was posted to the study website on April 23, 2008**
- **New Form version is effective as of April 23, 2008**

If you have any questions, please contact **Marcella Moore** at ACRIN Headquarters at mmoore@acr.org or 215-574-3162.

Thank you

FORM REVISION NOTICE

STUDY: ACRIN 6657

FROM: ACRIN Data Management Department

DATE: December 12, 2007

RE: **ACRIN 6657 Forms: Revised Forms – Effective 12/12/07**

Please find the attached copy of the 6657 Case Report Form Set which includes all of the 6657 forms that will be used for the extension phase of the trial. These are the most current forms and must be used when collecting data for this study.

- **The forms revisions were posted to the study website on December 12, 2007**
- **New Forms versions are effective as of December 12, 2007**

Please remember that it is very important to use only the newest version of the form to preserve data. All preliminary form versions that were distributed to participants during the 2007 ACRIN Fall Meeting are currently outdated and should be discarded.

If you have any questions, please contact **Marcella Moore** at ACRIN Headquarters at mmoore@acr.org or 215-574-3162.

Thank you

Visit 1

Pre-Registration / Baseline Visit – Within 4 weeks prior to start of neoadjuvant treatment

A0

ACRIN 6657 Registration Form

If this is a revised or corrected form, indicate by checking box. ☐

ACRIN Study 6657

PLACE LABEL HERE

Institution **Institution No.**

Patient Initials **Case No.**

Instructions: The following questions will be asked at Study Registration. This form is submitted via the ACRIN website. Submit a paper form only in the event the website is down. Please retain source documents with patients age, weight, serum creatinine level, and date of draw in patient file.

_____ 1. Name of institutional person registering this case? *(initials only)* [1]

_____(Y) 2. Has the Eligibility Checklist been completed? [2]
- 1 No
- 2 Yes

_____(Y) 3. Is the participant eligible for this study? [3]
- 1 No
- 2 Yes

_____ 4. Date the study-specific Consent Form was signed? *(mm-dd-yyyy)* ***(must be prior to study entry)*** [4]

_____ 5. Participant Initials (Last, First) [5]

_____ 6. Verifying Physician *(site PI)* [6]

_____ 7. Participant's ID Number *(Optional do not utilize a medical record number or radiology assigned number)* [7]

_____ 8. Date of Birth *(mm-dd-yyyy)* [8]

_____ 9. Ethnic Category [9]
- 1 Hispanic or Latino
- 2 Not Hispanic of Latino
- 9 Unknown

_____ 10. Race [10]
- 1 American Indian of Alaskan Native
- 2 Asian
- 3 Black of African American
- 4 Native Hawaiian or other Pacific Islander
- 5 White
- 6 More than one race
- 9 Unknown

_____ 11. Gender [11]
- 1 Male
- 2 Female

_____ 12. Participant's Country of Residence [12]
- 1 United States
- 2 Canada
- 3 Other

_____ 13. Zip Code [13]

_____ 14. Participant's Insurance Status [14]
- 0 Other
- 1 Private Insurance
- 2 Medicare
- 3 Medicare and Private Insurance
- 4 Medicaid
- 5 Medicare and Medicaid
- 6 Military or Veterans Administration
- 7 Self Pay
- 8 No means of payment
- 9 Unknown / Decline to Answer

PLACE LABEL HERE

Institution **Institution No.**

Patient Initials **Case No.**

_____(Y/N) 15. Will any component of the participant's care be given at a military or VA facility? [15]
1 No
2 Yes

_____ 16. Calendar Base Date [16]

_____ 17. Registration Date *(mm-dd-yyyy)* [17]

_____ 18. Treatment Date *(mm-dd-yyyy)* [18]

_____ 19. Date of Pre-Treatment MRI *(mm-dd-yyyy)* [19]

_____ 20. Name of Medical Oncologist [20]

_____(Y/N) 21. Is the participant enrolled in CALGB 49808 or CALGB Limited Access Trial? ***** [21]
1 No
2 Yes

CALGB Protocol # _____ [22]

CALGB Case # _____[23]

_____(Y/N) 22. Is the participant receiving neoadjuvant chemotherapy consisting of a taxane based regimen only or followed by anthracycline? [32]
1 No
2 Yes
**** Either Q21 or Q22 must be Yes***

_____(N) 23. Is the participant pregnant? [25]
1 No
2 Yes

_____(N) 24. Are there any contraindications to the MRI procedure? [26]
(Ferromagnetic prostheses, claustrophobia, etc?)
1 No
2 Yes

_____(Y/N) 25. Was the participant's serum creatinine clearance > 30 mL/min within 28 days prior to or up to day of registration? [30]
1 No
2 Yes

Calculated serum creatinine clearance _____ mL/min [33]

COMMENTS: _____

_____ [27]

_____ |__|__|-|__|__|-2|0|0|__| [29]

Research Associate [28] **Date form completed** (mm-dd-yyyy)

A0 Completion Instructions

The ACRIN 6657 study coordinator will receive the CALGB registration form and signed informed consent within 5 days of subject enrollment. The subject will subsequently be registered via the ACRIN website. All available dates should be reported as MM-DD-YYYY. Code all questions unless otherwise specified. Do not leave mandatory questions blank. Please note that online logic requires date of Imaging to be after the activation date **(9/1/07)** but no later than **current date.** *FYI - For auditing purpose, please retain a source document with the age, weight, serum creatinine level and date of draw in the patient file.*

REGISTRATION / ELIGIBILITY INFORMATION

4. Date the study-specific consent form was signed

Response to this question is mandatory. Please provide the date, on which the study-specific consent form was signed. This must be on or after the consent date but not later than the current date.

17. Date of registration:

Response to this question is mandatory. The date of registration must be on or after the consent date but not later than the current date.

21. Is the participant enrolled in CALGB 49808 or CALGB Limited Access Trial:

Either Q21 or Q22 must be "Yes." If "Yes," CALGB protocol and case numbers must also be provided.

22. Is the participant receiving neoadjuvant chemotherapy consisting of taxane based regimen only followed by anthracycline?

Either Q21 or Q22 must be "Yes."

23. Is the participant pregnant?

Response to this question is mandatory.

24. Are there any contraindications to the MRI procedure? *(Ferromagnetic prostheses, claustrophobia, etc?)*

Response to this question is mandatory.

25. **Was the participant's serum creatinine clearance >30 mL/min within 28 days prior to or up to day of registration?**

Response to this question is mandatory.

Calculated serum creatinine clearance

Must be documented in mL/min. The following formula must be used to calculate serum Creatinine:

Creatinine Clearance for Males: ([140-age (years)] X weight (kg)/(serum creatinine X 72)

Creatinine Clearance for Females: Creatinine Clearance (male) X 0.85

Research Associate:

Legible initials of the research associate responsible for collating / reviewing the data and ensuring completion of the CRF (paper or web). If completing a web CRF only, without completing a paper CRF, the electronic summary must be printed and signed by the staff member responsible for the data. The Research Associate's (RA) signature must be on the original document (whether paper or web).

Date form completed:

Record the date the original CRF, whether paper or web, was completed. If completing a paper CRF this refers to the date the data was originally recorded on the paper CRF; the date/time of web entry is automatically recorded by the database. If completing the web CRF only, without completing a paper CRF, this refers to the date the data was originally recorded in the web module.

N1 ACRIN 6657 Extension Mammography Interpretation Form

ACRIN Study 6657

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

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

PRE-TREATMENT

Instructions: In accordance with the protocol, two mammograms will be performed. The first mammogram, within 3 months prior to or 2 weeks after MRI-1 but before start of treatment. The second mammogram, after the final chemotherapy treatment and before surgery. This form is to be completed for each mammogram by the study radiologist. Report only clinically relevant findings. Report index lesion if visualized. When reporting index lesion, the index lesion corresponds to the tumor used to define participant eligibility. Submit this form within 2 weeks of each study mammogram via the ACRIN website. Submit paper form only for revisions or corrections.

1. Protocol Time Point [1]
- o Pre-Treatment
  Anticipated Treatment start date

  _____-_____-_____ *(mm-dd-yyyy)* [2]

2. Date of Mammogram: _____-_____-_____ [4]
(mm-dd-yyyy)

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

4. Reader Name: _____ [6]

5. Reader ID: ☐☐☐☐☐☐☐ [7]

6. Clinically Relevant Lesion(s) Identified [8]
- o No *(proceed to question 15)*
- o Yes

7. Study Breast [9]
- o Right
- o Left
- o Bilateral

8. Density of Breast Parenchyma [10]
- o Mostly fat
- o Scattered fibroglandular densities
- o Heterogeneously dense
- o Extremely dense

12. Index Lesion Identified on Mammogram [17]
- o No
- o Yes

9. Clinically Relevant Mass(es) Identified [11]
- o No
- o Yes *(report in section A)*

Total Number ☐ [12]

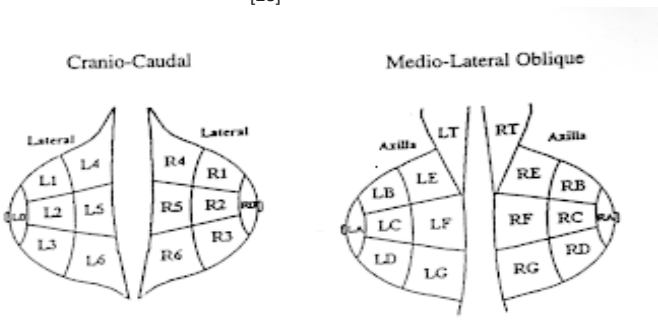
10. Remember to complete Clinically Relevant Calcification Cluster on page 3 - Section B

11. Remember to complete Clinically Relevant Architectural Distortions on page 5 - Section C

SECTION A: CLINICALLY RELEVANT MASSES

(Report index lesion if visualized. Report descriptive data for the three most prominent masses.)

Reporting Mass # ☐ [18]



Mass Location:

Cranio-Caudal *(select all that apply)*

☐	L0 [19]	☐	R0 [26]
☐	L1 [20]	☐	R1 [27]
☐	L2 [21]	☐	R2 [28]
☐	L3 [22]	☐	R3 [29]
☐	L4 [23]	☐	R4 [30]
☐	L5 [24]	☐	R5 [31]
☐	L6 [25]	☐	R6 [32]

Medio-Lateral *(select all that apply)*

☐	LT [33]	☐	RT [41]
☐	LA [34]	☐	RA [42]
☐	LB [35]	☐	RB [43]
☐	LC [36]	☐	RC [44]
☐	LD [37]	☐	RD [45]
☐	LE [38]	☐	RE [46]
☐	LF [39]	☐	RF [47]
☐	LG [40]	☐	RG [48]

Size of Mass *(record all three measurements)*

x = ☐☐☐ **mm** (medial-lateral) [49]

y = ☐☐☐ **mm** (superior-inferior) [50]

z = ☐☐☐ **mm** (anterior-posterior) [51]

Largest Dimension of Mass ☐☐☐ **mm** [52]

N1

ACRIN 6657 Extension
Mammography Interpretation Form

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

ACRIN Study **6657**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Mass Shape *(select one)* [53]
- o Round
- o Oval
- o Lobulated
- o Irregular

Mass Margins *(select one)* [54]
- o Circumscribed
- o Microlobulated
- o Obscured
- o Indistinct
- o Spiculated

Distance Between Ends of Spiculation
(answer if margin is spiculated)
└┴┘ **mm** [55]

Mass Density *(select one)* [56]
- o High
- o Equal
- o Low
- o Fat containing

Associated Features *(select all that apply)*
- ☐ Calcifications [57]
- ☐ Architectural distortions [58]
- ☐ Skin thickening [59]
- ☐ Solitary dilated duct [60]
- ☐ Multiple dilated ducts [61]
- ☐ None [62]

Mass Corresponds to Index Lesion [63]
- o No
- o Yes

Additional Masses [64]
- o No *(proceed to section B)*
- o Yes *(continue)*

Reporting Mass # └┘ [65]

Mass Location:
Cranio-Caudal *(select all that apply)*

☐	L0 [66]	☐	R0 [73]
☐	L1 [67]	☐	R1 [74]
☐	L2 [68]	☐	R2 [75]
☐	L3 [69]	☐	R3 [76]
☐	L4 [70]	☐	R4 [77]
☐	L5 [71]	☐	R5 [78]
☐	L6 [72]	☐	R6 [79]

PRE-TREATMENT

Medio-Lateral *(select all that apply)*

☐	LT [80]	☐	RT [88]
☐	LA [81]	☐	RA [89]
☐	LB [82]	☐	RB [90]
☐	LC [83]	☐	RC [91]
☐	LD [84]	☐	RD [92]
☐	LE [85]	☐	RE [93]
☐	LF [86]	☐	RF [94]
☐	LG [87]	☐	RG [95]

Size of Mass *(record all three measurements)*
x = └┴┘**mm** (medial-lateral) [96]
y = └┴┘**mm** (superior-inferior) [97]
z = └┴┘**mm** (anterior-posterior) [98]

Largest Dimension of Mass └┴┘ **mm** [99]

Mass Shape *(select one)* [100]
- o Round
- o Oval
- o Lobulated
- o Irregular

Mass Margins *(select one)* [101]
- o Circumscribed
- o Microlobulated
- o Obscured
- o Indistinct
- o Spiculated

Distance Between Ends of Spiculation
(answer if margin is spiculated)
└┴┘ **mm** [102]

Mass Density *(select one)* [103]
- o High
- o Equal
- o Low
- o Fat containing

Associated Features *(select all that apply)*
- ☐ Calcifications [104]
- ☐ Architectural distortions [105]
- ☐ Skin thickening [106]
- ☐ Solitary dilated duct [107]
- ☐ Multiple dilated ducts [108]
- ☐ None [109]

Mass Corresponds to Index Lesion [110]
- o No
- o Yes

N1 **ACRIN 6657 Extension Mammography Interpretation Form**

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

ACRIN Study 6657

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Additional Masses [111]
- o No *(proceed to section B)*
- o Yes *(continue)*

Reporting Mass # ___ [112]

Mass Location:

Cranio-Caudal *(select all that apply)*

☐	L0 [113]	☐	R0 [120]
☐	L1 [114]	☐	R1 [121]
☐	L2 [115]	☐	R2 [122]
☐	L3 [116]	☐	R3 [123]
☐	L4 [117]	☐	R4 [124]
☐	L5 [118]	☐	R5 [125]
☐	L6 [119]	☐	R6 [126]

Medio-Lateral *(select all that apply)*

☐	LT [127]	☐	RT [135]
☐	LA [128]	☐	RA [136]
☐	LB [129]	☐	RB [137]
☐	LC [130]	☐	RC [138]
☐	LD [131]	☐	RD [139]
☐	LE [132]	☐	RE [140]
☐	LF [133]	☐	RF [141]
☐	LG [134]	☐	RG [142]

Size of Mass *(record all three measurements)*

x = ___ **mm** (medial-lateral) [143]

y = ___ **mm** (superior-inferior) [144]

z = ___ **mm** (anterior-posterior) [145]

Largest Dimension of Mass ___ **mm** [146]

Mass Shape *(select one)* [147]
- o Round
- o Oval
- o Lobulated
- o Irregular

Mass Margins *(select one)* [148]
- o Circumscribed
- o Microlobulated
- o Obscured
- o Indistinct
- o Spiculated

Distance Between Ends of Spiculation *(answer if margin is spiculated)*

___ **mm** [149]

Mass Density *(select one)* [150]
- o High
- o Equal
- o Low
- o Fat containing

PRE-TREATMENT

Associated Features *(select all that apply)*
- ☐ Calcifications [151]
- ☐ Architectural distortions [152]
- ☐ Skin thickening [153]
- ☐ Solitary dilated duct [154]
- ☐ Multiple dilated ducts [155]
- ☐ None [156]

Mass Corresponds to Index Lesion [157]
- o No
- o Yes

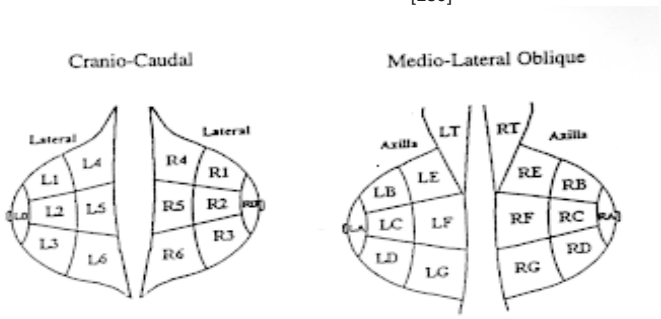
Additional Masses [158]
- o No
- o Yes

SECTION B: CLINICALLY RELEVANT CALCIFICATION CLUSTERS *(Report index lesion if visualized. Report descriptive data for the three most prominent calcification clusters.)*

Calcification Cluster(s) Identified [13]
- o No
- o Yes *(report in section B)*

Total Number ___ [14]

Reporting Calcification Cluster# ___ [159]



Calcification Location:

Cranio-Caudal *(select all that apply)*

☐	L0 [160]	☐	R0 [167]
☐	L1 [161]	☐	R1 [168]
☐	L2 [162]	☐	R2 [169]
☐	L3 [163]	☐	R3 [170]
☐	L4 [164]	☐	R4 [171]
☐	L5 [165]	☐	R5 [172]
☐	L6 [166]	☐	R6 [173]

N1

ACRIN 6657 Extension
Mammography Interpretation Form

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

ACRIN Study 6657
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Medio-Lateral *(select all that apply)*

☐	LT [174]	☐	RT [182]
☐	LA [175]	☐	RA [183]
☐	LB [176]	☐	RB [184]
☐	LC [177]	☐	RC [185]
☐	LD [178]	☐	RD [186]
☐	LE [179]	☐	RE [187]
☐	LF [180]	☐	RF [188]
☐	LG [181]	☐	RG [189]

Largest Dimension of Calcification Cluster

⌊_⌊_⌊_ **mm** [190]

Morphology of Calcification: *(select one)*

Benign Appearing [191]

- o Skin Calcifications
- o Vascular Calcifications
- o Coarse ("Pop-corn-like")
- o Large Rod-like
- o Round
- o Lucent centered
- o Eggshell or Rim
- o Milk of Calcium
- o Suture
- o Dystrophic
- o Punctate

Intermediate Concern

- o Amorphous or Indistinct

Higher Probability

- o Pleomorphic or Heterogenous (Granular)
- o Fine, Linear, Branching (Casting)

Calcification Distribution *(select one)* [192]

- o Grouped/Clustered
- o Linear
- o Segmental
- o Regional
- o Diffuse/Scattered

Calcification Cluster Associated with Mass Reported on This Form [193]

- o No
- o Yes, associated with previously identified mass # ⌊_⌊ (#1-3) [194]

Calcification Cluster Corresponds to Index Lesion [195]

- o No
- o Yes

Additional Calcification Clusters [196]

- o No *(proceed to section C)*
- o Yes *(continue)*

PRE-TREATMENT

Reporting Calcification Cluster# ⌊_⌊ [197]

Calcification Location:

Cranio-Caudal *(select all that apply)*

☐	L0 [198]	☐	R0 [205]
☐	L1 [199]	☐	R1 [206]
☐	L2 [200]	☐	R2 [207]
☐	L3 [201]	☐	R3 [208]
☐	L4 [202]	☐	R4 [209]
☐	L5 [203]	☐	R5 [210]
☐	L6 [204]	☐	R6 [211]

Medio-Lateral *(select all that apply)*

☐	LT [212]	☐	RT [220]
☐	LA [213]	☐	RA [221]
☐	LB [214]	☐	RB [222]
☐	LC [215]	☐	RC [223]
☐	LD [216]	☐	RD [224]
☐	LE [217]	☐	RE [225]
☐	LF [218]	☐	RF [226]
☐	LG [219]	☐	RG [227]

Largest Dimension of Calcification Cluster

⌊_⌊_⌊_ **mm** [228]

Morphology of Calcification: *(select one)* [229]

Benign Appearing

- o Skin Calcifications
- o Vascular Calcifications
- o Coarse ("Pop-corn-like")
- o Large Rod-like
- o Round
- o Lucent centered
- o Eggshell or Rim
- o Milk of Calcium
- o Suture
- o Dystrophic
- o Punctate

Intermediate Concern

- o Amorphous or Indistinct

Higher Probability

- o Pleomorphic or Heterogenous (Granular)
- o Fine, Linear, Branching (Casting)

Calcification Distribution *(select one)* [230]

- o Grouped/Clustered
- o Linear
- o Segmental
- o Regional
- o Diffuse/Scattered

N1 **ACRIN 6657 Extension Mammography Interpretation Form**

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

ACRIN Study **6657**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Calcification Cluster Associated with Mass Reported on This Form [231]
- o No
- o Yes, associated with previously identified mass # ☐ (#1-3) [232]

Calcification Cluster Corresponds to Index Lesion [233]
- o No
- o Yes

Additional Calcification Clusters [234]
- o No *(proceed to section C)*
- o Yes *(continue)*

Reporting Calcification Cluster# ☐ [235]

Calcification Location:

Cranio-Caudal *(select all that apply)*

☐	L0 [236]	☐	R0 [243]
☐	L1 [237]	☐	R1 [244]
☐	L2 [238]	☐	R2 [245]
☐	L3 [239]	☐	R3 [246]
☐	L4 [240]	☐	R4 [247]
☐	L5 [241]	☐	R5 [248]
☐	L6 [242]	☐	R6 [249]

Medio-Lateral *(select all that apply)*

☐	LT [250]	☐	RT [258]
☐	LA [251]	☐	RA [259]
☐	LB [252]	☐	RB [260]
☐	LC [253]	☐	RC [261]
☐	LD [254]	☐	RD [262]
☐	LE [255]	☐	RE [263]
☐	LF [256]	☐	RF [264]
☐	LG [257]	☐	RG [265]

Largest Dimension of Calcification Cluster

☐☐☐ **mm** [266]

Morphology of Calcification: *(select one)* [267]

Benign Appearing
- o Skin Calcifications
- o Vascular Calcifications
- o Coarse ("Pop-corn-like")
- o Large Rod-like
- o Round
- o Lucent centered
- o Eggshell or Rim
- o Milk of Calcium
- o Suture
- o Dystrophic
- o Punctate

Intermediate Concern
- o Amorphous or Indistinct

Higher Probability
- o Pleomorphic or Heterogenous (Granular)
- o Fine, Linear, Branching (Casting)

PRE-TREATMENT

Calcification Distribution *(select one)* [268]
- o Grouped/Clustered
- o Linear
- o Segmental
- o Regional
- o Diffuse/Scattered

Calcification Cluster Associated with Mass Reported on This Form [269]
- o No
- o Yes, associated with previously identified mass # ☐ (#1-3) [270]

Calcification Cluster Corresponds to Index Lesion [271]
- o No
- o Yes

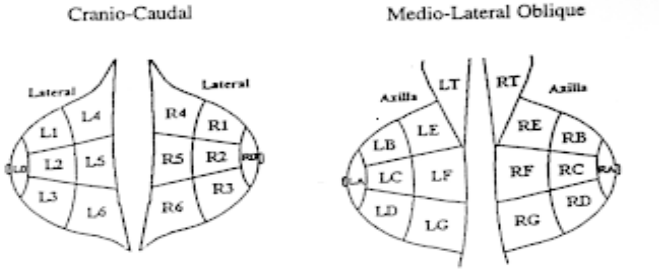
Additional Calcification Clusters [272]
- o No
- o Yes

SECTION C: CLINICALLY RELEVANT ARCHITECTURAL DISTORTIONS *(Report index lesion if visualized. Report descriptive data for the three most prominent architectural distortions.)*

Architectural Distortion(s) Identified [15]
- o No
- o Yes *(report in section C)*

Total Number ☐ [16]

Reporting Architectural Distortion # ☐ [273]



Architectural Distortion Location:

Cranio-Caudal *(select all that apply)*

☐	L0 [274]	☐	R0 [281]
☐	L1 [275]	☐	R1 [282]
☐	L2 [276]	☐	R2 [283]
☐	L3 [277]	☐	R3 [284]
☐	L4 [278]	☐	R4 [285]
☐	L5 [279]	☐	R5 [286]
☐	L6 [280]	☐	R6 [287]

N1 **ACRIN 6657 Extension Mammography Interpretation Form**

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

ACRIN Study 6657

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Medio-Lateral *(select all that apply)*

☐	LT [288]	☐	RT [296]
☐	LA [289]	☐	RA [297]
☐	LB [290]	☐	RB [298]
☐	LC [291]	☐	RC [299]
☐	LD [292]	☐	RD [300]
☐	LE [293]	☐	RE [301]
☐	LF [294]	☐	RF [302]
☐	LG [295]	☐	RG [303]

Largest Dimension of Architectural Distortion

|_|_|_| **mm** [304]

Architectural Distortion Associated with Mass Reported on This Form [305]

o No

o Yes, associated with previously identified mass # |_| (#1-3) [306]

Architectural Distortion Corresponds to Index Lesion [307]

o No

o Yes

Additional Architectural Distortions [308]

o No *(proceed to question 13)*

o Yes *(continue)*

Reporting Architectural Distortion # |_| [309]

Architectural Distortion Location: Cranio-Caudal *(select all that apply)*

☐	L0 [310]	☐	R0 [317]
☐	L1 [311]	☐	R1 [318]
☐	L2 [312]	☐	R2 [319]
☐	L3 [313]	☐	R3 [320]
☐	L4 [314]	☐	R4 [321]
☐	L5 [315]	☐	R5 [322]
☐	L6 [316]	☐	R6 [323]

Medio-Lateral *(select all that apply)*

☐	LT [324]	☐	RT [332]
☐	LA [325]	☐	RA [333]
☐	LB [326]	☐	RB [334]
☐	LC [327]	☐	RC [335]
☐	LD [328]	☐	RD [336]
☐	LE [329]	☐	RE [337]
☐	LF [330]	☐	RF [338]
☐	LG [331]	☐	RG [339]

Largest Dimension of Architectural Distortion

|_|_|_| **mm** [340]

PRE-TREATMENT

Architectural Distortion Associated with Mass Reported on This Form [341]

o No

o Yes, associated with previously identified mass # |_| (#1-3) [342]

Architectural Distortion Corresponds to Index Lesion [343]

o No

o Yes

Additional Architectural Distortions [344]

o No *(proceed to question 13)*

o Yes *(continue)*

Reporting Architectural Distortion # |_| [345]

Architectural Distortion Location: Cranio-Caudal *(select all that apply)*

☐	L0 [346]	☐	R0 [353]
☐	L1 [347]	☐	R1 [354]
☐	L2 [348]	☐	R2 [355]
☐	L3 [349]	☐	R3 [356]
☐	L4 [350]	☐	R4 [357]
☐	L5 [351]	☐	R5 [358]
☐	L6 [352]	☐	R6 [359]

Medio-Lateral *(select all that apply)*

☐	LT [360]	☐	RT [368]
☐	LA [361]	☐	RA [369]
☐	LB [362]	☐	RB [370]
☐	LC [363]	☐	RC [371]
☐	LD [364]	☐	RD [372]
☐	LE [365]	☐	RE [373]
☐	LF [366]	☐	RF [374]
☐	LG [367]	☐	RG [375]

Largest Dimension of Architectural Distortion

|_|_|_| **mm** [376]

Architectural Distortion Associated with Mass Reported on This Form [377]

o No

o Yes, associated with previously identified mass # |_| (#1-3) [378]

Architectural Distortion Corresponds to Index Lesion [379]

o No

o Yes

N1 **ACRIN 6657 Extension Mammography Interpretation Form**

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

ACRIN Study **6657**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

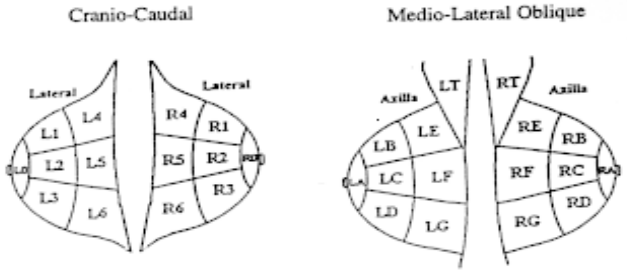
Participant Initials _____ **Case No.** _____

Additional Architectural Distortions [380]
- o No
- o Yes

13. Special Cases [381]
- o No *(proceed to question 14)*
- o Yes *(report special cases below)*

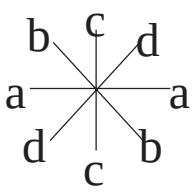
Indicate Special Cases *(select all that apply)*
- ☐ Intramammary Lymph Node [382]
- ☐ Asymmetric Breast Tissue [383]
- ☐ Focal Asymmetric Density [384]

14. Full Extent of Disease
(spanning all disease present)



Direction for Longest Diameter Measurement
(refer to above diagrams - use same direction for all mammograms) [385]
- o Cranio-caudal
- o Medio-lateral

PRE-TREATMENT



Orientation of Longest Diameter Measurement
(refer to above diagrams - use same orientation for all mammograms) [386]
- o a
- o b
- o c
- o d

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** [387]

15. BIRADS Lexicon [388]
- o Category 1 Negative
- o Category 2 Benign Finding
- o Category 3 Probably Benign Finding – Short interval follow-up suggested
- o Category 4 Suspicious Abnormality – Biopsy should be considered
- o Category 5 Highly Suggestive of Malignancy – Appropriate action should be taken

COMMENTS: _____

_____ [389]

_____
Radiologist Signature
(radiologist must sign either the completed paper form or the completed/printed web form)

_____ [390]
Signature of person responsible for data

_____-_____-**2 0 0**___ [391]
Date form completed (mm-dd-yyyy)

_____ [392]
Signature of person entering data onto web

N1 Mammography Interpretation Form - Completion Instructions

In accordance with the protocol, two mammograms will be performed. The first mammogram, reported on the N1 form, must be performed within 3 months prior to or 2 weeks after MRI-1 but before start of treatment. This form is to be completed by the study radiologist. Report only clinically relevant findings. Report index lesion if visualized. When reporting index lesion, the index lesion corresponds to the tumor used to define participant eligibility. Date must be in the mm/dd/yyyy format. Submit this form within 2 weeks of the study mammogram via the ACRIN website. Submit paper form only for revisions or corrections.

TIME-POINT INFORMATION

1. Protocol imaging time point:

Record the appropriate response. The response to this question is mandatory and the default is set according to the form being completed; N1- Pre-Treatment Form.

2. Date of Mammogram:

Mandatory. Record the date that the mammogram was performed (date must not be in the future).

3. Date of Interpretation:

Mandatory. Record the date that the mammogram was interpreted by the radiologist (date must not be in the future).

5. Reader ID:

This 7 alphanumeric character user specific Id is required.

6. Clinically Relevant Lesion(s) Identified?

Response to this question is mandatory. If clinically relevant lesion(s) were identified, complete question 6 through the remainder of the form. If clinically relevant lesion(s) were not identified, skip to question 15 and complete the remainder of the form.

12. Index Lesion Identified on Mammogram

Question 12 has been moved to correspond with the data entry screen. If the response is “Yes”, indicate which mass(es), calcification cluster(s), and/or architectural distortion(s) correspond to index lesion when completing remainder of the form.

9. Clinically Relevant Mass(es) Identified?

Response to this question is mandatory. If clinically relevant mass(es) were identified, complete Section A. Indicate total number of clinically relevant masses (1-10). If clinically relevant mass(es) were not identified, skip to Section B.

10. Remember to complete Clinically Relevant Calcification Cluster on page 3 - Section B.

This is an important reminder to the radiologist to complete Section B.

11. Remember to complete Clinically Relevant Architectural Distortions on page 5 - Section C.

This is an important reminder to the radiologist to complete Section C.

Section A: Clinically Relevant Masses

Report index lesion if visualized. Complete this section if there are clinically relevant masses to report. Provide descriptive data for up to three of the most prominent masses.

Mass Location: For each reported mass, at least one choice must be selected in the Cranio-Caudal or Medio-Lateral view.

Size of Mass: At least one of x, y, or z must be greater than 0.

Largest Dimension of Mass: Record the largest of "Size of Mass" (x, y, or z) therefore, the "Largest Dimension of Mass" must equal x, y, or z.

Mass Corresponds to Index lesion: A "Yes" response is allowed only if the response to Q12 "Index Lesion Identified on Mammogram" equals "Yes".

Additional Masses: If the response is "No" for this or any additional Mass being reported in this section, skip to section B on page 3. If the response is "Yes" for this or any other additional mass, complete responses are required for each relevant mass.

Section B: Clinically Relevant Calcifications Clusters

Calcification Cluster(s) Identified?

Response to this question is mandatory. If clinically relevant calcifications cluster(s) were identified, complete Section B. Indicate total number of clinically relevant calcifications clusters (1-10). If clinically relevant calcifications cluster(s) were not identified, skip to Section C.

Calcification Location: For each reported calcification cluster, at least one choice must be selected in the Cranio-Caudal or Medio-Lateral view.

Calcification Cluster Associated with Mass Reported on This Form: If "Yes", identify which mass (in Section A) calcification cluster is associated with – mass number 1, 2 or 3.

Calcification Cluster Corresponds to Index lesion: "Yes" response is allowed only if the response to Q12 "Index Lesion Identified on Mammogram" equals "Yes".

Additional Calcification Clusters: If the response is "No" for this or any additional Calcification Cluster being reported in this section, skip to section C on page 5. If the response is "Yes" for this or any other additional calcification cluster, complete responses are required for each relevant calcification cluster.

Section C: Clinically Relevant Architectural Distortions

Architectural Distortion(s) Identified?

Response to this question is mandatory. If clinically relevant architectural distortion(s) were identified, complete Section C. Indicate total number of clinically relevant architectural distortion(s) (1-10). If clinically relevant architectural distortion(s) were not identified, skip to Question 13.

Architectural Distortion Location: For each reported architectural distortion, at least one choice must be selected in the Cranio-Caudal or Medio-Lateral view.

Architectural Distortion Associated with Mass Reported on This Form: If "Yes", identify which mass (in Section A) architectural distortion is associated with – mass number 1, 2 or 3.

Architectural Distortion Corresponds to Index lesion: "Yes" response is allowed only if the response to Q12 "Index Lesion Identified on Mammogram" equals "Yes".

Additional Architectural Distortions: If the response is "No" for this or any additional architectural distortion being reported in this section, skip to question 13. If the response is "Yes" for this or any other additional architectural distortion, complete responses are required for each relevant architectural distortion.

14. Full Extent of Disease:

Direction for Longest Diameter Measurement: Either the Cranio-Caudal or the Medio-Lateral Oblique diagram must be selected. The same direction must be used for each mammogram.

Orientation of Longest Diameter Measurement: Indicate the direction (a, b, c, or d) of orientation. The same direction must be used for each mammogram.

Radiologist Signature: Legible signature of the Radiologist. If completing a web CRF only, without completing a paper CRF, the electronic summary must be printed and signed by the Radiologist. The Radiologist's signature must be on the original document (whether paper or web).

Signature of person responsible for data: Legible signature/name of the staff member responsible for Collating/reviewing the data and ensuring completion of the CRF (paper or web). If completing a web CRF only, without completing a paper CRF, the electronic summary must be printed and signed by the staff member responsible for the data. The RA's signature must be on the original document (whether paper or web).

Date form completed: Record the date the original CRF, whether paper or web, was completed. If completing a Paper CRF this refers to the date the data was originally recorded on the paper CRF; the date/time of web entry is automatically recorded by the database. If completing the web CRF only, without completing a paper CRF, this refers to the date the data was originally recorded in the web module.

Signature of person entering data onto web: Record the signature/name of the staff member submitting the Data on-line. If completing a web CRF only, without completing a paper CRF, the electronic summary must be printed and signed by the staff member entering the data onto the web.

T1

ACRIN 6657 Extension
MRI Form: Baseline / Pre-Treatment MRI 1

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

ACRIN Study 6657 Case #

PLACE LABEL HERE

Institution Institution No.

Participant's Initials Participant's I.D. No.

BASELINE / PRE-TREATMENT

Instructions: In accordance with the protocol, four MRI exams are required for each participant. MRI-1, pre-treatment MRI, is to occur within 2 weeks prior to start of neoadjuvant treatment. This form is to be completed by the study radiologist and used for pre-treatment MR Imaging only. Forms TA, T2, T3, and T4 are for treatment and post-treatment MR imaging (MRI-1.1, 2, 3, 4). Report only clinically relevant findings (up to 3 masses and/or 3 regional enhancements) for the study breast only. Report index lesion if visualized. When reporting index lesion, the index lesion corresponds to the tumor used to define participant eligibility. Report all dates as mm-dd-yyyy. Submit this form within 2 weeks of the MRI via the ACRIN website. Please remember to complete page 8. Submit paper form only for revisions or corrections.

1. Protocol Time Point [1]
- O Baseline / Pre-Treatment

1a. Was MRI performed? [407]
- o No* (complete Q1b, then sign and date form)
- o Yes (proceed to Q2 and continue with form)

1b. *If No, provide reason: [408]
- o Scheduling problem
- o Equipment failure
- o Participant refusal
- o Medical reason
- o Injection site complications
- o Claustrophobia
- o Participant withdrew consent
- o Progressive disease
- o Participant death
- o Other, specify: _____ [409]
- o Unknown

2. Date of MRI ____ - ____ - **20** ____ (mm-dd-yyyy) [3]

3. Date of Interpretation ____ - ____ - **20** ____ [4]
(mm-dd-yyyy)

4. Reader Name: _____ [5]

5. Reader ID: ____|____|____|____|____|____|____|____ [6]

6. Patient Weight (kgs) ____|____|____ [7]

6a. Patient Height (cm) ____|____|____ [390]

7. Total Amount of Gadolinium Injected (cc) ____|____ [8]

8. Were Clinically Relevant Enhancing Lesion(s) Identified [9]
- O No *(sign and date form)*
- O Yes

Complete For Study Breast Only

9. Study Breast [10]
- O Right
- O Left

10. Density of Breast Parenchyma [11]
- O Mostly fat
- O Scattered fibroglandular tissue
- O Heterogeneously dense
- O Extremely dense

11. Index Lesion Identified on this MRI Exam [16]
- O No
- O Yes

12. Were Clinically Relevant Mass(es) Identified [12]
- O No
- O Yes *(report in Section A)*

Total Number ____ [13]

13. Remember to complete clinically revelant regional enhancements located on page 5 - Section B

T1 If this is a revised or corrected form, please √box. ☐

ACRIN Study 6657 Case #

PLACE LABEL HERE

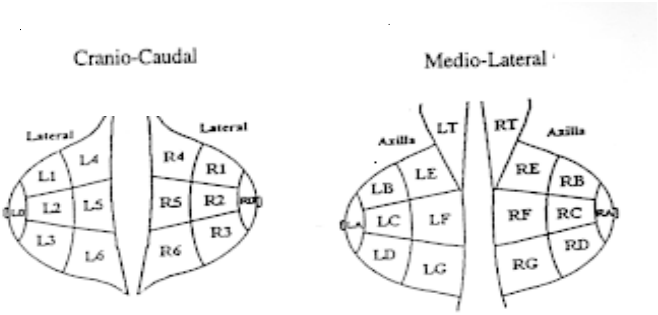
Institution Institution No.

Participant's Initials Participant's I.D. No.

BASELINE / PRE-TREATMENT

Section A: Clinically Relevant Masses
Report on the study breast only. Report descriptive data for up to three masses. If more than three masses are present, report only the three most prominent to include the index lesion, if visualized.

1. Reporting Mass # 1 ___ [17]



1a. Location:

Cranio-Caudal *(select all that apply)*

☐ L0 [18]	☐ R0 [25]
☐ L1 [19]	☐ R1 [26]
☐ L2 [20]	☐ R2 [27]
☐ L3 [21]	☐ R3 [28]
☐ L4 [22]	☐ R4 [29]
☐ L5 [23]	☐ R5 [30]
☐ L6 [24]	☐ R6 [31]

Medio-Lateral *(select all that apply)*

☐ LT [32]	☐ RT [40]
☐ LA [33]	☐ RA [41]
☐ LB [34]	☐ RB [42]
☐ LC [35]	☐ RC [43]
☐ LD [36]	☐ RD [44]
☐ LE [37]	☐ RE [45]
☐ LF [38]	☐ RF [46]
☐ LG [39]	☐ RG [47]

1b. Size *(record all three measurements [0 = not seen])*

x = ___ **mm** (medial-lateral) [48]

y = ___ **mm** (superior-inferior) [49]

z = ___ **mm** (anterior-posterior) [50]

1c. Shape/Margin *(select one)* [51]
- O Smooth round
- O Smooth oval
- O Lobulated
- O Irregular
- O Spiculated

1d. Internal Enhancement *(select one)* [52]
- O Homogeneous confluent
- O Heterogeneous
- O Rim enhanced
- O Centrally enhanced
- O Dark septation(s)
- O Enhancing septation(s)

1e. T2 Appearance *(select one)* [53]
- O Hyperintense to surrounding breast tissue
- O Hypointense to surrounding breast tissue
- O Isointense to surrounding breast tissue
- O Unable to evaluate

1f. Degree of Enhancement
(characterize by strongest degree seen) [54]
- O Minimal
- O Moderate
- O Marked

1g. Enhancement Pattern
(characterize by strongest pattern seen) [55]
- O Gradual
- O Sustained
- O Washout

1h. Series and Image Number of Representative Slices *(list up to 3)*

Series ___ : [339] **Image #** ___ [340]

Series ___ : [341] **Image #** ___ [342]

Series ___ : [343] **Image #** ___ [344]

1i. Corresponds to Index Lesion [56]
- O No
- O Yes (skip Q1j)

1j. Has this been independently biopsied? [393]
- o No
- o Yes
- o Don't know

Comments about this mass: _____

_____

_____

_____ [345]

1k. Additional Masses [394]
- o No
- o Yes

If no additional masses to report complete page 5

T1 If this is a revised or corrected form, please √box. ☐

ACRIN Study 6657 Case #

PLACE LABEL HERE

Institution Institution No.

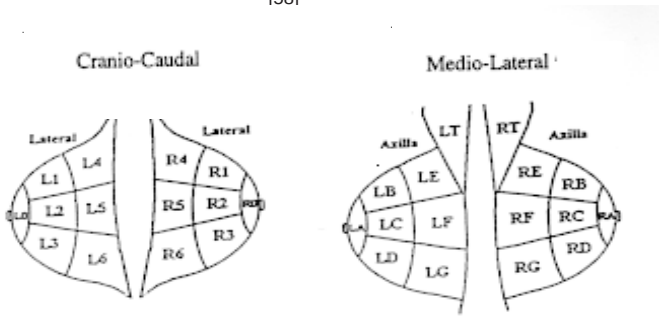
Participant's Initials Participant's I.D. No.

BASELINE / PRE-TREATMENT

Section A: Clinically Relevant Masses

Report on the study breast only. Report descriptive data for up to three masses. If more than three masses are present, report only the three most prominent to include the index lesion, if visualized.

2. Reporting Mass # 2 ____ [58]



2a. Location:

Cranio-Caudal *(select all that apply)*

☐ L0	[59]	☐ R0	[66]
☐ L1	[60]	☐ R1	[67]
☐ L2	[61]	☐ R2	[68]
☐ L3	[62]	☐ R3	[69]
☐ L4	[63]	☐ R4	[70]
☐ L5	[64]	☐ R5	[71]
☐ L6	[65]	☐ R6	[72]

Medio-Lateral *(select all that apply)*

☐ LT	[73]	☐ RT	[81]
☐ LA	[74]	☐ RA	[82]
☐ LB	[75]	☐ RB	[83]
☐ LC	[76]	☐ RC	[84]
☐ LD	[77]	☐ RD	[85]
☐ LE	[78]	☐ RE	[86]
☐ LF	[79]	☐ RF	[87]
☐ LG	[80]	☐ RG	[88]

2b. Size *(record all three measurements [0 = not seen])*

x = ___ **mm** (medial-lateral) [89]

y = ___ **mm** (superior-inferior) [90]

z = ___ **mm** (anterior-posterior) [91]

2c. Shape/Margin *(select one)* [92]

O Smooth round
O Smooth oval
O Lobulated
O Irregular
O Spiculated

2d. Internal Enhancement *(select one)* [93]

O Homogeneous confluent
O Heterogeneous
O Rim enhanced
O Centrally enhanced
O Dark septation(s)
O Enhancing septation(s)

2e. T2 Appearance *(select one)* [94]

O Hyperintense to surrounding breast tissue
O Hypointense to surrounding breast tissue
O Isointense to surrounding breast tissue
O Unable to evaluate

2f. Degree of Enhancement

(characterize by strongest degree seen) [95]

O Minimal
O Moderate
O Marked

2g. Enhancement Pattern

(characterize by strongest pattern seen) [96]

O Gradual
O Sustained
O Washout

2h. Series and Image Number of Representative Slices *(list up to 3)*

Series ___ : [347] **Image #** ___ [348]

Series ___ : [349] **Image #** ___ [350]

Series ___ : [351] **Image #** ___ [352]

2i. Corresponds to Index Lesion [97]

O No
O Yes (Skip Q2j)

2j. Has this been independently biopsied? [395]

O No
O Yes
O Don't know

Comments about this mass: _____

_____

_____

_____ [353]

2k. Additional Masses [396]

O No
O Yes

*** If no additional masses to report complete page 5**

T1 If this is a revised or corrected form, please √box. ☐

ACRIN Study 6657 Case #

PLACE LABEL HERE

Institution Institution No.

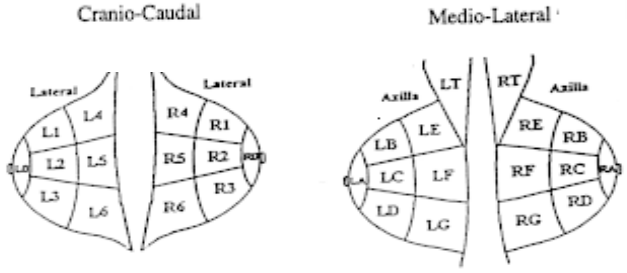
Participant's Initials Participant's I.D. No.

BASELINE / PRE-TREATMENT

Section A: Clinically Relevant Masses

Report on the study breast only. Report descriptive data for up to three masses. If more than three masses are present, report only the three most prominent to include the index lesion, if visualized.

3. Reporting Mass # 3 ____ [99]



3a.

Cranio-Caudal *(select all that apply)*

☐ L0	[100]	☐ R0	[107]
☐ L1	[101]	☐ R1	[108]
☐ L2	[102]	☐ R2	[109]
☐ L3	[103]	☐ R3	[110]
☐ L4	[104]	☐ R4	[111]
☐ L5	[105]	☐ R5	[112]
☐ L6	[106]	☐ R6	[113]

Medio-Lateral *(select all that apply)*

☐ LT	[114]	☐ RT	[122]
☐ LA	[115]	☐ RA	[123]
☐ LB	[116]	☐ RB	[124]
☐ LC	[117]	☐ RC	[125]
☐ LD	[118]	☐ RD	[126]
☐ LE	[119]	☐ RE	[127]
☐ LF	[120]	☐ RF	[128]
☐ LG	[121]	☐ RG	[129]

3b. Size *(record all three measurements [0 = not seen])*

x = ___ **mm** (medial-lateral) [130]

y = ___ **mm** (superior-inferior) [131]

z = ___ **mm** (anterior-posterior) [132]

3c. Shape/Margin *(select one)* [133]
- O Smooth round
- O Smooth oval
- O Lobulated
- O Irregular
- O Spiculated

3d. Internal Enhancement *(select one)* [134]
- O Homogeneous confluent
- O Heterogeneous
- O Rim enhanced
- O Centrally enhanced
- O Dark septation(s)
- O Enhancing septation(s)

3e. T2 Appearance *(select one)* [135]
- O Hyperintense to surrounding breast tissue
- O Hypointense to surrounding breast tissue
- O Isointense to surrounding breast tissue
- O Unable to evaluate

3f. Degree of Enhancement
(characterize by strongest degree seen) [136]
- O Minimal
- O Moderate
- O Marked

3g. Enhancement Pattern
(characterize by strongest pattern seen) [137]
- O Gradual
- O Sustained
- O Washout

3h. Series and Image Number of Representative Slices *(list up to 3)*

Series ____ : [355] **Image #** ____ [356]

Series ____ : [357] **Image #** ____ [358]

Series ____ : [359] **Image #** ____ [360]

3i. Corresponds to Index Lesion [138]
- O No
- O Yes (Skip Q3j)

3j. Has this been independently biopsied? [397]
- O No
- O Yes
- O Don't know

Comments about this mass: _____

_____

_____

_____ [361]

3k. Additional Masses [398]
- O No
- O Yes

*** Remember to complete Section B - Clinically Relevant Regional Enhancements on page 5**

T1 If this is a revised or corrected form, please √box. ☐

ACRIN Study 6657 Case #

PLACE LABEL HERE

Institution Institution No.

Participant's Initials Participant's I.D. No.

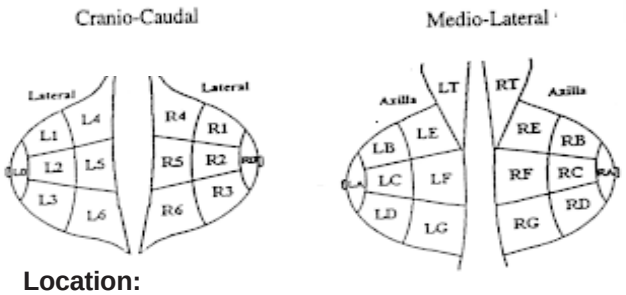
BASELINE / PRE-TREATMENT

Section B: Clinically Relevant Regional Enhancements
Report on the study breast only. Report descriptive data for up to three regional enhancements. If more than three are present, report only the three most prominent to include the index lesion, if visualized.

1. Were Clinically Relevant Regional Enhancements Identified [14]
O No
O Yes *(report in Section B)*

Total Number ____ [15]

Reporting Regional Enhancement # 1 ____ [140]



1a. Location:

Cranio-Caudal *(select all that apply)*

☐ L0 [141]	☐ R0 [148]
☐ L1 [142]	☐ R1 [149]
☐ L2 [143]	☐ R2 [150]
☐ L3 [144]	☐ R3 [151]
☐ L4 [145]	☐ R4 [152]
☐ L5 [146]	☐ R5 [153]
☐ L6 [147]	☐ R6 [154]

Medio-Lateral *(select all that apply)*

☐ LT [155]	☐ RT [163]
☐ LA [156]	☐ RA [164]
☐ LB [157]	☐ RB [165]
☐ LC [158]	☐ RC [166]
☐ LD [159]	☐ RD [167]
☐ LE [160]	☐ RE [168]
☐ LF [161]	☐ RF [169]
☐ LG [162]	☐ RG [170]

1b. Largest Dimension ____ **mm** [171]

1c. Distribution Subtype *(select one)* [172]
O Diffuse non-specific
O Linear non-specific
O Linear ductal: Smooth
O Linear ductal: Irregular
O Linear ductal: Clumped
O Segmental
O Regional
O Diffuse patchy

1d. Internal Enhancement *(select one)* [173]
O Homogeneous confluent
O Heterogeneous non-specific
O Heterogeneous stippled, punctate
O Heterogeneous clumped
O Septal, dendritic
O Asymmetric
O Symmetric
O Not applicable

1e. T2 Appearance *(select one)* [174]
O Hyperintense to surrounding breast tissue
O Hypointense to surrounding breast tissue
O Isointense to surrounding breast tissue
O Unable to evaluate

1f. Degree of Enhancement
(characterize by strongest degree seen) [175]
O Minimal
O Moderate
O Marked

1g. Enhancement Pattern
(characterize by strongest pattern seen) [176]
O Gradual
O Sustained
O Washout

1h. Series and Image Number of Representative Slices *(list up to 3)*

Series ____ : [364] **Image #** ____ [365]

Series ____ : [366] **Image #** ____ [367]

Series ____ : [368] **Image #** ____ [369]

1i. Corresponds to Index Lesion [177]
O No
O Yes (Skip Q1j)

1j. Has this been independently biopsied? [399]
O No
O Yes
O Don't know

Comments about this regional enhancement: _____

_____

_____

_____ [370]

1k. Additional Regional Enhancements [400]
O No
O Yes

*** If no additional Clinically Relevant Regional Enhancements to report complete page 8 - Section C**

T1 If this is a revised or corrected form, please √box. ☐

ACRIN Study 6657 Case #

PLACE LABEL HERE

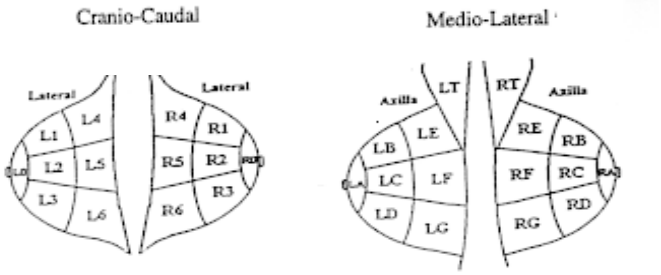
Institution Institution No.

Participant's Initials Participant's I.D. No.

BASELINE / PRE-TREATMENT

Section B: Clinically Relevant Regional Enhancements
Report on the study breast only. Report descriptive data for up to three regional enhancements. If more than three are present, report only the three most prominent to include the index lesion, if visualized.

2. Reporting Regional Enhancement # 2 ___ [179]



2a. Location:

Cranio-Caudal *(select all that apply)*

☐ L0 [180]	☐ R0 [187]
☐ L1 [181]	☐ R1 [188]
☐ L2 [182]	☐ R2 [189]
☐ L3 [183]	☐ R3 [190]
☐ L4 [184]	☐ R4 [191]
☐ L5 [185]	☐ R5 [192]
☐ L6 [186]	☐ R6 [193]

Medio-Lateral *(select all that apply)*

☐ LT [194]	☐ RT [202]
☐ LA [195]	☐ RA [203]
☐ LB [196]	☐ RB [204]
☐ LC [197]	☐ RC [205]
☐ LD [198]	☐ RD [206]
☐ LE [199]	☐ RE [207]
☐ LF [200]	☐ RF [208]
☐ LG [201]	☐ RG [209]

2b. Largest Dimension

___ **mm** [210]

2c. Distribution Subtype *(select one)* [211]

O Diffuse non-specific
O Linear non-specific
O Linear ductal: Smooth
O Linear ductal: Irregular
O Linear ductal: Clumped
O Segmental
O Regional
O Diffuse patchy

2d. Internal Enhancement *(select one)* [212]

O Homogeneous confluent
O Heterogeneous non-specific
O Heterogeneous stippled, punctate
O Heterogeneous clumped
O Septal, dendritic
O Asymmetric
O Symmetric
O Not applicable

2e. T2 Appearance *(select one)* [213]

O Hyperintense to surrounding breast tissue
O Hypointense to surrounding breast tissue
O Isointense to surrounding breast tissue
O Unable to evaluate

2f. Degree of Enhancement
(characterize by strongest degree seen) [214]

O Minimal
O Moderate
O Marked

2g. Enhancement Pattern
(characterize by strongest pattern seen) [215]

O Gradual
O Sustained
O Washout

2h. Series and Image Number of Representative Slices *(list up to 3)*

Series ___ : [372] **Image #** ___ [373]

Series ___ : [374] **Image #** ___ [375]

Series ___ : [376] **Image #** ___ [377]

2i. Corresponds to Index Lesion [216]

O No
O Yes (Skip Q2j)

2j. Has this been independently biopsied? [401]

O No
O Yes
O Don't know

Comments about this regional enhancement: _____

_____

_____

_____ [378]

2k. Additional Regional Enhancements [402]

O No
O Yes

*** If no additional Clinically Relevant Regional Enhancements to report complete page 8 - Section C**

T1 If this is a revised or corrected form, please √box. ☐

ACRIN Study 6657 Case #

PLACE LABEL HERE

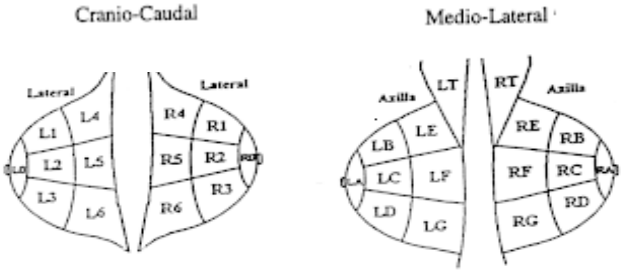
Institution Institution No.

Participant's Initials Participant's I.D. No.

BASELINE / PRE-TREATMENT

Section B: Clinically Relevant Regional Enhancements
Report on the study breast only. Report descriptive data for up to three regional enhancements. If more than three are present, report only the three most prominent to include the index lesion, if visualized.

3. Reporting Regional Enhancement # 3 ☐ [218]



3a. Location:

Cranio-Caudal *(select all that apply)*

☐ L0	[219]	☐ R0	[226]
☐ L1	[220]	☐ R1	[227]
☐ L2	[221]	☐ R2	[228]
☐ L3	[222]	☐ R3	[229]
☐ L4	[223]	☐ R4	[230]
☐ L5	[224]	☐ R5	[231]
☐ L6	[225]	☐ R6	[232]

Medio-Lateral *(select all that apply)*

☐ LT	[233]	☐ RT	[241]
☐ LA	[234]	☐ RA	[242]
☐ LB	[235]	☐ RB	[243]
☐ LC	[236]	☐ RC	[244]
☐ LD	[237]	☐ RD	[245]
☐ LE	[238]	☐ RE	[246]
☐ LF	[239]	☐ RF	[247]
☐ LG	[240]	☐ RG	[248]

3b. Largest Dimension

☐☐☐ **mm** [249]

3c. Distribution Subtype *(select one)* [250]

O Diffuse non-specific
O Linear non-specific
O Linear ductal: Smooth
O Linear ductal: Irregular
O Linear ductal: Clumped
O Segmental
O Regional
O Diffuse patchy

3d. Internal Enhancement *(select one)* [251]

O Homogeneous confluent
O Heterogeneous non-specific
O Heterogeneous stippled, punctate
O Heterogeneous clumped
O Septal, dendritic
O Asymmetric
O Symmetric
O Not applicable

3e. T2 Appearance *(select one)* [252]

O Hyperintense to surrounding breast tissue
O Hypointense to surrounding breast tissue
O Isointense to surrounding breast tissue
O Unable to evaluate

3f. Degree of Enhancement
(characterize by strongest degree seen) [253]

O Minimal
O Moderate
O Marked

3g. Enhancement Pattern
(characterize by strongest pattern seen) [254]

O Gradual
O Sustained
O Washout

3h. Series and Image Number of Representative Slices *(list up to 3)*

Series ☐☐: [380] **Image #** ☐☐☐ [381]

Series ☐☐: [382] **Image #** ☐☐☐ [383]

Series ☐☐: [384] **Image #** ☐☐☐ [385]

3i. Corresponds to Index Lesion [255]

O No
O Yes (Skip Q3j)

3j. Has this been independently biopsied? [403]

O No
O Yes
O Don't know

Comments about this regional enhancement: _____

_____

_____

_____ [386]

3k. Additional Regional Enhancements [404]

O No
O Yes

*** Remember to complete page 8 - Section C**

ACRIN Study 6657 Case #

PLACE LABEL HERE

Institution Institution No.

Participant's Initials Participant's I.D. No.

Section C: Other findings

14. Other Multi-focality *(select all that apply)*

☐ Other masses [257]
☐ Other regional enhancements [258]
☐ Diffuse enhancement(s) [259]
☐ Scattered, stippled enhancement(s) [260]
☐ Not applicable/None [261]

15. Other Findings [262]

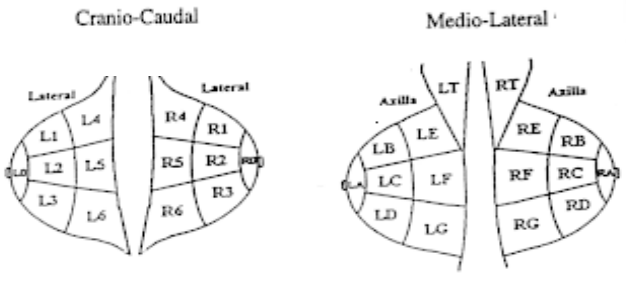
O No *(proceed to question 16)*
O Yes *(continue, characterize other findings)*

Characterization of Other Findings

(select all that apply)

☐ Nipple retraction [263]
☐ Nipple invasion [264]
☐ Pectoralis muscle invasion [265]
☐ Pre-contrast high duct signal [266]
☐ Skin thickening (focal) [267]
☐ Skin thickening (diffuse) [268]
☐ Skin invasion [269]
☐ Edema [270]
☐ Lymph Adenopathy [271]
☐ Hematoma/blood [272]
☐ Abnormal signal void [273]
☐ Cyst(s) [274]
☐ Other [388] _____ [389]

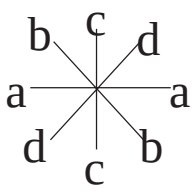
16. Full Extent of Disease (spanning all disease present)



Direction for Longest Diameter Measurement
(indicate which diagram above was used to determine measurement direction) [275]

O cranial - caudal
O medio-lateral

BASELINE / PRE-TREATMENT



Orientation of Longest Diameter Measurement
(indicate the orientation used to determine measurement direction) [276]

O a
O b
O c
O d

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** [277]

17. TFQ Staging Classification

T *(select one – size of dominant lesion only)* [278]

O T0 No primary
O Tis In Situ
O T1a <5 mm
O T1b 5-9 mm
O T1c 10-20 mm
O T2 21-50 mm
O T3 >50 mm
O T4a chest wall
O T4b skin
O T4c chest wall and skin
O T4d inflammatory

F *(select one – size of full extent of disease)* [279]

O F0 no other area of suspicious enhancement
O F1 ≤10mm
O F2 11-20 mm
O F3 21-30 mm
O F4 31-40 mm
O F5 41-50 mm
O F6 51-60 mm
O F7 61-70 mm
O F8 71-80 mm
O F9 81-90 mm
O F10 91-100 mm
O FX >100 mm, please record

size |___|___|___| mm. [280]

Q *(select one - number of quadrants involved)* [281]

O Q0 no quadrant of suspicious enhancement
O Q1 one quadrant of suspicious enhancement
O Q2 two quadrants of suspicious enhancement
O Q3 three quadrants of suspicious enhancement
O Q4 four quadrants of suspicious enhancement

T1 If this is a revised or corrected form, please √box. ☐

ACRIN Study 6657 Case #

PLACE LABEL HERE

Institution Institution No.

Participant's Initials Participant's I.D. No.

18. Morphologic Pattern Classification of Dominant Lesion [391]

- O Single uni-centric mass with well-defined margin
- O Multi-lobulated mass with well-defined margin
- O Area enhancement with irregular margins - with nodularity
- O Area enhancement with irregular margins - without nodularity
- O Septal spread; streaming

19. Participant to participate in the additional MRI [392]

- O No
- O Yes

COMMENTS: _____

_____

_____ [282]

_____

Radiologist Signature
(radiologist must sign either the completed paper form or the completed/printed web form)

_____ [283]
Signature of person responsible for data

_____ [285]
Signature of person entering data onto web

_____ - _____ - _____ [284]
Date form completed (mm-dd-yyyy)

*** Please remember complete page 8 - Section C**

T1 Baseline/Pre-Treatment MRI 1 Form - Completion Instructions

MRI-1, pre-treatment MRI, is to occur within 2 weeks prior to start of neoadjuvant treatment. This form is to be completed by the study radiologist and used for pre-treatment MR Imaging only. Report only clinically relevant findings (up to 3 masses and/or 3 regional enhancements) for the study breast only. Report index lesion if visualized. When reporting index lesion, the index lesion corresponds to the tumor used to define participant eligibility. Date must be in the mm/dd/yyyy format. Submit this form within 2 weeks of MRI via the ACRIN website. Submit paper form only for revisions or corrections. Please remember to complete page 8.

MRI TIME-POINT INFORMATION

1. Protocol imaging time point:

Record the appropriate response. The response to this question is mandatory and the default is set according to the form being completed; T1- Baseline / Pre-Treatment.

1a. Was MRS performed?

Mandatory. If the response is "Yes", skip Q1b and complete remaining questions. If the response is "No", specify reason in Q1b. Sign and date form on page 2.

2. Date of MRI:

Mandatory. Record the date that the MRI was performed (date must not be in the future).

3. Date of Interpretation:

Mandatory. Record the date the MRI was interpreted by the radiologist. Date must not be prior to the Date of MRI or a future date.

5. Reader ID:

This 7 alphanumeric character user specific Id is required.

8. Were Clinically Relevant Enhancing Lesion(s) Identified?

Response to this question is mandatory. If clinically relevant enhancing lesion(s) were identified, complete question 9 through the remainder of the form. If clinically relevant enhancing lesion(s) were not identified, sign and date form.

12. Were Clinically Relevant Mass(es) Identified?

Response to this question is mandatory. If clinically relevant mass(es) were identified, complete Section A. Indicate total number of clinically relevant masses (1-10); *provide descriptive data for up to three of the most prominent masses.* If clinically relevant mass(es) were not identified, skip to Section B.

13. Remember to complete Clinically Relevant Regional Enhancements on page 5 - Section B.

This is an important reminder to the radiologist to complete Section B.

Section A: Clinically Relevant Masses

Report index lesion if visualized. Complete this section if there are clinically relevant masses to report. Provide descriptive data for up to three of the most prominent masses.

a. Mass Location: For each reported mass, at least one choice must be selected in the Cranio-Caudal or Medio-Lateral view.

b. Size of Mass: At least one of x, y, or z must be greater than 0.

h. Series and Image Number of Representative Slices: If unknown, enter 99 for series and 999 for Image #.

i. Mass Corresponds to Index lesion: A “Yes” response is allowed only if the response to Q11 “Index Lesion Identified on this MRI Exam” equals “Yes”.

k. Additional Masses: If the response is “No” for this or any additional Mass being reported in this section, skip to section B on page 5. If the response is “Yes” for this or any other additional mass, complete responses are required for each relevant mass. Two additional masses may be reported in Section A.

Section B: Clinically Relevant Regional Enhancements

1. **Were Clinically Relevant Regional Enhancements Identified?**
   Response to this question is mandatory. If clinically relevant regional enhancements were identified, complete Section B. Indicate total number of clinically relevant regional enhancements (1-10). Provide descriptive data for up to three of the most prominent regional enhancements. If clinically relevant regional enhancement(s) were not identified, skip to Section C.

a. **Regional Enhancement Location:** For each reported regional enhancement, at least one choice must be selected in the Cranio-Caudal or Medio-Lateral view.

h. **Series and Image Number of Representative Slices:** If unknown, enter 99 for series and 999 for Image #.

i. **Mass Corresponds to Index lesion:** A "Yes" response is allowed only if the response to Q11 "Index Lesion Identified on this MRI Exam" equals "Yes".

k. **Additional Regional Enhancements:** If the response is "No" for this or any additional regional enhancements being reported in this section, skip to section C on page 8. If the response is "Yes" for this or any other additional regional enhancement, complete responses are required for each relevant regional enhancement. Two additional regional enhancements may be reported in Section B.

Section C: Other Findings

14. Other Multi-focality: Record the appropriate response(s). Select all that apply.

15. Other Findings: If the response is "No", skip to Question 16. If the response is "Yes", provide a **"Characterization of Other Findings"** by checking each of the characteristics that apply.

16. Full Extent of Disease (spanning all disease present)**:**
Direction for Longest Diameter Measurement: Either the Cranio-Caudal or the Medio-Lateral Oblique diagram must be selected. The same direction must be used for each MRI.

Orientation of Longest Diameter Measurement: Indicate the direction (a, b, c, or d) of orientation. The same direction (see diagram) must be used for each MRI.

19. Participant to participate in the additional MRI: Record the appropriate response(s). The response of "Yes" should be selected ***only*** if the participant has consented to participating in the Additional Baseline / Pre-Treatment Reproducibility MRI/MRS exam. If the response is "Yes", additional forms (TA, VA, ME, MR) will be generated to the calendar to collect data on the "additional" visit.

Radiologist Signature: Legible signature of the Radiologist. If completing a web CRF only, without completing a paper CRF, the electronic summary must be printed and signed by the Radiologist. The Radiologist's signature must be on the original document (whether paper or web).

Signature of person responsible for data: Legible signature/name of the staff member responsible for Collating/reviewing the data and ensuring completion of the CRF (paper or web). If completing a web CRF only, without completing a paper CRF, the electronic summary must be printed and signed by the staff member responsible for the data. The RA's signature must be on the original document (whether paper or web).

Date form completed: Record the date the original CRF, whether paper or web, was completed. Date must not be prior to "Date of MRI." If completing a Paper CRF this refers to the date the data was originally recorded on the paper CRF; the date/time of web entry is automatically recorded by the database. If completing the web CRF only, without completing a paper CRF, this refers to the date the data was originally recorded in the web module.

Signature of person entering data onto web: Record the signature/name of the staff member submitting the Data on-line. If completing a web CRF only, without completing a paper CRF, the electronic summary must be printed and signed by the staff member entering the data onto the web.

U1 ACRIN 6657 Extension Ultrasound Interpretation Form

ACRIN Study 6657

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

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

PRE-TREATMENT

Instructions: In accordance with protocol, two optional diagnostic ultrasound exams may be reported. This form is to be completed by the study radiologist if a diagnostic ultrasound is performed. Report only ultrasound exams corresponding to the first MRI exam. Please report characteristics of the index lesion only. The index lesion corresponds to the tumor used to define participant eligibility. Submit this form within two weeks of each ultrasound via the ACRIN website. Submit paper form only for revisions or corrections. **Do not submit this form if a diagnostic ultrasound was not performed.**

1. Protocol Time Point [1]
- o Pre-treatment

2. Date of Ultrasound ☐☐-☐☐-☐☐☐☐ (mm-dd-yyyy) [2]

3. Date of Interpretation ☐☐-☐☐-☐☐☐☐ [3]
(mm-dd-yyyy)

4. Reader Name: _____ [4]

5. Reader ID: ☐☐☐☐☐☐ [5]

6. Study Breast [6]
- o Right
- o Left
- o Bilateral

7. Clinically Relevant Lesion(s) Identified [7]
- o No *(sign and date form)*
- o Yes

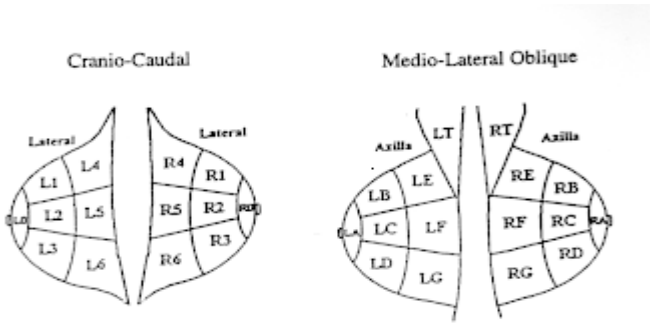
8. Total Number of Clinically Relevant Lesions ☐☐ [8]

9. Index Lesion Identified on Ultrasound [9]
- o No *(sign and date form)*
- o Yes

10. Doppler Characteristics [10]
- o Not applicable
- o Hypervascular
- o Hypovascular

11. Characterize the Index Lesion [11]
- o Cystic
- o Solid
- o Other, specify_____ [12]
- o Unknown

INDEX LESION:
(The index lesion corresponds to the tumor used to define participant eligibility.)



Index Lesion Location:

Cranio-Caudal *(select all that apply)*

☐	L0 [13]	☐	R0 [20]
☐	L1 [14]	☐	R1 [21]
☐	L2 [15]	☐	R2 [22]
☐	L3 [16]	☐	R3 [23]
☐	L4 [17]	☐	R4 [24]
☐	L5 [18]	☐	R5 [25]
☐	L6 [19]	☐	R6 [26]

Medio-Lateral *(select all that apply)*

☐	LT [27]	☐	RT [35]
☐	LA [28]	☐	RA [36]
☐	LB [29]	☐	RB [37]
☐	LC [30]	☐	RC [38]
☐	LD [31]	☐	RD [39]
☐	LE [32]	☐	RE [40]
☐	LF [33]	☐	RF [41]
☐	LG [34]	☐	RG [42]

Size of Index Lesion

x = ☐☐☐**mm** (medial-lateral) [43]

y = ☐☐☐**mm** (superior-inferior) [44]

z = ☐☐☐**mm** (anterior-posterior) [45]

Largest Dimension of Index Lesion

☐☐☐**mm** [46]

U1

ACRIN 6657 Extension
Ultrasound Interpretation Form

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

ACRIN Study 6657

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

PRE-TREATMENT

Homogeneity of Index Lesion *(select one)* [47]
- o Homogeneous
- o Heterogeneous without cysts
- o Heterogeneous with cysts

Echogenicity of Index Lesion *(select one)* [48]
- o Hypoechoic
- o Isoechoic
- o Hyperechoic

Border of Index Lesion *(select one)* [49]
- o Smooth
- o Spiculated
- o Lobular
- o Irregular
- o Other, specify, _____ [50]

COMMENTS: _____

_____ [51]

_____

Radiologist Signature
(radiologist must sign either the completed paper form or the completed/printed web form)

_____ [52]
Signature of person responsible for data

_____ [54]
Signature of person entering data onto web

_____-_____-**2 0 0**___ [53]
Date form completed (mm-dd-yyyy)

U1 Ultrasound Interpretation Form - Completion Instructions

In accordance with protocol, two optional diagnostic ultrasound exams may be reported. The first ultrasound, reported on U1, must be performed 4 weeks prior to start of neoadjuvant treatment. This form is to be completed by the study radiologist if a diagnostic ultrasound is performed. Report only the ultrasound exam corresponding to the first MRI exam on the U1 form. Please report characteristics of the index lesion only. The index lesion corresponds to the tumor used to define participant eligibility. Submit this form within two weeks of the ultrasound via the ACRIN website. Date must be in the mm/dd/yyyy format. Submit paper form only for revisions or corrections. **Do not submit this form if a diagnostic ultrasound was not performed. Please submit a General Communication Memo indicating that the ultrasound was not performed and the U1 will not be submitted.**

TIME-POINT INFORMATION

1. Protocol imaging time point:

Record the appropriate response. The response to this question is mandatory and the default is set according to the form being completed; U1- Pre-Treatment Form.

2. Date of Ultrasound:

Mandatory. Record the date that the ultrasound was performed (date must not be in the future).

3. Date of Interpretation:

Mandatory. Record the date that the ultrasound was interpreted by the radiologist (date must not be in the future).

5. Reader ID:

This 7 alphanumeric character user specific Id is required.

7. Clinically Relevant Lesion(s) Identified?

Response to this question is mandatory. If clinically relevant lesion(s) were identified, complete question 7 through the remainder of the form. If clinically relevant lesion(s) were not identified, skip to bottom of page 2 and sign and date form.

9. Index Lesion Identified on Ultrasound

Response to this question is mandatory. If index lesion(s) were identified, complete question 9 through the remainder of the form. If index lesion(s) were not identified, skip to bottom of page 2 and sign and date form.

Index Lesion:

Report index lesion if visualized. Complete this section if there are clinically relevant lesions to report. Provide descriptive data for the most prominent lesion.

Index Lesion Location: At least one choice must be selected in the Cranio-Caudal or Medio-Lateral view.

Size of Index Lesion: At least one of x, y, or z must be greater than 0.

Largest Dimension of Index Lesion: Record the largest of "Size of Mass" (x, y, or z) therefore, the "Largest Dimension of Mass" must equal x, y, or z.

Radiologist Signature: Legible signature of the Radiologist. If completing a web CRF only, without completing a paper CRF, the electronic summary must be printed and signed by the Radiologist. The Radiologist's signature must be on the original document (whether paper or web).

Signature of person responsible for data: Legible signature/name of the staff member responsible for Collating/reviewing the data and ensuring completion of the CRF (paper or web). If completing a web CRF only, without completing a paper CRF, the electronic summary must be printed and signed by the staff member responsible for the data. The RA's signature must be on the original document (whether paper or web).

Date form completed: Record the date the original CRF, whether paper or web, was completed. If completing a Paper CRF this refers to the date the data was originally recorded on the paper CRF; the date/time of web entry is automatically recorded by the database. If completing the web CRF only, without completing a paper CRF, this refers to the date the data was originally recorded in the web module.

Signature of person entering data onto web: Record the signature/name of the staff member submitting the Data on-line. If completing a web CRF only, without completing a paper CRF, the electronic summary must be printed and signed by the staff member entering the data onto the web.

V1

ACRIN 6657 Extension

MRS Form: Baseline / Pre-Treatment
MRS - 1

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

ACRIN Study **6657**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

BASELINE PRE-TREATMENT

INSTRUCTIONS: This is to be filled out during or very near to the actual acquisition of the data. Same magnet field strength and coil should be used at every imaging visit.

1. Timepoint [1]
- O MRS 1 Baseline Pre-Treatment

3. Was MRS performed? [4]
- O 1 No (if no, complete Q3a, sign and date form)
- O 2 Yes (If yes, continue with form)

3a. If no, specify reason: [5]
- O 1 No time
- O 2 Technical Problem
- O 88 Other, specify _____ [6]

General

4. Date of MRI ☐☐-☐☐-☐☐☐☐ *(mm-dd-yyyy)* [17]

5. Magnet field strength [18]
- O 1 1.5
- O 2 3
- O 88 Other, specify _____ [19]

6. Person responsible for voxel placement: [20]
(select one)
- O 1 MR Technologist
- O 2 Research Associate
- O 3 Nurse
- O 4 PI Radiologist
- O 5 Physician
- O 88 Other personnel (specify):

_____ [21]

Phantom QC Measurement

7. Phantom scan performed within past 7 days? [22]
- O 1 No (If no, complete Q7a)
- O 2 Yes

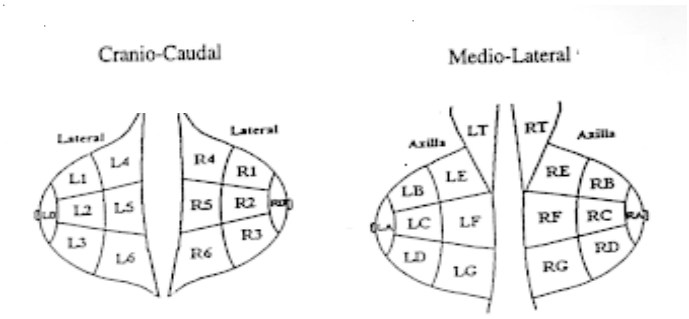
7a. If no, specify reason:

Specify, _____ [23]

7b. Date of last phantom scan

☐☐-☐☐-☐☐☐☐ [24]
(mm-dd-yyyy)

8. MRS Acquisition



Cranio-Caudal
(select all that apply)

- ☐ L0 [25]
- ☐ L1 [26]
- ☐ L2 [27]
- ☐ L3 [28]
- ☐ L4 [29]
- ☐ L5 [30]
- ☐ L6 [31]
- ☐ R0 [32]
- ☐ R1 [33]
- ☐ R2 [34]
- ☐ R3 [35]
- ☐ R4 [36]
- ☐ R5 [37]
- ☐ R6 [38]

Medio-Lateral
(select all that apply)

- ☐ LT [39]
- ☐ LA [40]
- ☐ LB [41]
- ☐ LC [42]
- ☐ LD [43]
- ☐ LE [44]
- ☐ LF [45]
- ☐ LG [46]
- ☐ RT [47]
- ☐ RA [48]
- ☐ RB [49]
- ☐ RC [50]
- ☐ RD [51]
- ☐ RE [52]
- ☐ RF [53]
- ☐ RG [54]

V1

ACRIN 6657 Extension

MRS Form: Baseline / Pre-Treatment
MRS - 1

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

ACRIN Study **6657**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

BASELINE PRE-TREATMENT

9. Pre-scan calibration

Shimming: [55] O manual O automatic

Water Suppression: [56] O manual O automatic

10. Confidence in accurate voxel placement *(check one):* [57]

Very Confident----------O **1** O **2** O **3** O **4** O **5**----------Not Confident

10a. Reasons for reduced confidence:
(select all that apply)

☐ Target lesion not clearly visualized [58]
☐ Clip artifact present [61]
☐ Other [62] _____

_____

_____

_____ [63]

COMMENTS: _____

_____

_____ [64]

_____ [65]
Signature of person responsible for the data

Date form completed ___ - ___ - ____ (mm-dd-yyyy) [66]

V1 MRS Form - Completion Instructions

In accordance with protocol, four to five spectroscopy exams may be reported. The first MRS exam, reported on V1, must be performed 4 weeks prior to start of neoadjuvant treatment. This form is to be completed by the study radiologist during or very near to the actual acquisition of the data. Same magnet field strength and coil should be used at every imaging visit. Submit this form within two weeks of the MRS via the ACRIN website. Date must be in the mm/dd/yyyy format. Submit paper form only for revisions or corrections. **The V1 form must be submitted via the ACRIN website regardless of whether an MRS was performed.**

MRS TIME-POINT INFORMATION

1. Timepoint:

Mandatory. Record the appropriate response. The response to this question is mandatory and the default is set according to the form being completed; V1- Baseline Pre-Treatment.

QUESTION 2 DELETED FROM FORM.

3. Was MRS performed?

Mandatory. If the response is “Yes”, skip Q3a and complete remaining questions. If the response is “No”, specify reason in Q3a. Sign and date form on page 2.

General

4. Date of MRS:

Mandatory. Record the date that the MRS was performed (date must not be in the future).

Phantom QC Measurement

7. Phantom scan performed within past 7 days?:

Mandatory. If the response is “Yes”, skip Q7a and complete remaining questions. If the response is “No”, specify reason in Q7a.

7b. Date of last phantom scan.

Mandatory. Record the date that the last phantom scan performed (date must not be in the future).

MRS Acquisition:

Mass Location: At least one choice must be selected in the Cranio-Caudal or Medio-Lateral view.

10. Confidence in accurate voxel placement: Provide confidence level.

10a. Reasons for reduced confidence:

Record the appropriate response(s). Select all that apply.

Signature of person responsible for data: Legible signature/name of the staff member responsible for Collating/reviewing the data and ensuring completion of the CRF (paper or web). If completing a web CRF only, without completing a paper CRF, the electronic summary must be printed and signed by the staff member responsible for the data. The RA's signature must be on the original document (whether paper or web).

Date form completed: Record the date the original CRF, whether paper or web, was completed. If completing a Paper CRF this refers to the date the data was originally recorded on the paper CRF; the date/time of web entry is automatically recorded by the database. If completing the web CRF only, without completing a paper CRF, this refers to the date the data was originally recorded in the web module.

Additional Visit

MRI/MRS
Additional Baseline / Pretreatment Reproducibility

Within 72 hours post Baseline prior to type 1 Chemotherapy
(For 30 consented patient's only)

TA

ACRIN 6657 Extension
MRI Form: Additional Baseline / Pre-Treatment Reproducibility MRI 1.1

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

ACRIN Study 6657 Case #

PLACE LABEL HERE

Institution Institution No.

Participant's Initials Participant's I.D. No.

ADDITIONAL BASELINE / PRE-TREATMENT

Instructions: In accordance with the protocol, each participant will receive three or four MRI exams. MRI-1.1 must be performed within 72 hours post baseline. This form is to be completed by the study radiologist and used for pre-treatment reproducibility MR Imaging only. When reporting index lesion, the index lesion corresponds to the tumor used to define participant eligibility. To enable lesion tracking from T1, use the TA to report on all lesions documented on the T1 form, use the same lesion category and number assignment. Submit this form within 2 weeks of MRI via the ACRIN website. Submit a paper form for the data corrections only.

1. Protocol Time Point [1]

o MRI 1.1 Additional Baseline / Pre-Treatment reproducibility

1a. Was MRI performed? [407]
- o No* (complete Q1b, then sign and date form)
- o Yes (proceed to Q2 and continue with form)

1b. *If No, provide reason: [408]
- o Scheduling problem
- o Equipment failure
- o Participant refusal
- o Medical reason
- o Injection site complications
- o Claustrophobia
- o Participant withdrew consent
- o Progressive disease
- o Participant death
- o Other, specify: _____ [409]
- o Unknown

2. Date of MRI ____ - ____ - **20** ____ (mm-dd-yyyy) [3]

3. Date of Interpretation ____ - ____ - **20** ____ [4] (mm-dd-yyyy)

4. Reader Name: _____ [5]

5. Reader ID: ____ ____ ____ ____ ____ ____ ____ [6]

6. Patient Weight (kgs) ____ ____ ____ [7]

7. Total Amount of Gadolinium Injected (cc) ____ ____ [8]

8. Were Clinically Relevant Enhancing Lesion(s) Identified [9]
- O No *(sign and date form)*
- O Yes

Complete For Study Breast Only

9. Study Breast (Same as identified in Baseline (T1 form)) [10]
- O Right
- O Left

10. Density of Breast Parenchyma [11]
- O Mostly fat
- O Scattered fibroglandular tissue
- O Heterogeneously dense
- O Extremely dense

11a. Were Clinically Relevant Mass(es) Identified on Baseline (T1) [12]
- O No
- O Yes *(report in Section A)*

Total Number ____ (enter same response from T1 Q11a) [13]

11b. Are New masses now seen that were not seen on Baseline [362]
- O No
- O Yes *(report on supplemental TS form)*

12a. Were Clinically Relevant Regional Enhancements Identified on Baseline (T1) [14]
- O No
- O Yes *(report in Section B)*

Total Number ____ (enter same response from T1 Q12a) [15]

12b. Are New Regional Enhancements now seen that were not seen on baseline [387]
- O No
- O Yes *(report on supplemental TS form)*

13. Index Lesion Identified on this MRI Exam [16]
- O No
- O Yes

*** Please remember to complete page 8**

TA

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

ACRIN Study 6657 Case #

PLACE LABEL HERE

Institution Institution No.

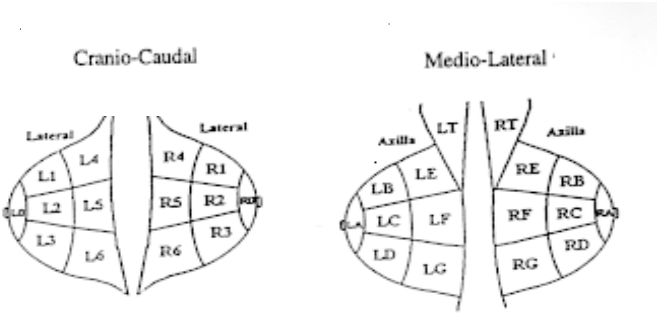
Participant's Initials Participant's I.D. No.

ADDITIONAL BASELINE / PRE-TREATMENT

Section A: Masses

All masses documented on the T1 Form must be reported in this section. If new masses are now present, report on the supplemental TS Form.

1. Is the lesion identified as Mass #1 on the T1 Form still visible? [338]
- o No (skip 1a-1j)
- o Yes (complete 1a-1k)
- o Not Applicable



1a. Location:

Cranio-Caudal *(select all that apply)*

☐ L0 [18]	☐ R0 [25]
☐ L1 [19]	☐ R1 [26]
☐ L2 [20]	☐ R2 [27]
☐ L3 [21]	☐ R3 [28]
☐ L4 [22]	☐ R4 [29]
☐ L5 [23]	☐ R5 [30]
☐ L6 [24]	☐ R6 [31]

Medio-Lateral *(select all that apply)*

☐ LT [32]	☐ RT [40]
☐ LA [33]	☐ RA [41]
☐ LB [34]	☐ RB [42]
☐ LC [35]	☐ RC [43]
☐ LD [36]	☐ RD [44]
☐ LE [37]	☐ RE [45]
☐ LF [38]	☐ RF [46]
☐ LG [39]	☐ RG [47]

1b. Size *(record all three measurements [0 = not seen])*

x = ___ **mm** (medial-lateral) [48]

y = ___ **mm** (superior-inferior) [49]

z = ___ **mm** (anterior-posterior) [50]

1c. Shape/Margin *(select one)* [51]
- o Smooth round
- o Smooth oval
- o Lobulated
- o Irregular
- o Spiculated
- o No longer a mass

1d. Internal Enhancement *(select one)* [52]
- o Homogeneous confluent
- o Heterogeneous
- o Rim enhanced
- o Centrally enhanced
- o Dark septation(s)
- o Enhancing septation(s)
- o No longer a mass

1e. T2 Appearance *(select one)* [53]
- o Hyperintense to surrounding breast tissue
- o Hypointense to surrounding breast tissue
- o Isointense to surrounding breast tissue
- o Unable to evaluate

1f. Degree of Enhancement
(characterize by strongest degree seen) [54]
- o Minimal
- o Moderate
- o Marked

1g. Enhancement Pattern
(characterize by strongest pattern seen) [55]
- o Gradual
- o Sustained
- o Washout

1h. Series and Image Number of Representative Slices *(list up to 3)*

Series ___ : [339] **Image #** ___ [340]

Series ___ : [341] **Image #** ___ [342]

Series ___ : [343] **Image #** ___ [344]

1i. Corresponds to Index Lesion [56]
- o No
- o Yes

1j. Has this been independently biopsied? [393]
- o No
- o Yes

1k. Additional Masses [394]
- o No
- o Yes

COMMENTS: _____

_____

_____

_____ [345]

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

ACRIN Study 6657 Case #

PLACE LABEL HERE

Institution Institution No.

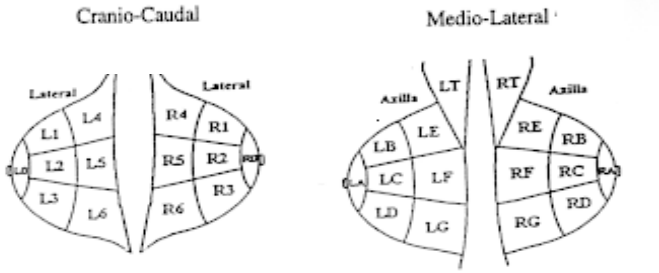
Participant's Initials Participant's I.D. No.

ADDITIONAL BASELINE / PRE-TREATMENT

Section A: Masses

All masses documented on the T1 Form must be reported in this section. If new masses are now present, report on the supplemental TS Form.

2. Is the lesion identified as Mass #2 on the T1 Form still visible? [346]
- o No (skip 2a-2j)
- o Yes (complete 2a-2k)
- o Not Applicable



2a. Location:

Cranio-Caudal *(select all that apply)*

☐ L0 [59]	☐ R0 [66]
☐ L1 [60]	☐ R1 [67]
☐ L2 [61]	☐ R2 [68]
☐ L3 [62]	☐ R3 [69]
☐ L4 [63]	☐ R4 [70]
☐ L5 [64]	☐ R5 [71]
☐ L6 [65]	☐ R6 [72]

Medio-Lateral *(select all that apply)*

☐ LT [73]	☐ RT [81]
☐ LA [74]	☐ RA [82]
☐ LB [75]	☐ RB [83]
☐ LC [76]	☐ RC [84]
☐ LD [77]	☐ RD [85]
☐ LE [78]	☐ RE [86]
☐ LF [79]	☐ RF [87]
☐ LG [80]	☐ RG [88]

2b. Size *(record all three measurements [0 = not seen])*

x = ___ **mm** (medial-lateral) [89]

y = ___ **mm** (superior-inferior) [90]

z = ___ **mm** (anterior-posterior) [91]

2c. Shape/Margin *(select one)* [92]
- o Smooth round
- o Smooth oval
- o Lobulated
- o Irregular
- o Spiculated
- o No longer a mass

2d. Internal Enhancement *(select one)* [93]
- o Homogeneous confluent
- o Heterogeneous
- o Rim enhanced
- o Centrally enhanced
- o Dark septation(s)
- o Enhancing septation(s)
- o No longer a mass

2e. T2 Appearance *(select one)* [94]
- o Hyperintense to surrounding breast tissue
- o Hypointense to surrounding breast tissue
- o Isointense to surrounding breast tissue
- o Unable to evaluate

2f. Degree of Enhancement
(characterize by strongest degree seen) [95]
- o Minimal
- o Moderate
- o Marked

2g. Enhancement Pattern
(characterize by strongest pattern seen) [96]
- o Gradual
- o Sustained
- o Washout

2h. Series and Image Number of Representative Slices *(list up to 3)*

Series ___ : [347] **Image #** ___ [348]

Series ___ : [349] **Image #** ___ [350]

Series ___ : [351] **Image #** ___ [352]

2i. Corresponds to Index Lesion [97]
- o No
- o Yes

2j. Has this been independently biopsied? [395]
- o No
- o Yes

2k. Additional Masses [396]
- o No
- o Yes

COMMENTS: _____

_____

_____

_____ [353]

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

ACRIN Study 6657 Case #

PLACE LABEL HERE

Institution Institution No.

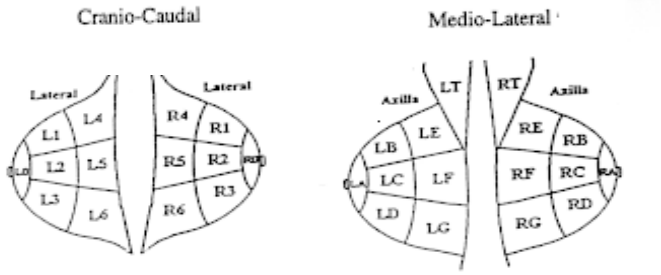
Participant's Initials Participant's I.D. No.

ADDITIONAL BASELINE / PRE-TREATMENT

Section A: Masses

All masses documented on the T1 Form must be reported in this section. If new masses are now present, report on the supplemental TS Form.

3. Is the lesion identified as Mass #3 on the T1 Form still visible? [354]
- o No (skip 3a-3j)
- o Yes (complete 3a-3k)
- o Not Applicable



3a. Location:

Cranio-Caudal *(select all that apply)*

☐ L0 [100]	☐ R0 [107]
☐ L1 [101]	☐ R1 [108]
☐ L2 [102]	☐ R2 [109]
☐ L3 [103]	☐ R3 [110]
☐ L4 [104]	☐ R4 [111]
☐ L5 [105]	☐ R5 [112]
☐ L6 [106]	☐ R6 [113]

Medio-Lateral *(select all that apply)*

☐ LT [114]	☐ RT [122]
☐ LA [115]	☐ RA [123]
☐ LB [116]	☐ RB [124]
☐ LC [117]	☐ RC [125]
☐ LD [118]	☐ RD [126]
☐ LE [119]	☐ RE [127]
☐ LF [120]	☐ RF [128]
☐ LG [121]	☐ RG [129]

3b. Size *(record all three measurements [0 = not seen])*

x = ___ ___ ___ **mm** (medial-lateral) [130]

y = ___ ___ ___ **mm** (superior-inferior) [131]

z = ___ ___ ___ **mm** (anterior-posterior) [132]

3c. Shape/Margin *(select one)* [133]
- o Smooth round
- o Smooth oval
- o Lobulated
- o Irregular
- o Spiculated
- o No longer a mass

3d. Internal Enhancement *(select one)* [134]
- o Homogeneous confluent
- o Heterogeneous
- o Rim enhanced
- o Centrally enhanced
- o Dark septation(s)
- o Enhancing septation(s)
- o No longer a mass

3e. T2 Appearance *(select one)* [135]
- o Hyperintense to surrounding breast tissue
- o Hypointense to surrounding breast tissue
- o Isointense to surrounding breast tissue
- o Unable to evaluate

3f. Degree of Enhancement

(characterize by strongest degree seen) [136]
- o Minimal
- o Moderate
- o Marked

3g. Enhancement Pattern

(characterize by strongest pattern seen) [137]
- o Gradual
- o Sustained
- o Washout

3h. Series and Image Number of Representative Slices *(list up to 3)*

Series ___ ___ : [355] **Image #** ___ ___ ___ [356]

Series ___ ___ : [357] **Image #** ___ ___ ___ [358]

Series ___ ___ : [359] **Image #** ___ ___ ___ [360]

3i. Corresponds to Index Lesion [138]
- o No
- o Yes

3j. Has this been independently biopsied? [397]
- o No
- o Yes

3k. Additional Masses [398]
- o No
- o Yes

COMMENTS: _____

_____

_____

_____ [361]

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

ACRIN Study 6657 Case #

PLACE LABEL HERE

Institution Institution No.

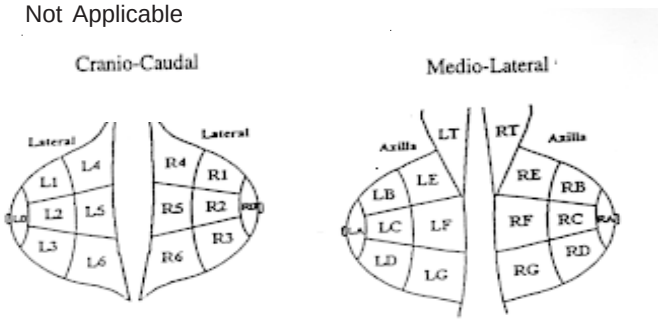
Participant's Initials Participant's I.D. No.

ADDITIONAL BASELINE / PRE-TREATMENT

Section B: Regional Enhancements

All regional enhancements documented on the T1 Form must be reported in this section. If new regional enhancements are now present, report on the supplemental TS Form.

1. Is the lesion identified as Regional Enhancement #1 from the T1 Form still visible? [363]
- o No (skip 1a-1j)
- o Yes (complete 1a-1k)
- o Not Applicable



1a. Location:

Cranio-Caudal *(select all that apply)*

☐ L0	[141]	☐ R0	[148]
☐ L1	[142]	☐ R1	[149]
☐ L2	[143]	☐ R2	[150]
☐ L3	[144]	☐ R3	[151]
☐ L4	[145]	☐ R4	[152]
☐ L5	[146]	☐ R5	[153]
☐ L6	[147]	☐ R6	[154]

Medio-Lateral *(select all that apply)*

☐ LT	[155]	☐ RT	[163]
☐ LA	[156]	☐ RA	[164]
☐ LB	[157]	☐ RB	[165]
☐ LC	[158]	☐ RC	[166]
☐ LD	[159]	☐ RD	[167]
☐ LE	[160]	☐ RE	[168]
☐ LF	[161]	☐ RF	[169]
☐ LG	[162]	☐ RG	[170]

1b. Largest Dimension

|_|_|_| **mm** [171]

1c. Distribution Subtype *(select one)* [172]
- o Diffuse non-specific
- o Linear non-specific
- o Linear ductal: Smooth
- o Linear ductal: Irregular
- o Linear ductal: Clumped
- o Segmental
- o Regional
- o Diffuse patchy

1d. Internal Enhancement *(select one)* [173]
- o Homogeneous confluent
- o Heterogeneous non-specific
- o Heterogeneous stippled, punctate
- o Heterogeneous clumped
- o Septal, dendritic
- o Asymmetric
- o Symmetric
- o Not applicable

1e. T2 Appearance *(select one)* [174]
- o Hyperintense to surrounding breast tissue
- o Hypointense to surrounding breast tissue
- o Isointense to surrounding breast tissue
- o Unable to evaluate

1f. Degree of Enhancement
(characterize by strongest degree seen) [175]
- o Minimal
- o Moderate
- o Marked

1g. Enhancement Pattern
(characterize by strongest pattern seen) [176]
- o Gradual
- o Sustained
- o Washout

1h. Series and Image Number of Representative Slices *(list up to 3)*

Series |_|_| : [364] **Image #** |_|_|_| [365]

Series |_|_| : [366] **Image #** |_|_|_| [367]

Series |_|_| : [368] **Image #** |_|_|_| [369]

1i. Corresponds to Index Lesion [177]
- o No
- o Yes

1j. Has this been independently biopsied? [399]
- o No
- o Yes

1k. Additional Regional Enhancements [400]
- o No
- o Yes

COMMENTS: _____

_____

_____

_____ [370]

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

ACRIN Study 6657 Case #

PLACE LABEL HERE

Institution Institution No.

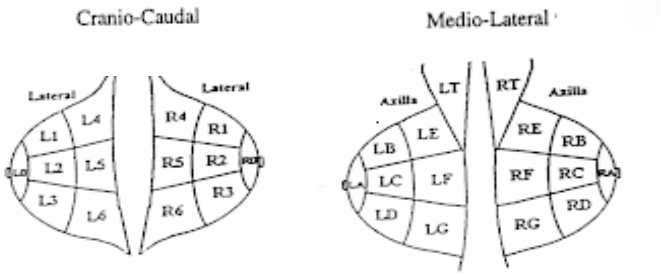
Participant's Initials Participant's I.D. No.

ADDITIONAL BASELINE / PRE-TREATMENT

Section B: Regional Enhancements

All regional enhancements documented on the T1 Form must be reported in this section. If new regional enhancements are now present, report on the supplemental TS Form.

2. Is the lesion identified as Regional Enhancement #2 on the T1 Form still visible? [371]
- o No (skip 2a-2j)
- o Yes (complete 2a-2k)
- o Not Appliable



2a. Location:

Cranio-Caudal *(select all that apply)*

☐ L0	[180]	☐ R0	[187]
☐ L1	[181]	☐ R1	[188]
☐ L2	[182]	☐ R2	[189]
☐ L3	[183]	☐ R3	[190]
☐ L4	[184]	☐ R4	[191]
☐ L5	[185]	☐ R5	[192]
☐ L6	[186]	☐ R6	[193]

Medio-Lateral *(select all that apply)*

☐ LT	[194]	☐ RT	[202]
☐ LA	[195]	☐ RA	[203]
☐ LB	[196]	☐ RB	[204]
☐ LC	[197]	☐ RC	[205]
☐ LD	[198]	☐ RD	[206]
☐ LE	[199]	☐ RE	[207]
☐ LF	[200]	☐ RF	[208]
☐ LG	[201]	☐ RG	[209]

2b. Largest Dimension

___ ___ ___ **mm** [210]

2c. Distribution Subtype *(select one)* [211]
- o Diffuse non-specific
- o Linear non-specific
- o Linear ductal: Smooth
- o Linear ductal: Irregular
- o Linear ductal: Clumped
- o Segmental
- o Regional
- o Diffuse patchy

2d. Internal Enhancement *(select one)* [212]
- o Homogeneous confluent
- o Heterogeneous non-specific
- o Heterogeneous stippled, punctate
- o Heterogeneous clumped
- o Septal, dendritic
- o Asymmetric
- o Symmetric
- o Not applicable

2e. T2 Appearance *(select one)* [213]
- o Hyperintense to surrounding breast tissue
- o Hypointense to surrounding breast tissue
- o Isointense to surrounding breast tissue
- o Unable to evaluate

2f. Degree of Enhancement
(characterize by strongest degree seen) [214]
- o Minimal
- o Moderate
- o Marked

2g. Enhancement Pattern
(characterize by strongest pattern seen) [215]
- o Gradual
- o Sustained
- o Washout

2h. Series and Image Number of Representative Slices *(list up to 3)*

Series ___ ___ : [372] **Image #** ___ ___ ___ [373]

Series ___ ___ : [374] **Image #** ___ ___ ___ [375]

Series ___ ___ : [376] **Image #** ___ ___ ___ [377]

2i. Corresponds to Index Lesion [216]
- o No
- o Yes

2j. Has this been independently biopsied? [401]
- o No
- o Yes

2k. Additional Regional Enhancements [402]
- o No
- o Yes

COMMENTS: _____

_____

_____

_____ [378]

TA

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

ACRIN Study 6657 Case #

PLACE LABEL HERE

Institution Institution No.

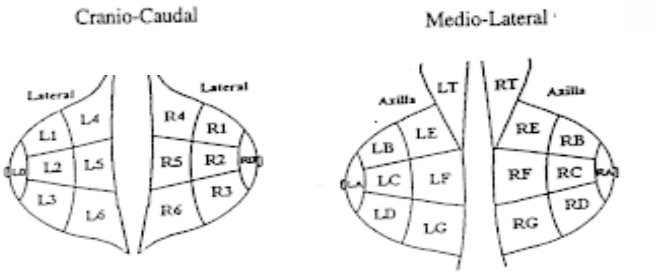
Participant's Initials Participant's I.D. No.

ADDITIONAL BASELINE / PRE-TREATMENT

Section B: Regional Enhancements

All regional enhancements documented on the T1 Form must be reported in this section. If new regional enhancements are now present, report on the supplemental TS Form.

3. Is the lesion identified as Regional Enhancement #3 on the T1 Form still visible? [379]
- o No (skip 3a-3j)
- o Yes (complete 3a-3k)
- o Not Applicable



3a. Location:

Cranio-Caudal *(select all that apply)*

☐ L0	[219]	☐ R0	[226]
☐ L1	[220]	☐ R1	[227]
☐ L2	[221]	☐ R2	[228]
☐ L3	[222]	☐ R3	[229]
☐ L4	[223]	☐ R4	[230]
☐ L5	[224]	☐ R5	[231]
☐ L6	[225]	☐ R6	[232]

Medio-Lateral *(select all that apply)*

☐ LT	[233]	☐ RT	[241]
☐ LA	[234]	☐ RA	[242]
☐ LB	[235]	☐ RB	[243]
☐ LC	[236]	☐ RC	[244]
☐ LD	[237]	☐ RD	[245]
☐ LE	[238]	☐ RE	[246]
☐ LF	[239]	☐ RF	[247]
☐ LG	[240]	☐ RG	[248]

3b. Largest Dimension

|___|___|___| **mm** [249]

3c. Distribution Subtype *(select one)* [250]
- o Diffuse non-specific
- o Linear non-specific
- o Linear ductal: Smooth
- o Linear ductal: Irregular
- o Linear ductal: Clumped
- o Segmental
- o Regional
- o Diffuse patchy

3d. Internal Enhancement *(select one)* [251]
- o Homogeneous confluent
- o Heterogeneous non-specific
- o Heterogeneous stippled, punctate
- o Heterogeneous clumped
- o Septal, dendritic
- o Asymmetric
- o Symmetric
- o Not applicable

3e. T2 Appearance *(select one)* [252]
- o Hyperintense to surrounding breast tissue
- o Hypointense to surrounding breast tissue
- o Isointense to surrounding breast tissue
- o Unable to evaluate

3f. Degree of Enhancement

(characterize by strongest degree seen) [253]
- o Minimal
- o Moderate
- o Marked

3g. Enhancement Pattern

(characterize by strongest pattern seen) [254]
- o Gradual
- o Sustained
- o Washout

3h. Series and Image Number of Representative Slices *(list up to 3)*

Series |___|___| : [380] **Image #** |___|___|___| [381]

Series |___|___| : [382] **Image #** |___|___|___| [383]

Series |___|___| : [384] **Image #** |___|___|___| [385]

3i. Corresponds to Index Lesion [255]
- o No
- o Yes

3j. Has this been independently biopsied? [403]
- o No
- o Yes

3k. Additional Regional Enhancements [404]
- o No
- o Yes

COMMENTS: _____

_____

_____ [386]

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

ACRIN Study 6657 Case #

PLACE LABEL HERE

Institution Institution No.

Participant's Initials Participant's I.D. No.

ADDITIONAL BASELINE / PRE-TREATMENT

14. Other Multi-focality *(select all that apply)*

☐ Other masses [257]
☐ Other regional enhancements [258]
☐ Diffuse enhancement(s) [259]
☐ Scattered, stippled enhancement(s) [260]
☐ Not applicable/None [261]

15. Other Findings [262]

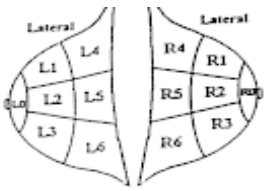
O No *(proceed to question 16)*
O Yes *(continue, characterize other findings)*

Characterization of Other Findings
(select all that apply)

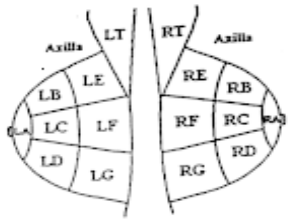
☐ Nipple retraction [263]
☐ Nipple invasion [264]
☐ Pectoralis muscle invasion [265]
☐ Pre-contrast high duct signal [266]
☐ Skin thickening (focal) [267]
☐ Skin thickening (diffuse) [268]
☐ Skin invasion [269]
☐ Edema [270]
☐ Lymph Adenopathy [271]
☐ Hematoma/blood [272]
☐ Abnormal signal void [273]
☐ Cyst(s) [274]
☐ Other [388] _____ [389]

16. Full Extent of Disease (spanning all disease present)
If any new lesions were identified, report description data on the TS form but include these when determining the full extent of disease below.

Cranio-Caudal

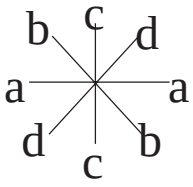


Medio-Lateral



Direction for Longest Diameter Measurement
(indicate which diagram above was used to determine measurement direction) [275]

O cranial - caudal
O medio-lateral



Orientation of Longest Diameter Measurement
(indicate the orientation used to determine measurement direction) [276]

O a
O b
O c
O d

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** [277]

17. TFQ Staging Classification

T *(select one – size of dominant lesion only)* [278]

O T0 No primary
O Tis In Situ
O T1a <5 mm
O T1b 5-9 mm
O T1c 10-20 mm
O T2 21-50 mm
O T3 >50 mm
O T4a chest wall
O T4b skin
O T4c chest wall and skin
O T4d inflammatory

F *(select one – size of full extent of disease)* [279]

O F0 no other area of suspicious enhancement
O F1 ≤10mm
O F2 11-20 mm
O F3 21-30 mm
O F4 31-40 mm
O F5 41-50 mm
O F6 51-60 mm
O F7 61-70 mm
O F8 71-80 mm
O F9 81-90 mm
O F10 91-100 mm
O FX >100 mm, please record size |___|___|___| mm. [280]

Q *(select one - number of quadrants involved)* [281]

O Q0 no quadrant of suspicious enhancement
O Q1 one quadrant of suspicious enhancement
O Q2 two quadrants of suspicious enhancement
O Q3 three quadrants of suspicious enhancement
O Q4 four quadrants of suspicious enhancement

18. Morphologic Pattern Classification of Dominant Lesion [391]

O Single uni-centric mass with well-defined margin
O Multi-lobulated mass with well-defined margin
O Area enhancement with irregular margins - with nodularity
O Area enhancement with irregular margins - without nodularity
O Septal spread; streaming

19. Total number of masses seen on this exam |___|___| [405]

20. Total number of regional enhancements seen on this exam |___|___| [406]

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

ACRIN Study 6657 Case #

PLACE LABEL HERE

Institution Institution No.

Participant's Initials Participant's I.D. No.

COMMENTS: _____

_____

_____

_____

_____ [282]

_____

Radiologist Signature
(radiologist must sign either the completed paper form or the completed/printed web form)

_____ [283]
Signature of person responsible for data

_____ [285]
Signature of person entering data onto web

_____ - _____ - _____ [284]
Date form completed (mm-dd-yyyy)

*** Please remember to complete page 8**

TA MRI Form - Completion Instructions

MRI-1.1, Additional Baseline / Pre-Treatment Reproducibility MRI, must be performed within 72 hours post baseline. This form is to be completed by the study radiologist and used for pre-treatment reproducibility MR Imaging only. Report only clinically relevant findings (up to 3 masses and/or 3 regional enhancements) for the study breast only. Report index lesion if visualized. When reporting index lesion, the index lesion corresponds to the tumor used to define participant eligibility. To enable lesion tracking from T1, use the TA to report on all lesions documented on the T1 form; use the same lesion category and number assignment. Date must be in the mm/dd/yyyy format. Submit this form within 2 weeks of the MRI via the ACRIN website. Submit paper form only for revisions or corrections. Please remember to complete page 8.

MRI TIME-POINT INFORMATION

1. Protocol imaging time point:

Record the appropriate response. The response to this question is mandatory and the default is set according to MRI 1.1 – Additional Baseline / Pre-Treatment Reproducibility.

1a. Was MRS performed?

Mandatory. If the response is "Yes", skip Q1b and complete remaining questions. If the response is "No", specify reason in Q1b. Sign and date form on page 2.

2. Date of MRI:

Mandatory. Record the date that the MRI was performed (date must not be in the future).

3. Date of Interpretation:

Mandatory. Record the date the MRI was interpreted by the radiologist. Date must not be prior to the Date of MRI or a future date.

5. Reader ID:

This 7 alphanumeric character user specific Id is required.

8. Were Clinically Relevant Enhancing Lesion(s) Identified?

Response to this question is mandatory. If clinically relevant enhancing lesion(s) were identified, complete question 9 through the remainder of the form. If clinically relevant enhancing lesion(s) were not identified, sign and date form.

11a. Were Clinically Relevant Mass(es) Identified on Baseline (T1)?

Response to this question is mandatory. If clinically relevant mass(es) were identified, complete Section A. Indicate total number of clinically relevant masses (1-10); the total number of masses must equal the response to question 12 on the T1 form. Provide descriptive data for up to three of the most prominent masses. If clinically relevant mass(es) were not identified, skip to Section B.

11b. Are new masses now seen that were not seen on Baseline?

Response to this question is mandatory. If the response is "Yes," a TS form will be generated to the calendar. Information regarding new mass(es) must be reported on the TS.

12a. Were Clinically Relevant Regional Enhancements Identified on Baseline (T1)?

Response to this question is mandatory. If clinically relevant regional enhancement(s) were identified, complete Section B. Indicate total number of clinically relevant regional enhancements (1-10); the total number of Clinically Relevant Regional Enhancements must equal the response in Section B, question 1, of the T1 form. Provide descriptive data for up to three of the most prominent masses. If clinically relevant regional enhancement(s) were not identified, skip to Section C.

12b. Are new regional enhancements now seen that were not seen on Baseline?

Response to this question is mandatory. If the response is "Yes," a TS form will be generated to the calendar. Information regarding the new regional enhancement(s) must be reported on the TS.

Section A: Masses

Report index lesion if visualized. Complete this section if there are clinically relevant masses to report. All masses documented on the T1 Form must be reported in this section. If new masses are now present, report on the supplemental TS Form.

Is the lesion identified as Mass #__ on the T1 Form still visible?

If the response is "No" for this or any additional mass being reported in this section, skip to Question K. If the response is "Yes" for this or any additional mass being reported in this section, complete Questions A through K. The response of "Not Applicable" must be selected if there are no clinically relevant masses to report.

a. Mass Location: For each reported mass, at least one choice must be selected in the Cranio-Caudal or Medio-Lateral view.

b. Size of Mass: At least one of x, y, or z must be greater than 0.

h. Series and Image Number of Representative Slices: If unknown, enter 99 for series and 999 for Image #.

i. Corresponds to Index lesion: A "Yes" response is allowed only if the response to Q13 "Index Lesion Identified on this MRI Exam" equals "Yes".

k. Additional Masses: If the response is "No" for this or any additional Mass being reported in this section, skip to the next page in Section A and provide responses. If the response is "Yes" for this or any other additional mass, complete responses are required for each relevant mass. Two additional masses may be reported in Section A.

Section B: Regional Enhancements

Report index lesion if visualized. Complete this section if there are regional enhancements masses to report. All regional enhancements documented on the T1 Form must be reported in this section. If new regional enhancements are now present, report on the supplemental TS Form.

Is the lesion identified as Regional Enhancements #__ on the T1 Form still visible?

If the response is "No" for this or any additional regional enhancements being reported in this section, skip to Question K. If the response is "Yes" for this or any additional regional enhancements being reported in this section, complete Questions A through K. The response of "Not Applicable" must be selected if there are no regional enhancements to report.

a. Regional Enhancement Location: For each reported regional enhancement, at least one choice must be selected in the Cranio-Caudal or Medio-Lateral view.

h. Series and Image Number of Representative Slices: If unknown, enter 99 for series and 999 for Image #.

i. **Mass Corresponds to Index lesion:** A "Yes" response is allowed only if the response to Q13 "Index Lesion Identified on this MRI Exam" equals "Yes".

k. **Additional Regional Enhancements:** If the response is "No" for this or any additional regional enhancements being reported in this section, skip to the next page in Section B and provide responses. If the response is "Yes" for this or any other additional regional enhancement, complete responses are required for each relevant regional enhancement. Two additional regional enhancements may be reported in Section B.

Section C: Other Findings

14. Other Multi-focality: Record the appropriate response(s). Select all that apply.

15. Other Findings: If the response is "No", skip to Question 16. If the response is "Yes", provide a **"Characterization of Other Findings"** by checking each of the characteristics that apply.

16. Full Extent of Disease (spanning all disease present)**:**

If any new lesions were identified, report description data on the TS form but include these when determining the full extent of disease below.

Direction for Longest Diameter Measurement: Either the Cranio-Caudal or the Medio-Lateral Oblique diagram must be selected. Indicate which diagram was used to determine measurement direction for the MRI. The direction used on the T1 **must** be used for subsequent MRIs.

Orientation of Longest Diameter Measurement: Indicate the direction (a, b, c, or d) of orientation. The direction used on the T1 **must** be used for subsequent MRIs.

19. Total number of masses seen on this exam: Indicate the total number of masses, both old and new that were seen on this exam.

20. Total number of regional enhancements seen on this exam: Indicate the total number of regional enhancements, both old and new that were seen on this exam.

Radiologist Signature: Legible signature of the Radiologist. If completing a web CRF only, without completing a paper CRF, the electronic summary must be printed and signed by the Radiologist. The Radiologist's signature must be on the original document (whether paper or web).

Signature of person responsible for data: Legible signature/name of the staff member responsible for Collating/reviewing the data and ensuring completion of the CRF (paper or web). If completing a web CRF only, without completing a paper CRF, the electronic summary must be printed and signed by the staff member responsible for the data. The RA's signature must be on the original document (whether paper or web).

Date form completed: Record the date the original CRF, whether paper or web, was completed. Date must not be prior to "Date of MRI." If completing a Paper CRF this refers to the date the data was originally recorded on the paper CRF; the date/time of web entry is automatically recorded by the database. If completing the web CRF only, without completing a paper CRF, this refers to the date the data was originally recorded in the web module.

Signature of person entering data onto web: Record the signature/name of the staff member submitting the Data on-line. If completing a web CRF only, without completing a paper CRF, the electronic summary must be printed and signed by the staff member entering the data onto the web.

VA

ACRIN 6657 Extension

MRS Form: Additional Baseline / Pre-Treatment Reproducibility
MRS 1.1

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

ACRIN Study **6657**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

ADDITIONAL BASELINE / PRE-TREATMENT

INSTRUCTIONS: This is to be filled out during or very near to the actual acquisition of the data. Pretreatment baseline films (hard copy or online) with voxel positioning are required at time of study. Same magnet field strength and coil should be used at every imaging visit.

1. Timepoint [1]
O MRS 1.1 Additional Baseline / Pre-Treatment reproducibility

3. Was MRS performed? [4]
O 1 No (if no, complete Q3a, sign and date form)
O 2 Yes (If yes, continue with form)

3a. If no, specify reason: [5]
O 1 No time
O 2 Technical Problem
O 88 Other, specify _____ [6]

4. Were baseline studies with voxel positioning used to determine MRS asquisition? [7]
O 1 No (Complete Q4a)
O 2 Yes (If yes, complete Q4b)

4a. If no, specify reason:
Specify, _____ [8]

4b. Which previous images were used for voxel placement?
MRI -1: ☐ hardcopy [9] ☐ online [10]

General

5. Date of MRI __-__-____ *(mm-dd-yyyy)* [17]

6. Magnet field strength [18]
O 1 1.5
O 2 3
O 88 Other, specify _____ [19]

7. Person responsible for voxel placement: [20]
(select one)
O 1 MR Technologist
O 2 Research Associate
O 3 Nurse
O 4 PI Radiologist
O 5 Physician
O 88 Other personnel (specify):
_____ [21]

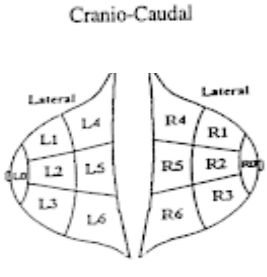
Phantom QC Measurement

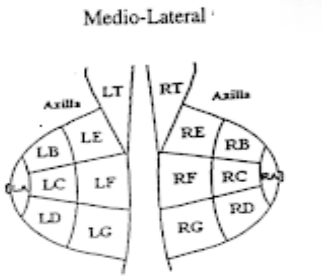
8. Phantom scan performed within past 7 days? [22]
O 1 No (If no, complete Q8a)
O 2 Yes

8a. If no, specify reason:
Specify, _____ [23]

8b. Date of last phantom scan
__-__-____ *(mm-dd-yyyy)* [24]

9. MRS Acquisition





Cranio-Caudal
(select all that apply)

- ☐ L0 [25]
- ☐ L1 [26]
- ☐ L2 [27]
- ☐ L3 [28]
- ☐ L4 [29]
- ☐ L5 [30]
- ☐ L6 [31]
- ☐ R0 [32]
- ☐ R1 [33]
- ☐ R2 [34]
- ☐ R3 [35]
- ☐ R4 [36]
- ☐ R5 [37]
- ☐ R6 [38]

Medio-Lateral
(select all that apply)

- ☐ LT [39]
- ☐ LA [40]
- ☐ LB [41]
- ☐ LC [42]
- ☐ LD [43]
- ☐ LE [44]
- ☐ LF [45]
- ☐ LG [46]
- ☐ RT [47]
- ☐ RA [48]
- ☐ RB [49]
- ☐ RC [50]
- ☐ RD [51]
- ☐ RE [52]
- ☐ RF [53]
- ☐ RG [54]

VA

ACRIN 6657 Extension

MRS Form: Additional Baseline / Pre-Treatment Reproducibility
MRS 1.1

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

ACRIN Study **6657**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

ADDITIONAL BASELINE / PRE-TREATMENT

10. Pre-scan calibration

Shimming: [55] O manual O automatic

Water Suppression: [56] O manual O automatic

11. Confidence in accurate reproduction of voxel placement *(check one):* [57]

Very Confident----------O **1** O **2** O **3** O **4** O **5**----------Not Confident

11a. Reasons for reduced confidence:
(select all that apply)

- ☐ Target lesion not clearly visualized [58]
- ☐ Lesion has changed in size and/or shape [59]
- ☐ Subject position is different [60]
- ☐ Clip artifact present [61]
- ☐ Other [62] _____

_____

_____

_____ [63]

12. Is the scanner and breast coil the same as was used for the baseline MRS exam? [67]

O No (Complete Q12a)
O Yes

12a. If no, specify system used

Specify, _____ [68]

COMMENTS: _____

_____

_____ [64]

_____ [65]
Signature of person responsible for the data

Date form completed ___ - ___ - ____ (mm-dd-yyyy) [66]

ACRIN - 6657 COMPLETION INSTRUCTIONS

Visit 1.1 – Additional Baseline / Pre-Treatment Reproducibility Visit

(within 72 hours post Baseline)

VA MRS Form - Completion Instructions

In accordance with protocol, four to five spectroscopy exams may be reported. **The Additional Baseline / Pre-Treatment Reproducibility MRS exam will be performed on 30 consented patient's only (not all patients will receive this exam).** The 1.1 visit, reported on the VA form, must be performed within 72 hours post Baseline treatment. This form is to be completed by the study radiologist during or very near to the actual acquisition of the data. Pretreatment baseline films (hard copy or online) with voxel positioning are required at time of study. The same magnet field strength and coil should be used at every imaging visit. Submit this form within two weeks of the MRS via the ACRIN website. Date must be in the mm/dd/yyyy format. Submit paper form only for revisions or corrections. **The VA form must be submitted via the ACRIN website regardless of whether an MRS was performed.**

MRS TIME-POINT INFORMATION

1. Timepoint:

Mandatory. Record the appropriate response. The response to this question is mandatory and the default is set according to the form being completed; VA = MRS 1.1 Additional Baseline / Pre-Treatment Reproducibility.

QUESTION 2 DELETED FROM FORM.

3. Was MRS performed?

Mandatory. If the response is "Yes", skip Q3a and complete remaining questions. If the response is "No", specify reason in Q3a. Sign and date form on page 2.

4. Were baseline studies with voxel positioning used to determine MRS acquisition?

Mandatory. If the response is "No", specify reason in Q4a; skip Q4b. If the response is "Yes", indicate **"Which previous images were used for voxel placement"** in Q4b.

General

5. Date of MRS:

Mandatory. Record the date that the MRS was performed (date must not be in the future).

Phantom QC Measurement

8. Phantom scan performed within past 7 days?:

Mandatory. If the response is "Yes", skip Q8a and complete remaining questions. If the response is "No", specify reason in Q8a.

87b. Date of last phantom scan.

Mandatory. Record the date that the last phantom scan performed (date must not be in the future).

9. MRS Acquisition:

Mass Location: At least one choice must be selected in the Cranio-Caudal or Medio-Lateral view.

11. Confidence in accurate voxel placement: Provide confidence level.

11a. Reasons for reduced confidence:

Record the appropriate response(s). Select all that apply.

12. Is the scanner and breast coil the same as was used for the baseline MRS exam?

Mandatory. If the response is "No", specify system used in Q12a. *Please be persistent in using the same scanner and breast coil used in the baseline MRS exam.*

Signature of person responsible for data: Legible signature/name of the staff member responsible for Collating/reviewing the data and ensuring completion of the CRF (paper or web). If completing a web CRF only, without completing a paper CRF, the electronic summary must be printed and signed by the staff member responsible for the data. The RA's signature must be on the original document (whether paper or web).

Date form completed: Record the date the original CRF, whether paper or web, was completed. If completing a Paper CRF this refers to the date the data was originally recorded on the paper CRF; the date/time of web entry is automatically recorded by the database. If completing the web CRF only, without completing a paper CRF, this refers to the date the data was originally recorded in the web module.

Visit 2
MRI/MRS within 20-28 or 48-96 hours post Baseline

T2

ACRIN 6657 Extension
MRI Form: Treatment MRI 2

ACRIN Study 6657 Case #

PLACE LABEL HERE

Institution Institution No.

Participant's Initials Participant's I.D. No.

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

TREATMENT

Instructions: In accordance with the protocol, each participant will receive three or four MRI exams. MRI-2 is to occur within 20-28 or 48-96 hours after chemo and prior to surgery. This form is to be completed by the study radiologist and used for treatment reproducibility MR Imaging only. When reporting index lesion, the index lesion corresponds to the tumor used to define participant eligibility. To enable lesion tracking from T1, use the T2 to report on all lesions documented on the T1 form, use the same lesion category and number assignment. Submit this form within 2 weeks of MRI via the ACRIN website. Submit a paper form for the data corrections only.

1. Protocol Time Point [1]

O Early Treatment

1a. Was MRI performed? [407]
- O No* (complete Q1b, then sign and date form)
- O Yes (proceed to Q2 and continue with form)

1b. *If No, provide reason: [408]
- O Scheduling problem
- O Equipment failure
- O Participant refusal
- O Medical reason
- O Injection site complications
- O Claustrophobia
- O Participant withdrew consent
- O Progressive disease
- O Participant death
- O Other, specify: _____ [409]
- O Unknown

2. Date of MRI ____ - ____ - **20**____ (mm-dd-yyyy) [3]

3. Date of Interpretation ____ - ____ - **20**____ [4]
(mm-dd-yyyy)

4. Reader Name: _____ [5]

5. Reader ID: |_|_|_|_|_|_|_| [6]

6. Patient Weight (kgs) |_|_|_| [7]

7. Total Amount of Gadolinium Injected (cc) |_|_| [8]

8. Were Clinically Relevant Enhancing Lesion(s) Identified [9]
- o No *(sign and date form)*
- o Yes

Complete For Study Breast Only

9. Study Breast (same as identified in (T1) baseline)) [10]
- o Right
- o Left

10. Density of Breast Parenchyma [11]
- o Mostly fat
- o Scattered fibroglandular tissue
- o Heterogeneously dense
- o Extremely dense

11a. Were Clinically Relevant Mass(es) Identified on the Baseline (T1 Form) [12]
- o No
- o Yes *(report in Section A)*

Total Number |_| [13] (enter same response from T1 Q11a)

11b. Are New Masses now seen that were not seen on Baseline [362]
- o No
- o Yes *(report on supplemental TS form)*

12a Were Clinically Relevant Regional Enhancements Identified on the baseline (T1 Form) [14]
- o No
- o Yes *(report in Section B)*

Total Number |_| [15] (enter same response from T1 Q12a)

12b. Are New Regional Enhancements now seen that were not seen on Baseline [387]
- o No
- o Yes *(report on supplemental TS form)*

13. Index Lesion Identified on this MRI Exam [16]
- o No
- o Yes

*** Please remember to complete page 8**

T2 If this is a revised or corrected form, please √box. ☐

ACRIN Study 6657 Case #

PLACE LABEL HERE

Institution Institution No.

Participant's Initials Participant's I.D. No.

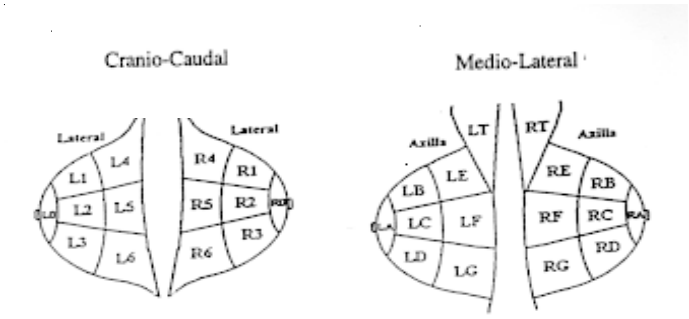
TREATMENT

Section A: Masses

All masses documented on the T1 Form must be reported in this section. If new masses are now present, report on the supplemental TS Form.

1. Is the lesion identified as Mass #1 on the T1 Form still visible? [338]

- o No (skip 1a-1i)
- o Yes (complete 1a-1i)
- o Not Applicable



1a. Location:

Cranio-Caudal *(select all that apply)*

☐ L0 [18]	☐ R0 [25]
☐ L1 [19]	☐ R1 [26]
☐ L2 [20]	☐ R2 [27]
☐ L3 [21]	☐ R3 [28]
☐ L4 [22]	☐ R4 [29]
☐ L5 [23]	☐ R5 [30]
☐ L6 [24]	☐ R6 [31]

Medio-Lateral *(select all that apply)*

☐ LT [32]	☐ RT [40]
☐ LA [33]	☐ RA [41]
☐ LB [34]	☐ RB [42]
☐ LC [35]	☐ RC [43]
☐ LD [36]	☐ RD [44]
☐ LE [37]	☐ RE [45]
☐ LF [38]	☐ RF [46]
☐ LG [39]	☐ RG [47]

1b. Size *(record all three measurements [0 = not seen])*

x = ___ **mm** (medial-lateral) [48]

y = ___ **mm** (superior-inferior) [49]

z = ___ **mm** (anterior-posterior) [50]

1c. Shape/Margin *(select one)* [51]

- o Smooth round
- o Smooth oval
- o Lobulated
- o Irregular
- o Spiculated
- o No longer a mass

1d. Internal Enhancement *(select one)* [52]

- o Homogeneous confluent
- o Heterogeneous
- o Rim enhanced
- o Centrally enhanced
- o Dark septation(s)
- o Enhancing septation(s)
- o No longer a mass

1e. T2 Appearance *(select one)* [53]

- o Hyperintense to surrounding breast tissue
- o Hypointense to surrounding breast tissue
- o Isointense to surrounding breast tissue
- o Unable to evaluate

1f. Degree of Enhancement

(characterize by strongest degree seen) [54]

- o Minimal
- o Moderate
- o Marked

1g. Enhancement Pattern

(characterize by strongest pattern seen) [55]

- o Gradual
- o Sustained
- o Washout

1h. Series and Image Number of Representative Slices *(list up to 3)*

Series ___ : [339] **Image #** ___ [340]

Series ___ : [341] **Image #** ___ [342]

Series ___ : [343] **Image #** ___ [344]

1i. Corresponds to Index Lesion [56]

- o No
- o Yes

COMMENTS: _____

_____

_____

_____ [345]

T2

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

ACRIN Study 6657 Case #

PLACE LABEL HERE

Institution Institution No.

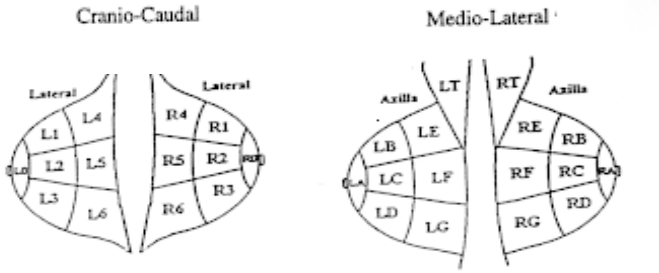
Participant's Initials Participant's I.D. No.

Section A: Masses

All masses documented on the T1 Form must be reported in this section. If new masses are now present, report on the supplemental TS Form.

2. Is the lesion identified as Mass #2 on the T1 Form still visible? [346]

- o No (skip 2a-2i)
- o Yes (complete 2a-2i)
- o Not Applicable



2a. Location:

Cranio-Caudal *(select all that apply)*

☐ L0 [59]	☐ R0 [66]
☐ L1 [60]	☐ R1 [67]
☐ L2 [61]	☐ R2 [68]
☐ L3 [62]	☐ R3 [69]
☐ L4 [63]	☐ R4 [70]
☐ L5 [64]	☐ R5 [71]
☐ L6 [65]	☐ R6 [72]

Medio-Lateral *(select all that apply)*

☐ LT [73]	☐ RT [81]
☐ LA [74]	☐ RA [82]
☐ LB [75]	☐ RB [83]
☐ LC [76]	☐ RC [84]
☐ LD [77]	☐ RD [85]
☐ LE [78]	☐ RE [86]
☐ LF [79]	☐ RF [87]
☐ LG [80]	☐ RG [88]

2b. Size *(record all three measurements [0 = not seen])*

x = ___ **mm** (medial-lateral) [89]

y = ___ **mm** (superior-inferior) [90]

z = ___ **mm** (anterior-posterior) [91]

2c. Shape/Margin *(select one)* [92]

- o Smooth round
- o Smooth oval
- o Lobulated
- o Irregular
- o Spiculated
- o No longer a mass

TREATMENT

2d. Internal Enhancement *(select one)* [93]

- o Homogeneous confluent
- o Heterogeneous
- o Rim enhanced
- o Centrally enhanced
- o Dark septation(s)
- o Enhancing septation(s)
- o No longer a mass

2e. T2 Appearance *(select one)* [94]

- o Hyperintense to surrounding breast tissue
- o Hypointense to surrounding breast tissue
- o Isointense to surrounding breast tissue
- o Unable to evaluate

2f. Degree of Enhancement

(characterize by strongest degree seen) [95]

- o Minimal
- o Moderate
- o Marked

2g. Enhancement Pattern

(characterize by strongest pattern seen) [96]

- o Gradual
- o Sustained
- o Washout

2h. Series and Image Number of Representative Slices *(list up to 3)*

Series ___ : [347] **Image #** ___ [348]

Series ___ : [349] **Image #** ___ [350]

Series ___ : [351] **Image #** ___ [352]

2i. Corresponds to Index Lesion [97]

- o No
- o Yes

COMMENTS: _____

_____

_____

_____ [353]

T2 If this is a revised or corrected form, please √box. ☐

ACRIN Study 6657 Case #

PLACE LABEL HERE

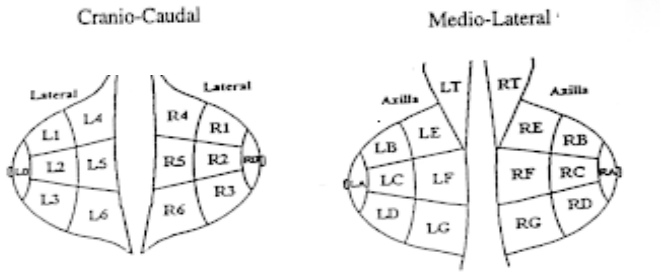
Institution Institution No.

Participant's Initials Participant's I.D. No.

Section A: Masses

All masses documented on the T1 Form must be reported in this section. If new masses are now present, report on the supplemental TS Form.

3. Is the lesion identified as Mass #3 on the T1 Form still visible? [354]
- o No (skip 3a-3i)
- o Yes (complete 3a-3i)
- o Not Applicable



3a. Location:

Cranio-Caudal *(select all that apply)*

☐ L0 [100]	☐ R0 [107]
☐ L1 [101]	☐ R1 [108]
☐ L2 [102]	☐ R2 [109]
☐ L3 [103]	☐ R3 [110]
☐ L4 [104]	☐ R4 [111]
☐ L5 [105]	☐ R5 [112]
☐ L6 [106]	☐ R6 [113]

Medio-Lateral *(select all that apply)*

☐ LT [114]	☐ RT [122]
☐ LA [115]	☐ RA [123]
☐ LB [116]	☐ RB [124]
☐ LC [117]	☐ RC [125]
☐ LD [118]	☐ RD [126]
☐ LE [119]	☐ RE [127]
☐ LF [120]	☐ RF [128]
☐ LG [121]	☐ RG [129]

3b. Size *(record all three measurements [0 = not seen])*

x = ___ **mm** (medial-lateral) [130]

y = ___ **mm** (superior-inferior) [131]

z = ___ **mm** (anterior-posterior) [132]

3c. Shape/Margin *(select one)* [133]
- o Smooth round
- o Smooth oval
- o Lobulated
- o Irregular
- o Spiculated
- o No longer a mass

TREATMENT

3d. Internal Enhancement *(select one)* [134]
- o Homogeneous confluent
- o Heterogeneous
- o Rim enhanced
- o Centrally enhanced
- o Dark septation(s)
- o Enhancing septation(s)
- o No longer a mass

3e. T2 Appearance *(select one)* [135]
- o Hyperintense to surrounding breast tissue
- o Hypointense to surrounding breast tissue
- o Isointense to surrounding breast tissue
- o Unable to evaluate

3f. Degree of Enhancement
(characterize by strongest degree seen) [136]
- o Minimal
- o Moderate
- o Marked

3g. Enhancement Pattern
(characterize by strongest pattern seen) [137]
- o Gradual
- o Sustained
- o Washout

3h. Series and Image Number of Representative Slices *(list up to 3)*

Series ___ : [355] **Image #** ___ [356]

Series ___ : [357] **Image #** ___ [358]

Series ___ : [359] **Image #** ___ [360]

3i. Corresponds to Index Lesion [138]
- o No
- o Yes

COMMENTS: _____

_____

_____

_____ [361]

T2 If this is a revised or corrected form, please √box. ☐

ACRIN Study 6657 Case #

PLACE LABEL HERE

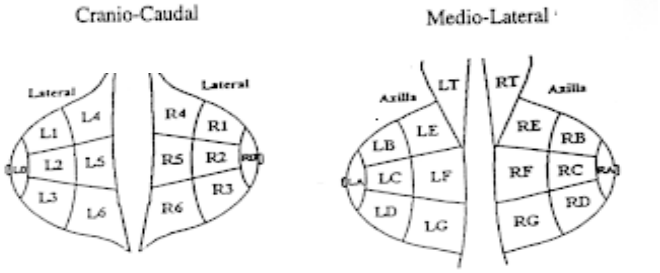
Institution Institution No.

Participant's Initials Participant's I.D. No.

Section B: Regional Enhancements

All regional enhancements documented on the T1 Form must be reported in this section. If new regional enhancements are now present, report on the supplemental TS Form.

1. Is the lesion identified as Regional Enhancement #1 from the T1 Form still visible? [363]
- o No (skip 1a-1i)
- o Yes (complete 1a-1i)
- o Not Applicable



1a. Location:

Cranio-Caudal *(select all that apply)*

☐	L0 [141]	☐	R0 [148]
☐	L1 [142]	☐	R1 [149]
☐	L2 [143]	☐	R2 [150]
☐	L3 [144]	☐	R3 [151]
☐	L4 [145]	☐	R4 [152]
☐	L5 [146]	☐	R5 [153]
☐	L6 [147]	☐	R6 [154]

Medio-Lateral *(select all that apply)*

☐	LT [155]	☐	RT [163]
☐	LA [156]	☐	RA [164]
☐	LB [157]	☐	RB [165]
☐	LC [158]	☐	RC [166]
☐	LD [159]	☐	RD [167]
☐	LE [160]	☐	RE [168]
☐	LF [161]	☐	RF [169]
☐	LG [162]	☐	RG [170]

1b. Largest Dimension

|_|_|_| **mm** [171]

1c. Distribution Subtype *(select one)* [172]
- o Diffuse non-specific
- o Linear non-specific
- o Linear ductal: Smooth
- o Linear ductal: Irregular
- o Linear ductal: Clumped
- o Segmental
- o Regional
- o Diffuse patchy

TREATMENT

1d. Internal Enhancement *(select one)* [173]
- o Homogeneous confluent
- o Heterogeneous non-specific
- o Heterogeneous stippled, punctate
- o Heterogeneous clumped
- o Septal, dendritic
- o Asymmetric
- o Symmetric
- o Not applicable

1e. T2 Appearance *(select one)* [174]
- o Hyperintense to surrounding breast tissue
- o Hypointense to surrounding breast tissue
- o Isointense to surrounding breast tissue
- o Unable to evaluate

1f. Degree of Enhancement
(characterize by strongest degree seen) [175]
- o Minimal
- o Moderate
- o Marked

1g. Enhancement Pattern
(characterize by strongest pattern seen) [176]
- o Gradual
- o Sustained
- o Washout

1h. Series and Image Number of Representative Slices *(list up to 3)*

Series |_|_| : [364] **Image #** |_|_|_| [365]

Series |_|_| : [366] **Image #** |_|_|_| [367]

Series |_|_| : [368] **Image #** |_|_|_| [369]

1i. Corresponds to Index Lesion [177]
- o No
- o Yes

COMMENTS: _____

_____

_____

_____ [370]

T2 If this is a revised or corrected form, please √box. ☐

ACRIN Study 6657 Case #

PLACE LABEL HERE

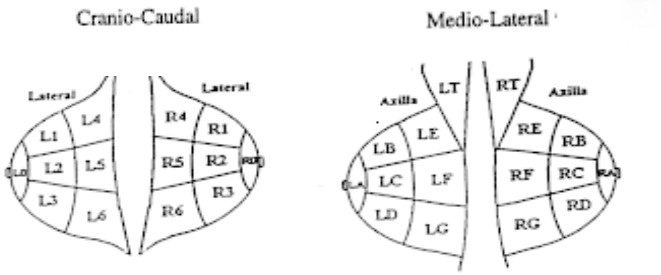
Institution Institution No.

Participant's Initials Participant's I.D. No.

Section B: Regional Enhancements

All regional enhancements documented on the T1 Form must be reported in this section. If new regional enhancements are now present, report on the supplemental TS Form.

2. Is the lesion identified as Regional Enhancement #2 on the T1 Form still visible? [371]
- o No (skip 2a-2i)
- o Yes (complete 2a-2i)
- o Not Appliable



2a. Location:

Cranio-Caudal *(select all that apply)*

☐ L0	[180]	☐ R0	[187]
☐ L1	[181]	☐ R1	[188]
☐ L2	[182]	☐ R2	[189]
☐ L3	[183]	☐ R3	[190]
☐ L4	[184]	☐ R4	[191]
☐ L5	[185]	☐ R5	[192]
☐ L6	[186]	☐ R6	[193]

Medio-Lateral *(select all that apply)*

☐ LT	[194]	☐ RT	[202]
☐ LA	[195]	☐ RA	[203]
☐ LB	[196]	☐ RB	[204]
☐ LC	[197]	☐ RC	[205]
☐ LD	[198]	☐ RD	[206]
☐ LE	[199]	☐ RE	[207]
☐ LF	[200]	☐ RF	[208]
☐ LG	[201]	☐ RG	[209]

2b. Largest Dimension

___ ___ ___ **mm** [210]

2c. Distribution Subtype *(select one)* [211]
- o Diffuse non-specific
- o Linear non-specific
- o Linear ductal: Smooth
- o Linear ductal: Irregular
- o Linear ductal: Clumped
- o Segmental
- o Regional
- o Diffuse patchy

TREATMENT

2d. Internal Enhancement *(select one)* [212]
- o Homogeneous confluent
- o Heterogeneous non-specific
- o Heterogeneous stippled, punctate
- o Heterogeneous clumped
- o Septal, dendritic
- o Asymmetric
- o Symmetric
- o Not applicable

2e. T2 Appearance *(select one)* [213]
- o Hyperintense to surrounding breast tissue
- o Hypointense to surrounding breast tissue
- o Isointense to surrounding breast tissue
- o Unable to evaluate

2f. Degree of Enhancement
(characterize by strongest degree seen) [214]
- o Minimal
- o Moderate
- o Marked

2g. Enhancement Pattern
(characterize by strongest pattern seen) [215]
- o Gradual
- o Sustained
- o Washout

2h. Series and Image Number of Representative Slices *(list up to 3)*

Series ___ ___ : [372] **Image #** ___ ___ ___ [373]

Series ___ ___ : [374] **Image #** ___ ___ ___ [375]

Series ___ ___ : [376] **Image #** ___ ___ ___ [377]

2i. Corresponds to Index Lesion [216]
- o No
- o Yes

COMMENTS: _____

_____

_____

_____ [378]

T2 If this is a revised or corrected form, please √box. ☐

ACRIN Study 6657 Case #

PLACE LABEL HERE

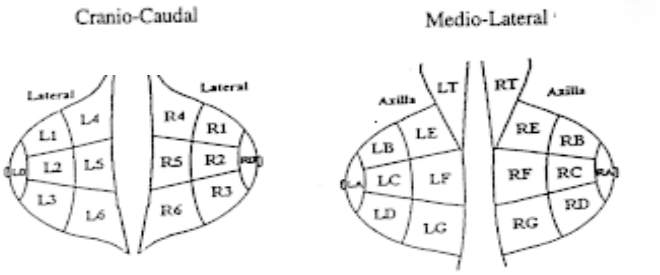
Institution Institution No.

Participant's Initials Participant's I.D. No.

Section B: Regional Enhancements

All regional enhancements documented on the T1 Form must be reported in this section. If new regional enhancements are now present, report on the supplemental TS Form.

3. Is the lesion identified as Regional Enhancement #3 on the T1 Form still visible? [379]
- o No (skip 3a-3i)
- o Yes (complete 3a-3i)
- o Not Applicable



3a. Location:

Cranio-Caudal *(select all that apply)*

☐ L0	[219]	☐ R0	[226]
☐ L1	[220]	☐ R1	[227]
☐ L2	[221]	☐ R2	[228]
☐ L3	[222]	☐ R3	[229]
☐ L4	[223]	☐ R4	[230]
☐ L5	[224]	☐ R5	[231]
☐ L6	[225]	☐ R6	[232]

Medio-Lateral *(select all that apply)*

☐ LT	[233]	☐ RT	[241]
☐ LA	[234]	☐ RA	[242]
☐ LB	[235]	☐ RB	[243]
☐ LC	[236]	☐ RC	[244]
☐ LD	[237]	☐ RD	[245]
☐ LE	[238]	☐ RE	[246]
☐ LF	[239]	☐ RF	[247]
☐ LG	[240]	☐ RG	[248]

3b. Largest Dimension

|___|___|___| **mm** [249]

3c. Distribution Subtype *(select one)* [250]
- o Diffuse non-specific
- o Linear non-specific
- o Linear ductal: Smooth
- o Linear ductal: Irregular
- o Linear ductal: Clumped
- o Segmental
- o Regional
- o Diffuse patchy

TREATMENT

3d. Internal Enhancement *(select one)* [251]
- o Homogeneous confluent
- o Heterogeneous non-specific
- o Heterogeneous stippled, punctate
- o Heterogeneous clumped
- o Septal, dendritic
- o Asymmetric
- o Symmetric
- o Not applicable

3e. T2 Appearance *(select one)* [252]
- o Hyperintense to surrounding breast tissue
- o Hypointense to surrounding breast tissue
- o Isointense to surrounding breast tissue
- o Unable to evaluate

3f. Degree of Enhancement
(characterize by strongest degree seen) [253]
- o Minimal
- o Moderate
- o Marked

3g. Enhancement Pattern
(characterize by strongest pattern seen) [254]
- o Gradual
- o Sustained
- o Washout

3h. Series and Image Number of Representative Slices *(list up to 3)*

Series |___|___| : [380] **Image #** |___|___|___| [381]

Series |___|___| : [382] **Image #** |___|___|___| [383]

Series |___|___| : [384] **Image #** |___|___|___| [385]

3i. Corresponds to Index Lesion [255]
- o No
- o Yes

COMMENTS: _____

_____

_____

_____ [386]

ACRIN Study 6657 Case #

PLACE LABEL HERE

Institution Institution No.

Participant's Initials Participant's I.D. No.

TREATMENT

14. Other Multi-focality *(select all that apply)*

- ☐ Other masses [257]
- ☐ Other regional enhancements [258]
- ☐ Diffuse enhancement(s) [259]
- ☐ Scattered, stippled enhancement(s) [260]
- ☐ Not applicable/None [261]

15. Other Findings [262]

- o No *(proceed to question 16)*
- o Yes *(continue, characterize other findings)*

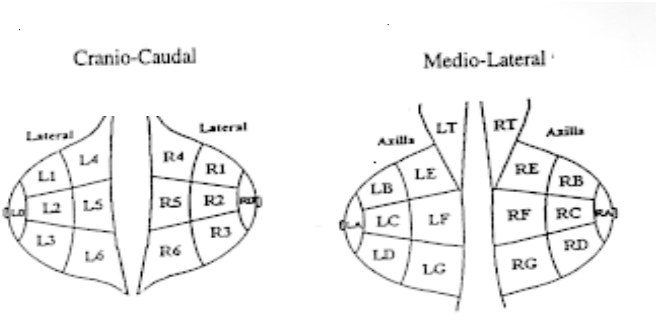
Characterization of Other Findings

(select all that apply)

- ☐ Nipple retraction [263]
- ☐ Nipple invasion [264]
- ☐ Pectoralis muscle invasion [265]
- ☐ Pre-contrast high duct signal [266]
- ☐ Skin thickening (focal) [267]
- ☐ Skin thickening (diffuse) [268]
- ☐ Skin invasion [269]
- ☐ Edema [270]
- ☐ Lymph Adenopathy [271]
- ☐ Hematoma/blood [272]
- ☐ Abnormal signal void [273]
- ☐ Cyst(s) [274]
- ☐ Other [388] _____ [389]

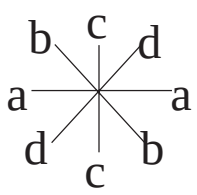
16. Full Extent of Disease

If any new lesions were identified, report description data on the TS form but include these when determining the full extent of disease below.



Direction for Longest Diameter Measurement
(indicate which diagram above was used to determine measurement direction) [275]

- o cranial - caudal
- o medio-lateral



Orientation of Longest Diameter Measurement
(indicate the orientation used to determine measurement direction) [276]

- o a
- o b
- o c
- o d

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** [277]

T2 If this is a revised or corrected form, please √box. ☐

ACRIN Study 6657 Case #

PLACE LABEL HERE

Institution Institution No.

Participant's Initials Participant's I.D. No.

TREATMENT

17. TFQ Staging Classification

T *(select one – size of dominant lesion only)* [278]

- O T0 No primary
- O Tis In Situ
- O T1a <5 mm
- O T1b 5-9 mm
- O T1c 10-20 mm
- O T2 21-50 mm
- O T3 >50 mm
- O T4a chest wall
- O T4b skin
- O T4c chest wall and skin
- O T4d inflammatory

F *(select one – size of full extent of disease)* [279]

- O F0 no other area of suspicious enhancement
- O F1 ≤10mm
- O F2 11-20 mm
- O F3 21-30 mm
- O F4 31-40 mm
- O F5 41-50 mm
- O F6 51-60 mm
- O F7 61-70 mm
- O F8 71-80 mm
- O F9 81-90 mm
- O F10 91-100 mm
- O FX >100 mm, please record

size ___|___|___ mm. [280]

Q *(select one - number of quadrants involved)* [281]

- O Q0 no quadrant of suspicious enhancement
- O Q1 one quadrant of suspicious enhancement
- O Q2 two quadrants of suspicious enhancement
- O Q3 three quadrants of suspicious enhancement
- O Q4 four quadrants of suspicious enhancement

18. Total number of masses seen on this exam ___|___ [405]

19. Total number of regional enhancements seen on this exam ___|___ [406]

COMMENTS: _____

_____ **[282]**

_____

Radiologist Signature
(radiologist must sign either the completed paper form or the completed/printed web form)

_____ **[283]**
Signature of person responsible for data

_____ **[285]**
Signature of person entering data onto web

_____ - _____ - **20**_____ **[284]**
Date form completed (mm-dd-yyyy)

*** Please remember to complete page 8**

T2 MRI Treatment Form - Completion Instructions

MRI-2, Treatment MRI, must be performed within 20-28 or 48-96 hours post baseline. This form is to be completed by the study radiologist and used for treatment MR Imaging only. Report only clinically relevant findings (up to 3 masses and/or 3 regional enhancements) for the study breast only. Report index lesion if visualized. When reporting index lesion, the index lesion corresponds to the tumor used to define participant eligibility. To enable lesion tracking from T1, use the T2 to report on all lesions documented on the T1 form; use the same lesion category and number assignment. Date must be in the mm/dd/yyyy format. Submit this form within 2 weeks of the MRI via the ACRIN website. Submit paper form only for revisions or corrections. Please remember to complete page 8.

MRI TIME-POINT INFORMATION

1. Protocol imaging time point:

Record the appropriate response. The response to this question is mandatory and the default is set according to MRI 2 – Early Treatment.

1a. Was MRS performed?

Mandatory. If the response is “Yes”, skip Q1b and complete remaining questions. If the response is “No”, specify reason in Q1b. Sign and date form on page 2.

2. Date of MRI:

Mandatory. Record the date that the MRI was performed (date must not be in the future).

3. Date of Interpretation:

Mandatory. Record the date the MRI was interpreted by the radiologist. Date must not be prior to the Date of MRI or a future date.

5. Reader ID:

This 7 alphanumeric character user specific Id is required.

8. Were Clinically Relevant Enhancing Lesion(s) Identified?

Response to this question is mandatory. If clinically relevant enhancing lesion(s) were identified, complete question 9 through the remainder of the form. If clinically relevant enhancing lesion(s) were not identified, sign and date form.

11a. Were Clinically Relevant Mass(es) Identified on Baseline (T1)?

Response to this question is mandatory. If clinically relevant mass(es) were identified, complete Section A. Indicate total number of clinically relevant masses (1-10); the total number of masses must equal the response to question 12 on the T1 form. Provide descriptive data for up to three of the most prominent masses. If clinically relevant mass(es) were not identified, skip to Section B.

11b. Are new masses now seen that were not seen on Baseline?

Response to this question is mandatory. If the response is "Yes," a TS form will be generated to the calendar. Information regarding new mass(es) must be reported on the TS.

12a. Were Clinically Relevant Regional Enhancements Identified on Baseline (T1)?

Response to this question is mandatory. If clinically relevant regional enhancement(s) were identified, complete Section B. Indicate total number of clinically relevant regional enhancements (1-10); the total number of Clinically Relevant Regional Enhancements must equal the response in Section B, question 1, of the T1 form. Provide descriptive data for up to three of the most prominent masses. If clinically relevant regional enhancement(s) were not identified, skip to Section C.

12b. Are new regional enhancements now seen that were not seen on Baseline?

Response to this question is mandatory. If the response is "Yes," a TS form will be generated to the calendar. Information regarding the new regional enhancement(s) must be reported on the TS.

Section A: Masses

Report index lesion if visualized. Complete this section if there are clinically relevant masses to report. All masses documented on the T1 Form must be reported in this section. If new masses are now present, report on the supplemental TS Form.

Is the lesion identified as Mass #__ on the T1 Form still visible?

If the response is "No" for mass #1, skip to "Comments". If the response is "No" for mass #2, skip to mass #3. If the response is "Yes" for this or any additional mass being reported in section A, complete the remainder of the section. The response of "Not Applicable" may not be selected.

a. Mass Location: For each reported mass, at least one choice must be selected in the Cranio-Caudal or Medio-Lateral view.

b. Size of Mass: At least one of x, y, or z must be greater than 0.

h. Series and Image Number of Representative Slices: If unknown, enter 99 for series and 999 for Image #.

i. Corresponds to Index lesion: A "Yes" response is allowed only if the response to Q13 "Index Lesion Identified on this MRI Exam" equals "Yes".

Section B: Regional Enhancements

Report index lesion if visualized. Complete this section if there are regional enhancements masses to report. All regional enhancements documented on the T1 Form must be reported in this section. If new regional enhancements are now present, report on the supplemental TS Form.

Is the lesion identified as Regional Enhancements #__ on the T1 Form still visible?

If the response is "No" for regional enhancement #1, skip to "Comments". If the response is "No" for regional enhancement #2, skip to regional enhancement #3. If the response is "Yes" for this or any additional regional enhancement being reported in section A, complete the remainder of the section. The response of "Not Applicable" may not be selected.

a. Regional Enhancement Location: For each reported regional enhancement, at least one choice must be selected in the Cranio-Caudal or Medio-Lateral view.

h. Series and Image Number of Representative Slices: If unknown, enter 99 for series and 999 for Image #.

i. Mass Corresponds to Index lesion: A "Yes" response is allowed only if the response to Q13 "Index Lesion Identified on this MRI Exam" equals "Yes".

Section C: Other Findings

14. Other Multi-focality: Record the appropriate response(s). Select all that apply.

15. Other Findings: If the response is "No", skip to Question 16. If the response is "Yes", provide a **"Characterization of Other Findings"** by checking each of the characteristics that apply.

16. Full Extent of Disease (spanning all disease present)**:**

If any new lesions were identified, report description data on the TS form but include these when determining the full extent of disease below.

Direction for Longest Diameter Measurement: Either the Cranio-Caudal or the Medio-Lateral Oblique diagram must be selected. Indicate which diagram was used to determine measurement direction for the MRI. The direction used on the T1 **must** be used for subsequent MRIs.

Orientation of Longest Diameter Measurement: Indicate the direction (a, b, c, or d) of orientation. The direction used on the T1 **must** be used for subsequent MRIs.

18. Total number of masses seen on this exam: Indicate the total number of masses, both old and new, that were seen on this exam.

19. Total number of regional enhancements seen on this exam: Indicate the total number of regional enhancements, both old and new, that were seen on this exam.

Radiologist Signature: Legible signature of the Radiologist. If completing a web CRF only, without completing a paper CRF, the electronic summary must be printed and signed by the Radiologist. The Radiologist's signature must be on the original document (whether paper or web).

Signature of person responsible for data: Legible signature/name of the staff member responsible for Collating/reviewing the data and ensuring completion of the CRF (paper or web). If completing a web CRF only, without completing a paper CRF, the electronic summary must be printed and signed by the staff member responsible for the data. The RA's signature must be on the original document (whether paper or web).

Date form completed: Record the date the original CRF, whether paper or web, was completed. Date must not be prior to "Date of MRI." If completing a Paper CRF this refers to the date the data was originally recorded on the paper CRF; the date/time of web entry is automatically recorded by the database. If completing the web CRF only, without completing a paper CRF, this refers to the date the data was originally recorded in the web module.

Signature of person entering data onto web: Record the signature/name of the staff member submitting the Data on-line. If completing a web CRF only, without completing a paper CRF, the electronic summary must be printed and signed by the staff member entering the data onto the web.

V2

ACRIN 6657 Extension

MRS Form: Treatment MRS - 2

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

ACRIN Study **6657**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

TREATMENT

INSTRUCTIONS: This is to be filled out during or very near to the actual acquisition of the data. Pretreatment baseline films (hard copy or online) with voxel positioning are required at time of study. Same magnet field strength and coil should be used at every imaging visit.

1. Timepoint [1]
- O MRS 2 Treatment

2. Indicate actual treatment time window [69]
(This must reflect the actual time window that the participant was scanned; not the treatment window assigned at registration)
- O 1 20-28 hours
- O 2 40-96 hours
- O 88 Other, specify _____ [3]

3. Was MRS performed? [4]
- O 1 No (if no, complete Q3a, sign and date form)
- O 2 Yes (If yes, continue with form)

3a. If no, specify reason: [5]
- O 1 No time
- O 2 Technical Problem
- O 88 Other, specify _____ [6]

4. Were baseline studies with voxel positioning used to determine MRS asquisition? [7]
- O 1 No (Complete Q4a)
- O 2 Yes (If yes, complete Q4b)

4a. If no, specify reason:

Specify, _____ [8]

4b. Which previous images were used for voxel placement?

MRI -1: ☐ hardcopy [9] ☐ online [10]

MRI - 1.1: ☐ hardcopy [11] ☐ online [12]

General

5. Date of MRI ___-___-_____ *(mm-dd-yyyy)* [17]

6. Magnet field strength [18]
- O 1 1.5
- O 2 3
- O 88 Other, specify _____ [19]

7. Person responsible for voxel placement: [20]
(select one)
- O 1 MR Technologist
- O 2 Research Associate
- O 3 Nurse
- O 4 PI Radiologist
- O 5 Physician
- O 88 Other personnel (specify):

_____ [21]

Phantom QC Measurement

8. Phantom scan performed within past 7 days? [22]
- O 1 No (If no, complete Q8a)
- O 2 Yes

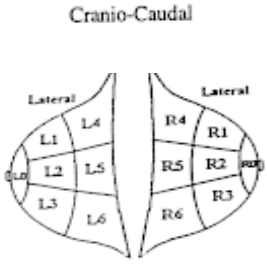
8a. If no, specify reason:

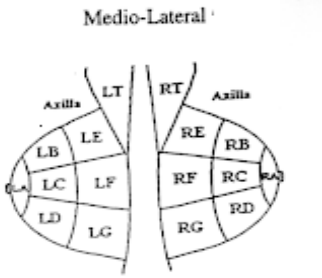
Specify, _____ [23]

8b. Date of last phantom scan

___-___-_____ [24]
(mm-dd-yyyy)

9. MRS Acquisition





Cranio-Caudal
(select all that apply)

- ☐ L0 [25]
- ☐ L1 [26]
- ☐ L2 [27]
- ☐ L3 [28]
- ☐ L4 [29]
- ☐ L5 [30]
- ☐ L6 [31]
- ☐ R0 [32]
- ☐ R1 [33]
- ☐ R2 [34]
- ☐ R3 [35]
- ☐ R4 [36]
- ☐ R5 [37]
- ☐ R6 [38]

Medio-Lateral
(select all that apply)

- ☐ LT [39]
- ☐ LA [40]
- ☐ LB [41]
- ☐ LC [42]
- ☐ LD [43]
- ☐ LE [44]
- ☐ LF [45]
- ☐ LG [46]
- ☐ RT [47]
- ☐ RA [48]
- ☐ RB [49]
- ☐ RC [50]
- ☐ RD [51]
- ☐ RE [52]
- ☐ RF [53]
- ☐ RG [54]

V2

ACRIN 6657 Extension

MRS Form: Treatment MRS - 2

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

ACRIN Study **6657**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

TREATMENT

10. Pre-scan calibration

Shimming: [55] O manual O automatic

Water Suppression: [56] O manual O automatic

11. Confidence in accurate reproduction of voxel placement *(check one):* [57]

Very Confident----------O **1** O **2** O **3** O **4** O **5**----------Not Confident

11a. Reasons for reduced confidence:
(select all that apply)

- ☐ Target lesion not clearly visualized [58]
- ☐ Lesion has changed in size and/or shape [59]
- ☐ Subject position is different [60]
- ☐ Clip artifact present [61]
- ☐ Other [62] _____

_____

_____

_____ [63]

12. Is the scanner and breast coil the same as was used for the baseline MRS exam? [67]

O No (Complete Q12a)
O Yes

12a. If no, specify system used

Specify, _____ [68]

COMMENTS: _____

_____

_____ [64]

_____ [65]
Signature of person responsible for the data

Date form completed ___ - ___ - ____ (mm-dd-yyyy) [66]

V2 MRS Form - Completion Instructions

In accordance with protocol, four to five spectroscopy exams may be reported. Visit #2 (Treatment visit), reported on the V2 form, must be performed within 20-28 or 48-96 hours post Baseline treatment. This form is to be completed by the study radiologist during or very near to the actual acquisition of the data. Pretreatment baseline films (hard copy or online) with voxel positioning are required at time of study. The same magnet field strength and coil should be used at every imaging visit. Submit this form within two weeks of the MRS via the ACRIN website. Date must be in the mm/dd/yyyy format. Submit paper form only for revisions or corrections. **The V2 form must be submitted via the ACRIN website regardless of whether an MRS was performed.**

MRS TIME-POINT INFORMATION

1. Timepoint:

Mandatory. Record the appropriate response. The response to this question is mandatory and the default is set according to the form being completed; V2 = MRS 2 Treatment.

2. Indicate actual treatment time window:

Mandatory. Record the actual time window that the participant was scanned; not the treatment window assigned at registration. A PR Form must be submitted if scan is performed outside of the last (96) hour window. Sites must submit a "note to file" if scan is performed outside of the randomized treatment time window (20-28 hours).

3. Was MRS performed?

Mandatory. If the response is "Yes", skip Q3a and complete remaining questions. If the response is "No", **specify reason** in Q3a. Sign and date form on page 2.

4. Were baseline studies with voxel positioning used to determine MRS acquisition?

Mandatory. If the response is "No", specify reason in Q4a; skip Q4b. If the response is "Yes", indicate **"Which previous images were used for voxel placement"** in Q4b.

General

5. Date of MRS:

Mandatory. Record the date that the MRS was performed (date must not be in the future).

Phantom QC Measurement

8. Phantom scan performed within past 7 days?:

Mandatory. If the response is "Yes", skip Q8a and complete remaining questions. If the response is "No", specify reason in Q8a.

8b. Date of last phantom scan.

Mandatory. Record the date that the last phantom scan performed (date must not be in the future).

9. MRS Acquisition:

Mass Location: At least one choice must be selected in the Cranio-Caudal or Medio-Lateral view.

11. Confidence in accurate voxel placement: Provide confidence level.

11a. Reasons for reduced confidence:

Record the appropriate response(s). Select all that apply.

12. Is the scanner and breast coil the same as was used for the baseline MRS exam?

Mandatory. If the response is "No", specify system used in Q12a. *Please be persistent in using the same scanner and breast coil used in the baseline MRS exam.*

Signature of person responsible for data: Legible signature/name of the staff member responsible for Collating/reviewing the data and ensuring completion of the CRF (paper or web). If completing a web CRF only, without completing a paper CRF, the electronic summary must be printed and signed by the staff member responsible for the data. The RA's signature must be on the original document (whether paper or web).

Date form completed: Record the date the original CRF, whether paper or web, was completed. If completing a Paper CRF this refers to the date the data was originally recorded on the paper CRF; the date/time of web entry is automatically recorded by the database. If completing the web CRF only, without completing a paper CRF, this refers to the date the data was originally recorded in the web module.

V2 MRS Form - Completion Instructions

In accordance with protocol, four to five spectroscopy exams may be reported. Visit #2 (Treatment visit), reported on the V2 form, must be performed within 20-28 or 48-96 hours post Baseline treatment. This form is to be completed by the study radiologist during or very near to the actual acquisition of the data. Pretreatment baseline films (hard copy or online) with voxel positioning are required at time of study. The same magnet field strength and coil should be used at every imaging visit. Submit this form within two weeks of the MRS via the ACRIN website. Date must be in the mm/dd/yyyy format. Submit paper form only for revisions or corrections. **The V2 form must be submitted via the ACRIN website regardless of whether an MRS was performed.**

MRS TIME-POINT INFORMATION

1. Timepoint:

Mandatory. Record the appropriate response. The response to this question is mandatory and the default is set according to the form being completed; V2 = MRS 2 Treatment.

2. Indicate Treatment time window:

Mandatory. Record the time window assigned during patient randomization. If participant is seen outside of treatment window, a PR must be submitted to HQ.

3. Was MRS performed?

Mandatory. If the response is “Yes”, skip Q3a and complete remaining questions. If the response is “No”, **specify reason** in Q3a. Sign and date form on page 2.

4. Were baseline studies with voxel positioning used to determine MRS acquisition?

Mandatory. If the response is “No”, specify reason in Q4a; skip Q4b. If the response is “Yes”, indicate **“Which previous images were used for voxel placement”** in Q4b.

General

5. Date of MRS:

Mandatory. Record the date that the MRS was performed (date must not be in the future).

Phantom QC Measurement

8. Phantom scan performed within past 7 days?:

Mandatory. If the response is “Yes”, skip Q8a and complete remaining questions. If the response is “No”, specify reason in Q8a.

8b. Date of last phantom scan.

Mandatory. Record the date that the last phantom scan performed (date must not be in the future).

9. MRS Acquisition:

Mass Location: At least one choice must be selected in the Cranio-Caudal or Medio-Lateral view.

11. Confidence in accurate voxel placement: Provide confidence level.

11a. Reasons for reduced confidence:

Record the appropriate response(s). Select all that apply.

12. Is the scanner and breast coil the same as was used for the baseline MRS exam?

Mandatory. If the response is "No", specify system used in Q12a. *Please be persistent in using the same scanner and breast coil used in the baseline MRS exam.*

Signature of person responsible for data: Legible signature/name of the staff member responsible for Collating/reviewing the data and ensuring completion of the CRF (paper or web). If completing a web CRF only, without completing a paper CRF, the electronic summary must be printed and signed by the staff member responsible for the data. The RA's signature must be on the original document (whether paper or web).

Date form completed: Record the date the original CRF, whether paper or web, was completed. If completing a Paper CRF this refers to the date the data was originally recorded on the paper CRF; the date/time of web entry is automatically recorded by the database. If completing the web CRF only, without completing a paper CRF, this refers to the date the data was originally recorded in the web module.

Visit 3
MRI/MRS
Inter-Regimen Treatment

T3

ACRIN 6657 Extension
MRI Form: Optional MRI Inter-regimen Treatment MRI 3

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

ACRIN Study 6657 Case #

PLACE LABEL HERE

Institution Institution No.

Participant's Initials Participant's I.D. No.

OPTIONAL MRI INTER-REGIMEN TREATMENT

Instructions: In accordance with the protocol, each participant will receive three or four MRI exams. MRI-3 should only be used if a clinical MRI is performed. This form is to be completed by the study radiologist and used for treatment reproducibility MR Imaging only. When reporting index lesion, the index lesion corresponds to the tumor used to define participant eligibility. To enable lesion tracking from T1, use the T3 to report on all lesions documented on the T1 form, use the same lesion category and number assignment. Submit this form within 2 weeks of MRI via the ACRIN website. Submit a paper form for the data corrections only.

1. Protocol Time Point [1]
- o Optional MRI Inter-regimen Treatment

1a. Was MRI performed? [407]
- o No* (complete Q1b, then sign and date form)
- o Yes (proceed to Q2 and continue with form)

1b. *If No, provide reason: [408]
- o Scheduling problem
- o Equipment failure
- o Participant refusal
- o Medical reason
- o Injection site complications
- o Claustrophobia
- o Participant withdrew consent
- o Progressive disease
- o Participant death
- o Other, specify: _____ [409]
- o Unknown

2. Date of MRI ____ - ____ - **20**____ (mm-dd-yyyy) [3]

3. Date of Interpretation ____ - ____ - **20**____ [4]
(mm-dd-yyyy)

4. Reader Name: _____ [5]

5. Reader ID: ____|____|____|____|____|____|____|____ [6]

6. Patient Weight (kgs) ____|____|____ [7]

7. Total Amount of Gadolinium Injected (cc) ____|____ [8]

8. Were Clinically Relevant Enhancing Lesion(s) Identified [9]
- o No *(sign and date form)*
- o Yes

Complete For Study Breast Only

9. Study Breast [10]
- o Right
- o Left

10. Density of Breast Parenchyma
(same as identified in (T1) baseline)) [11]
- o Mostly fat
- o Scattered fibroglandular tissue
- o Heterogeneously dense
- o Extremely dense

11a. Were Clinically Relevant Mass(es) Identified on the Baseline (T1 Form) [12]
- o No
- o Yes *(report in Section A)*

Total Number ____ [13] (enter same response from T1 Q11a)

11b. Are New Masses now seen that were not seen on Baseline [362]
- o No
- o Yes *(report on supplemental TS form)*

12a. Were Clinically Relevant Regional Enhancements Identified on the baseline (T1 Form) [14]
- o No
- o Yes *(report in Section B)*

Total Number ____ [15] (enter same response from T1 Q12a)

12b. Are New Regional Enhancements now seen that were not seen on Baseline [387]
- o No
- o Yes *(report on supplemental TS form)*

13. Index Lesion Identified on this MRI Exam [16]
- o No
- o Yes

*** Please remember to complete page 8**

T3 If this is a revised or corrected form, please √box. ☐

ACRIN Study 6657 Case #

PLACE LABEL HERE

Institution Institution No.

Participant's Initials Participant's I.D. No.

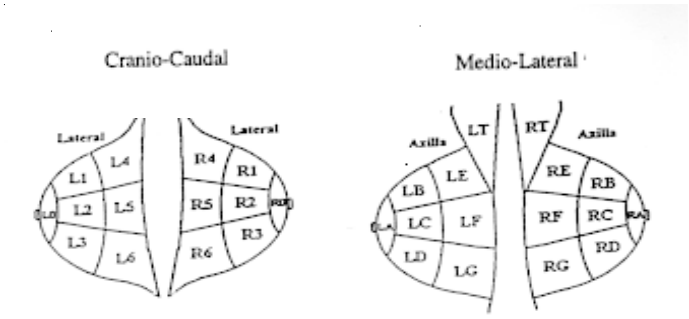
OPTIONAL MRI INTER-REGIMEN TREATMENT

Section A: Masses

All masses documented on the T1 Form must be reported in this section. If new masses are now present, report on the supplemental TS Form.

1. Is the lesion identified as Mass #1 on the T1 Form still visible? [338]

- o No (skip 1a-1i)
- o Yes (complete 1a-1i)
- o Not Applicable



1a. Location:

Cranio-Caudal *(select all that apply)*

☐ L0 [18]	☐ R0 [25]
☐ L1 [19]	☐ R1 [26]
☐ L2 [20]	☐ R2 [27]
☐ L3 [21]	☐ R3 [28]
☐ L4 [22]	☐ R4 [29]
☐ L5 [23]	☐ R5 [30]
☐ L6 [24]	☐ R6 [31]

Medio-Lateral *(select all that apply)*

☐ LT [32]	☐ RT [40]
☐ LA [33]	☐ RA [41]
☐ LB [34]	☐ RB [42]
☐ LC [35]	☐ RC [43]
☐ LD [36]	☐ RD [44]
☐ LE [37]	☐ RE [45]
☐ LF [38]	☐ RF [46]
☐ LG [39]	☐ RG [47]

1b. Size *(record all three measurements [0 = not seen])*

x = ___ **mm** (medial-lateral) [48]

y = ___ **mm** (superior-inferior) [49]

z = ___ **mm** (anterior-posterior) [50]

1c. Shape/Margin *(select one)* [51]

- o Smooth round
- o Smooth oval
- o Lobulated
- o Irregular
- o Spiculated
- o No longer a mass

1d. Internal Enhancement *(select one)* [52]

- o Homogeneous confluent
- o Heterogeneous
- o Rim enhanced
- o Centrally enhanced
- o Dark septation(s)
- o Enhancing septation(s)
- o No longer a mass

1e. T2 Appearance *(select one)* [53]

- o Hyperintense to surrounding breast tissue
- o Hypointense to surrounding breast tissue
- o Isointense to surrounding breast tissue
- o Unable to evaluate

1f. Degree of Enhancement

(characterize by strongest degree seen) [54]

- o Minimal
- o Moderate
- o Marked

1g. Enhancement Pattern

(characterize by strongest pattern seen) [55]

- o Gradual
- o Sustained
- o Washout

1h. Series and Image Number of Representative Slices *(list up to 3)*

Series ___ : [339] **Image #** ___ [340]

Series ___ : [341] **Image #** ___ [342]

Series ___ : [343] **Image #** ___ [344]

1i. Corresponds to Index Lesion [56]

- o No
- o Yes

COMMENTS: _____

_____

_____

_____ [345]

T3

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

ACRIN Study 6657 Case #

PLACE LABEL HERE

Institution Institution No.

Participant's Initials Participant's I.D. No.

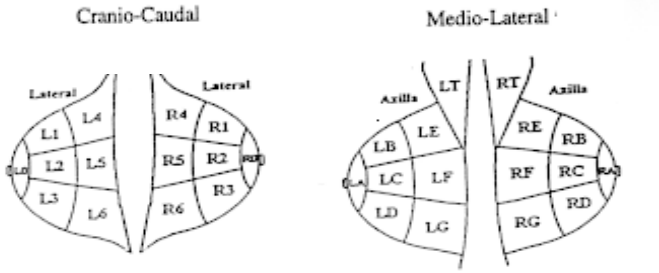
OPTIONAL MRI INTER-REGIMEN TREATMENT

Section A: Masses

All masses documented on the T1 Form must be reported in this section. If new masses are now present, report on the supplemental TS Form.

2. Is the lesion identified as Mass #2 on the T1 Form still visible? [346]

- o No (skip 2a-2i)
- o Yes (complete 2a-2i)
- o Not Applicable



2a. Location:

Cranio-Caudal *(select all that apply)*

☐ L0 [59]	☐ R0 [66]
☐ L1 [60]	☐ R1 [67]
☐ L2 [61]	☐ R2 [68]
☐ L3 [62]	☐ R3 [69]
☐ L4 [63]	☐ R4 [70]
☐ L5 [64]	☐ R5 [71]
☐ L6 [65]	☐ R6 [72]

Medio-Lateral *(select all that apply)*

☐ LT [73]	☐ RT [81]
☐ LA [74]	☐ RA [82]
☐ LB [75]	☐ RB [83]
☐ LC [76]	☐ RC [84]
☐ LD [77]	☐ RD [85]
☐ LE [78]	☐ RE [86]
☐ LF [79]	☐ RF [87]
☐ LG [80]	☐ RG [88]

2b. Size *(record all three measurements [0 = not seen])*

x = ___ ___ ___ **mm** (medial-lateral) [89]

y = ___ ___ ___ **mm** (superior-inferior) [90]

z = ___ ___ ___ **mm** (anterior-posterior) [91]

2c. Shape/Margin *(select one)* [92]

- o Smooth round
- o Smooth oval
- o Lobulated
- o Irregular
- o Spiculated
- o No longer a mass

2d. Internal Enhancement *(select one)* [93]

- o Homogeneous confluent
- o Heterogeneous
- o Rim enhanced
- o Centrally enhanced
- o Dark septation(s)
- o Enhancing septation(s)
- o No longer a mass

2e. T2 Appearance *(select one)* [94]

- o Hyperintense to surrounding breast tissue
- o Hypointense to surrounding breast tissue
- o Isointense to surrounding breast tissue
- o Unable to evaluate

2f. Degree of Enhancement

(characterize by strongest degree seen) [95]

- o Minimal
- o Moderate
- o Marked

2g. Enhancement Pattern

(characterize by strongest pattern seen) [96]

- o Gradual
- o Sustained
- o Washout

2h. Series and Image Number of Representative Slices *(list up to 3)*

Series ___ ___ : [347] **Image #** ___ ___ ___ [348]

Series ___ ___ : [349] **Image #** ___ ___ ___ [350]

Series ___ ___ : [351] **Image #** ___ ___ ___ [352]

2i. Corresponds to Index Lesion [97]

- o No
- o Yes

COMMENTS: _____

_____

_____

_____ [353]

T3

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

ACRIN Study 6657 Case #

PLACE LABEL HERE

Institution Institution No.

Participant's Initials Participant's I.D. No.

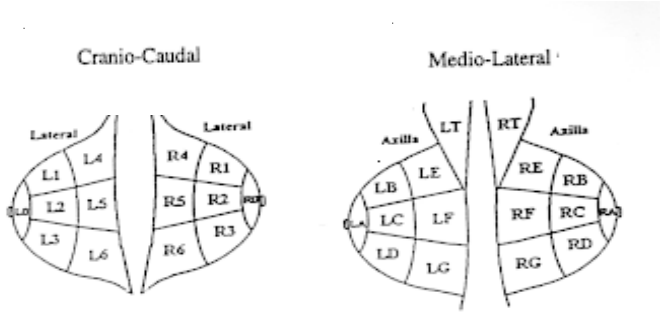
OPTIONAL MRI INTER-REGIMEN TREATMENT

Section A: Masses

All masses documented on the T1 Form must be reported in this section. If new masses are now present, report on the supplemental TS Form.

3. Is the lesion identified as Mass #3 on the T1 Form still visible? [354]

- o No (skip 3a-3i)
- o Yes (complete 3a-3i)
- o Not Applicable



3a. Location:

Cranio-Caudal *(select all that apply)*

☐ L0 [100]	☐ R0 [107]
☐ L1 [101]	☐ R1 [108]
☐ L2 [102]	☐ R2 [109]
☐ L3 [103]	☐ R3 [110]
☐ L4 [104]	☐ R4 [111]
☐ L5 [105]	☐ R5 [112]
☐ L6 [106]	☐ R6 [113]

Medio-Lateral *(select all that apply)*

☐ LT [114]	☐ RT [122]
☐ LA [115]	☐ RA [123]
☐ LB [116]	☐ RB [124]
☐ LC [117]	☐ RC [125]
☐ LD [118]	☐ RD [126]
☐ LE [119]	☐ RE [127]
☐ LF [120]	☐ RF [128]
☐ LG [121]	☐ RG [129]

3b. Size *(record all three measurements [0 = not seen])*

x = ___ **mm** (medial-lateral) [130]

y = ___ **mm** (superior-inferior) [131]

z = ___ **mm** (anterior-posterior) [132]

3c. Shape/Margin *(select one)* [133]

- o Smooth round
- o Smooth oval
- o Lobulated
- o Irregular
- o Spiculated
- o No longer a mass

3d. Internal Enhancement *(select one)* [134]

- o Homogeneous confluent
- o Heterogeneous
- o Rim enhanced
- o Centrally enhanced
- o Dark septation(s)
- o Enhancing septation(s)
- o No longer a mass

3e. T2 Appearance *(select one)* [135]

- o Hyperintense to surrounding breast tissue
- o Hypointense to surrounding breast tissue
- o Isointense to surrounding breast tissue
- o Unable to evaluate

3f. Degree of Enhancement

(characterize by strongest degree seen) [136]

- o Minimal
- o Moderate
- o Marked

3g. Enhancement Pattern

(characterize by strongest pattern seen) [137]

- o Gradual
- o Sustained
- o Washout

3h. Series and Image Number of Representative Slices *(list up to 3)*

Series ___ : [355] **Image #** ___ [356]

Series ___ : [357] **Image #** ___ [358]

Series ___ : [359] **Image #** ___ [360]

3i. Corresponds to Index Lesion [138]

- o No
- o Yes

COMMENTS: _____

_____

_____

_____ [361]

T3

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

ACRIN Study 6657 Case #

PLACE LABEL HERE

Institution Institution No.

Participant's Initials Participant's I.D. No.

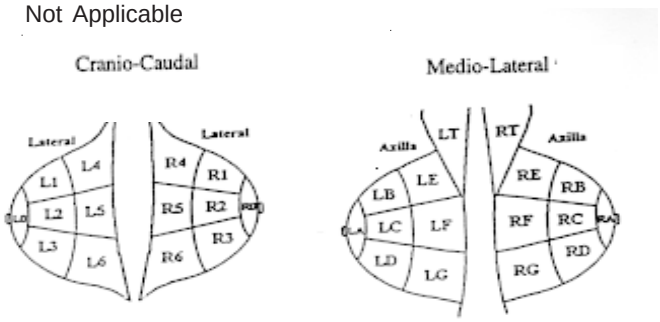
OPTIONAL MRI INTER-REGIMEN TREATMENT

Section B: Regional Enhancements

All regional enhancements documented on the T1 Form must be reported in this section. If new regional enhancements are now present, report on the supplemental TS Form.

1. Is the lesion identified as Regional Enhancement #1 from the T1 Form still visible? [363]

- o No (skip 1a-1i)
- o Yes (complete 1a-1i)
- o Not Applicable



1a. Location:

Cranio-Caudal *(select all that apply)*

☐	L0 [141]	☐	R0 [148]
☐	L1 [142]	☐	R1 [149]
☐	L2 [143]	☐	R2 [150]
☐	L3 [144]	☐	R3 [151]
☐	L4 [145]	☐	R4 [152]
☐	L5 [146]	☐	R5 [153]
☐	L6 [147]	☐	R6 [154]

Medio-Lateral *(select all that apply)*

☐	LT [155]	☐	RT [163]
☐	LA [156]	☐	RA [164]
☐	LB [157]	☐	RB [165]
☐	LC [158]	☐	RC [166]
☐	LD [159]	☐	RD [167]
☐	LE [160]	☐	RE [168]
☐	LF [161]	☐	RF [169]
☐	LG [162]	☐	RG [170]

1b. Largest Dimension

|___|___|___| **mm** [171]

1c. Distribution Subtype *(select one)* [172]

- o Diffuse non-specific
- o Linear non-specific
- o Linear ductal: Smooth
- o Linear ductal: Irregular
- o Linear ductal: Clumped
- o Segmental
- o Regional
- o Diffuse patchy

1d. Internal Enhancement *(select one)* [173]

- o Homogeneous confluent
- o Heterogeneous non-specific
- o Heterogeneous stippled, punctate
- o Heterogeneous clumped
- o Septal, dendritic
- o Asymmetric
- o Symmetric
- o Not applicable

1e. T2 Appearance *(select one)* [174]

- o Hyperintense to surrounding breast tissue
- o Hypointense to surrounding breast tissue
- o Isointense to surrounding breast tissue
- o Unable to evaluate

1f. Degree of Enhancement

(characterize by strongest degree seen) [175]

- o Minimal
- o Moderate
- o Marked

1g. Enhancement Pattern

(characterize by strongest pattern seen) [176]

- o Gradual
- o Sustained
- o Washout

1h. Series and Image Number of Representative Slices *(list up to 3)*

Series |___|___| : [364] **Image #** |___|___|___| [365]

Series |___|___| : [366] **Image #** |___|___|___| [367]

Series |___|___| : [368] **Image #** |___|___|___| [369]

1i. Corresponds to Index Lesion [177]

- o No
- o Yes

COMMENTS: _____

_____

_____

_____ [370]

ACRIN Study 6657 Case #

PLACE LABEL HERE

Institution Institution No.

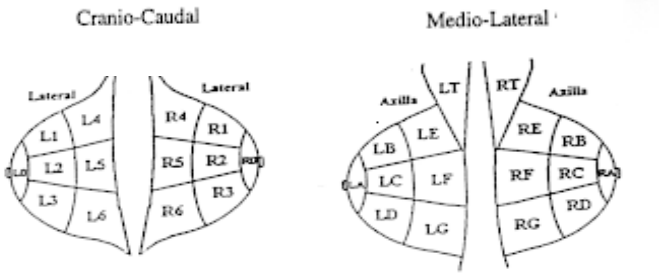
Participant's Initials Participant's I.D. No.

OPTIONAL MRI INTER-REGIMEN TREATMENT

Section B: Regional Enhancements

All regional enhancements documented on the T1 Form must be reported in this section. If new regional enhancements are now present, report on the supplemental TS Form.

2. Is the lesion identified as Regional Enhancement #2 on the T1 Form still visible? [371]
- o No (skip 2a-2i)
- o Yes (complete 2a-2i)
- o Not Appliable



2a. Location:

Cranio-Caudal *(select all that apply)*

☐ L0	[180]	☐ R0	[187]
☐ L1	[181]	☐ R1	[188]
☐ L2	[182]	☐ R2	[189]
☐ L3	[183]	☐ R3	[190]
☐ L4	[184]	☐ R4	[191]
☐ L5	[185]	☐ R5	[192]
☐ L6	[186]	☐ R6	[193]

Medio-Lateral *(select all that apply)*

☐ LT	[194]	☐ RT	[202]
☐ LA	[195]	☐ RA	[203]
☐ LB	[196]	☐ RB	[204]
☐ LC	[197]	☐ RC	[205]
☐ LD	[198]	☐ RD	[206]
☐ LE	[199]	☐ RE	[207]
☐ LF	[200]	☐ RF	[208]
☐ LG	[201]	☐ RG	[209]

2b. Largest Dimension

|___|___|___| **mm** [210]

2c. Distribution Subtype *(select one)* [211]
- o Diffuse non-specific
- o Linear non-specific
- o Linear ductal: Smooth
- o Linear ductal: Irregular
- o Linear ductal: Clumped
- o Segmental
- o Regional
- o Diffuse patchy

2d. Internal Enhancement *(select one)* [212]
- o Homogeneous confluent
- o Heterogeneous non-specific
- o Heterogeneous stippled, punctate
- o Heterogeneous clumped
- o Septal, dendritic
- o Asymmetric
- o Symmetric
- o Not applicable

2e. T2 Appearance *(select one)* [213]
- o Hyperintense to surrounding breast tissue
- o Hypointense to surrounding breast tissue
- o Isointense to surrounding breast tissue
- o Unable to evaluate

2f. Degree of Enhancement

(characterize by strongest degree seen) [214]
- o Minimal
- o Moderate
- o Marked

2g. Enhancement Pattern

(characterize by strongest pattern seen) [215]
- o Gradual
- o Sustained
- o Washout

2h. Series and Image Number of Representative Slices *(list up to 3)*

Series |___|___| : [372] **Image #** |___|___|___| [373]

Series |___|___| : [374] **Image #** |___|___|___| [375]

Series |___|___| : [376] **Image #** |___|___|___| [377]

2i. Corresponds to Index Lesion [216]
- o No
- o Yes

COMMENTS: _____

_____

_____

_____ [378]

T3 If this is a revised or corrected form, please √box. ☐

ACRIN Study 6657 Case #

PLACE LABEL HERE

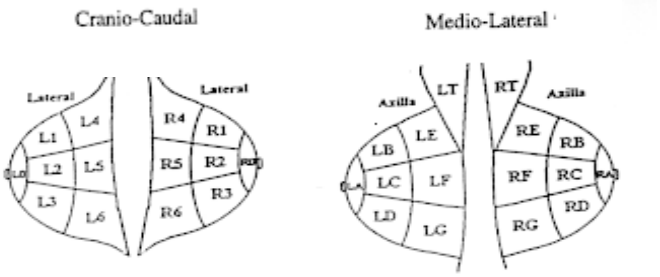
Institution Institution No.

Participant's Initials Participant's I.D. No.

Section B: Regional Enhancements

All regional enhancements documented on the T1 Form must be reported in this section. If new regional enhancements are now present, report on the supplemental TS Form.

3. Is the lesion identified as Regional Enhancement #3 on the T1 Form still visible? [379]
- o No (skip 3a-3i)
- o Yes (complete 3a-3i)
- o Not Applicable



3a. Location:

Cranio-Caudal *(select all that apply)*

☐ L0	[219]	☐ R0	[226]
☐ L1	[220]	☐ R1	[227]
☐ L2	[221]	☐ R2	[228]
☐ L3	[222]	☐ R3	[229]
☐ L4	[223]	☐ R4	[230]
☐ L5	[224]	☐ R5	[231]
☐ L6	[225]	☐ R6	[232]

Medio-Lateral *(select all that apply)*

☐ LT	[233]	☐ RT	[241]
☐ LA	[234]	☐ RA	[242]
☐ LB	[235]	☐ RB	[243]
☐ LC	[236]	☐ RC	[244]
☐ LD	[237]	☐ RD	[245]
☐ LE	[238]	☐ RE	[246]
☐ LF	[239]	☐ RF	[247]
☐ LG	[240]	☐ RG	[248]

3b. Largest Dimension

|___|___|___| **mm** [249]

3c. Distribution Subtype *(select one)* [250]
- o Diffuse non-specific
- o Linear non-specific
- o Linear ductal: Smooth
- o Linear ductal: Irregular
- o Linear ductal: Clumped
- o Segmental
- o Regional
- o Diffuse patchy

OPTIONAL MRI INTER-REGIMEN TREATMENT

3d. Internal Enhancement *(select one)* [251]
- o Homogeneous confluent
- o Heterogeneous non-specific
- o Heterogeneous stippled, punctate
- o Heterogeneous clumped
- o Septal, dendritic
- o Asymmetric
- o Symmetric
- o Not applicable

3e. T2 Appearance *(select one)* [252]
- o Hyperintense to surrounding breast tissue
- o Hypointense to surrounding breast tissue
- o Isointense to surrounding breast tissue
- o Unable to evaluate

3f. Degree of Enhancement
(characterize by strongest degree seen) [253]
- o Minimal
- o Moderate
- o Marked

3g. Enhancement Pattern
(characterize by strongest pattern seen) [254]
- o Gradual
- o Sustained
- o Washout

3h. Series and Image Number of Representative Slices *(list up to 3)*

Series |___|___| : [380] **Image #** |___|___|___| [381]

Series |___|___| : [382] **Image #** |___|___|___| [383]

Series |___|___| : [384] **Image #** |___|___|___| [385]

3i. Corresponds to Index Lesion [255]
- o No
- o Yes

COMMENTS: _____

_____

_____

_____ [386]

ACRIN Study 6657 Case #

PLACE LABEL HERE

Institution Institution No.

Participant's Initials Participant's I.D. No.

OPTIONAL MRI INTER-REGIMEN TREATMENT

14. Other Multi-focality *(select all that apply)*

- ☐ Other masses [257]
- ☐ Other regional enhancements [258]
- ☐ Diffuse enhancement(s) [259]
- ☐ Scattered, stippled enhancement(s) [260]
- ☐ Not applicable/None [261]

15. Other Findings [262]

- o No *(proceed to question 16)*
- o Yes *(continue, characterize other findings)*

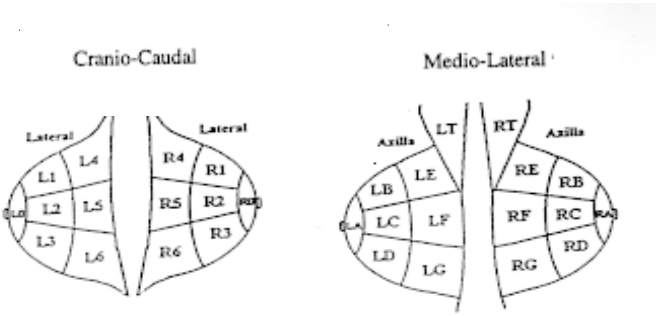
Characterization of Other Findings

(select all that apply)

- ☐ Nipple retraction [263]
- ☐ Nipple invasion [264]
- ☐ Pectoralis muscle invasion [265]
- ☐ Pre-contrast high duct signal [266]
- ☐ Skin thickening (focal) [267]
- ☐ Skin thickening (diffuse) [268]
- ☐ Skin invasion [269]
- ☐ Edema [270]
- ☐ Lymph Adenopathy [271]
- ☐ Hematoma/blood [272]
- ☐ Abnormal signal void [273]
- ☐ Cyst(s) [274]
- ☐ Other [388] _____ [389]

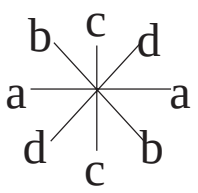
16. Full Extent of Disease

If any new lesions were identified, report description data on the TS form but include these when determining the full extent of disease below.



Direction for Longest Diameter Measurement
(indicate which diagram above was used to determine measurement direction) [275]

- o cranial - caudal
- o medio-lateral



Orientation of Longest Diameter Measurement
(indicate the orientation used to determine measurement direction) [276]

- o a
- o b
- o c
- o d

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** [277]

T3 If this is a revised or corrected form, please √box. ☐

ACRIN Study 6657 Case #

PLACE LABEL HERE

Institution Institution No.

Participant's Initials Participant's I.D. No.

17. TFQ Staging Classification

***T** (select one – size of dominant lesion only)* [278]

- O T0 No primary
- O Tis In Situ
- O T1a <5 mm
- O T1b 5-9 mm
- O T1c 10-20 mm
- O T2 21-50 mm
- O T3 >50 mm
- O T4a chest wall
- O T4b skin
- O T4c chest wall and skin
- O T4d inflammatory

F *(select one – size of full extent of disease)* [279]

- O F0 no other area of suspicious enhancement
- O F1 ≤10mm
- O F2 11-20 mm
- O F3 21-30 mm
- O F4 31-40 mm
- O F5 41-50 mm
- O F6 51-60 mm
- O F7 61-70 mm
- O F8 71-80 mm
- O F9 81-90 mm
- O F10 91-100 mm
- O FX >100 mm, please record

size ___ mm. [280]

Q *(select one - number of quadrants involved)* [281]

- O Q0 no quadrant of suspicious enhancement
- O Q1 one quadrant of suspicious enhancement
- O Q2 two quadrants of suspicious enhancement
- O Q3 three quadrants of suspicious enhancement
- O Q4 four quadrants of suspicious enhancement

OPTIONAL MRI INTER-REGIMEN TREATMENT

18. Total number of masses seen on this exam ___ [405]

19. Total number of regional enhancements seen on this exam ___ [406]

COMMENTS: _____

_____ **[282]**

_____

Radiologist Signature
(radiologist must sign either the completed paper form or the completed/printed web form)

_____ **[283]**
Signature of person responsible for data

_____ **[285]**
Signature of person entering data onto web

_____ - _____ - **20**_____ **[284]**
Date form completed (mm-dd-yyyy)

*** Please remember to complete page 8**

T3 MRI Inter-Regimen Treatment Form - Completion Instructions

MRI-3, Inter-Regimen Treatment MRI, must be performed 12 weeks after completing treatment. This form is to be completed by the study radiologist and used for treatment MR Imaging only. Report only clinically relevant findings (up to 3 masses and/or 3 regional enhancements) for the study breast only. Report index lesion if visualized. When reporting index lesion, the index lesion corresponds to the tumor used to define participant eligibility. To enable lesion tracking from T1, use the T3 to report on all lesions documented on the T1 form; use the same lesion category and number assignment. Date must be in the mm/dd/yyyy format. Submit this form within 2 weeks of the MRI via the ACRIN website. Submit paper form only for revisions or corrections. Please remember to complete page 8.

MRI TIME-POINT INFORMATION

1. Protocol imaging time point:

Record the appropriate response. The response to this question is mandatory and the default is set according to MRI 3 – Optional MRI Inter-regimen Treatment.

1a. Was MRS performed?

Mandatory. If the response is "Yes", skip Q1b and complete remaining questions. If the response is "No", specify reason in Q1b. Sign and date form on page 2.

2. Date of MRI:

Mandatory. Record the date that the MRI was performed (date must not be in the future).

3. Date of Interpretation:

Mandatory. Record the date the MRI was interpreted by the radiologist. Date must not be prior to the Date of MRI or a future date.

5. Reader ID:

This 7 alphanumeric character user specific Id is required.

8. Were Clinically Relevant Enhancing Lesion(s) Identified?

Response to this question is mandatory. If clinically relevant enhancing lesion(s) were identified, complete question 9 through the remainder of the form. If clinically relevant enhancing lesion(s) were not identified, sign and date form.

11a. Were Clinically Relevant Mass(es) Identified on Baseline (T1)?

Response to this question is mandatory. If clinically relevant mass(es) were identified, complete Section A. Indicate total number of clinically relevant masses (1-10); the total number of masses must equal the response to question 12 on the T1 form. Provide descriptive data for up to three of the most prominent masses. If clinically relevant mass(es) were not identified, skip to Section B.

11b. Are new masses now seen that were not seen on Baseline?

Response to this question is mandatory. If the response is "Yes," a TS form will be generated to the calendar. Information regarding new mass(es) must be reported on the TS.

12a. Were Clinically Relevant Regional Enhancements Identified on Baseline (T1)?

Response to this question is mandatory. If clinically relevant regional enhancement(s) were identified, complete Section B. Indicate total number of clinically relevant regional enhancements (1-10); the total number of Clinically Relevant Regional Enhancements must equal the response in Section B, question 1, of the T1 form. Provide descriptive data for up to three of the most prominent masses. If clinically relevant regional enhancement(s) were not identified, skip to Section C.

12b. Are new regional enhancements now seen that were not seen on Baseline?

Response to this question is mandatory. If the response is "Yes," a TS form will be generated to the calendar. Information regarding the new regional enhancement(s) must be reported on the TS.

Section A: Masses

Report index lesion if visualized. Complete this section if there are clinically relevant masses to report. All masses documented on the T1 Form must be reported in this section. If new masses are now present, report on the supplemental TS Form.

Is the lesion identified as Mass #__ on the T1 Form still visible?

If the response is "No" for mass #1, skip to "Comments". If the response is "No" for mass #2, skip to mass #3. If the response is "Yes" for this or any additional mass being reported in section A, complete the remainder of the section. The response of "Not Applicable" may not be selected.

a. Mass Location: For each reported mass, at least one choice must be selected in the Cranio-Caudal or Medio-Lateral view.

b. Size of Mass: At least one of x, y, or z must be greater than 0.

h. Series and Image Number of Representative Slices: If unknown, enter 99 for series and 999 for Image #.

i. Corresponds to Index lesion: A "Yes" response is allowed only if the response to Q13 "Index Lesion Identified on this MRI Exam" equals "Yes".

Section B: Regional Enhancements

Report index lesion if visualized. Complete this section if there are regional enhancements masses to report. All regional enhancements documented on the T1 Form must be reported in this section. If new regional enhancements are now present, report on the supplemental TS Form.

Is the lesion identified as Regional Enhancements #__ on the T1 Form still visible?

If the response is "No" for regional enhancement #1, skip to "Comments". If the response is "No" for regional enhancement #2, skip to regional enhancement #3. If the response is "Yes" for this or any additional regional enhancement being reported in section A, complete the remainder of the section. The response of "Not Applicable" may not be selected.

a. Regional Enhancement Location: For each reported regional enhancement, at least one choice must be selected in the Cranio-Caudal or Medio-Lateral view.

h. Series and Image Number of Representative Slices: If unknown, enter 99 for series and 999 for Image #.

i. Mass Corresponds to Index lesion: A "Yes" response is allowed only if the response to Q13 "Index Lesion Identified on this MRI Exam" equals "Yes".

Section C: Other Findings

14. Other Multi-focality: Record the appropriate response(s). Select all that apply.

15. Other Findings: If the response is "No", skip to Question 16. If the response is "Yes", provide a **"Characterization of Other Findings"** by checking each of the characteristics that apply.

16. Full Extent of Disease (spanning all disease present)**:**

If any new lesions were identified, report description data on the TS form but include these when determining the full extent of disease below.

Direction for Longest Diameter Measurement: Either the Cranio-Caudal or the Medio-Lateral Oblique diagram must be selected. Indicate which diagram was used to determine measurement direction for the MRI. The direction used on the T1 **must** be used for subsequent MRIs.

Orientation of Longest Diameter Measurement: Indicate the direction (a, b, c, or d) of orientation. The direction used on the T1 **must** be used for subsequent MRIs.

18. Total number of masses seen on this exam: Indicate the total number of masses, both old and new, that were seen on this exam.

19. Total number of regional enhancements seen on this exam: Indicate the total number of regional enhancements, both old and new, that were seen on this exam.

Radiologist Signature: Legible signature of the Radiologist. If completing a web CRF only, without completing a paper CRF, the electronic summary must be printed and signed by the Radiologist. The Radiologist's signature must be on the original document (whether paper or web).

Signature of person responsible for data: Legible signature/name of the staff member responsible for Collating/reviewing the data and ensuring completion of the CRF (paper or web). If completing a web CRF only, without completing a paper CRF, the electronic summary must be printed and signed by the staff member responsible for the data. The RA's signature must be on the original document (whether paper or web).

Date form completed: Record the date the original CRF, whether paper or web, was completed. Date must not be prior to "Date of MRI." If completing a Paper CRF this refers to the date the data was originally recorded on the paper CRF; the date/time of web entry is automatically recorded by the database. If completing the web CRF only, without completing a paper CRF, this refers to the date the data was originally recorded in the web module.

Signature of person entering data onto web: Record the signature/name of the staff member submitting the Data on-line. If completing a web CRF only, without completing a paper CRF, the electronic summary must be printed and signed by the staff member entering the data onto the web.

V3

ACRIN 6657 Extension

MRS Form: MRS Inter-regimen
MRS - 3

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

ACRIN Study **6657**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

MRS INTER-REGIMEN

INSTRUCTIONS: This is to be filled out during or very near to the actual acquisition of the data. Pretreatment baseline films (hard copy or online) with voxel positioning are required at time of study. Same magnet field strength and coil should be used at every imaging visit.

1. Timepoint [1]
- O MRS 3 MRS Inter-regimen Treatment

3. Was MRS performed? [4]
- O 1 No (if no, complete Q3a, sign and date form)
- O 2 Yes (If yes, continue with form)

3a. If no, specify reason: [5]
- O 1 No time
- O 2 Technical Problem
- O 88 Other, specify _____ [6]

4. Were baseline studies with voxel positioning used to determine MRS asquisition? [7]
- O 1 No (Complete Q4a)
- O 2 Yes (If yes, complete Q4b)

4a. If no, specify reason:

Specify, _____ [8]

4b. Which previous images were used for voxel placement?

MRI -1: ☐ hardcopy [9] ☐ online [10]

MRI - 1.1: ☐ hardcopy [11] ☐ online [12]

MRI -2: ☐ hardcopy [13] ☐ online [14]

General

5. Date of MRI ☐☐-☐☐-☐☐☐☐ *(mm-dd-yyyy)* [17]

6. Magnet field strength [18]
- O 1 1.5
- O 2 3
- O 88 Other, specify _____ [19]

7. Person responsible for voxel placement: [20]
(select one)
- O 1 MR Technologist
- O 2 Research Associate
- O 3 Nurse
- O 4 PI Radiologist
- O 5 Physician
- O 88 Other personnel (specify):

_____ [21]

Phantom QC Measurement

8. Phantom scan performed within past 7 days? [22]
- O 1 No (If no, complete Q8a)
- O 2 Yes

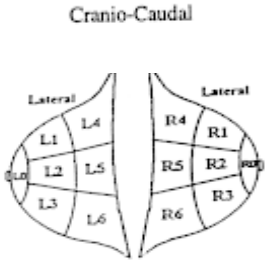
8a. If no, specify reason:

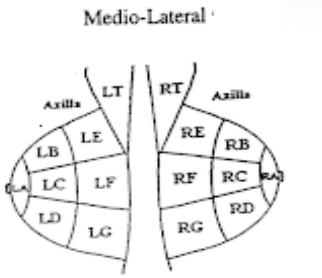
Specify, _____ [23]

8b. Date of last phantom scan

☐☐-☐☐-☐☐☐☐ [24]
(mm-dd-yyyy)

9. MRS Acquisition





Cranio-Caudal
(select all that apply)

- ☐ L0 [25]
- ☐ L1 [26]
- ☐ L2 [27]
- ☐ L3 [28]
- ☐ L4 [29]
- ☐ L5 [30]
- ☐ L6 [31]
- ☐ R0 [32]
- ☐ R1 [33]
- ☐ R2 [34]
- ☐ R3 [35]
- ☐ R4 [36]
- ☐ R5 [37]
- ☐ R6 [38]

Medio-Lateral
(select all that apply)

- ☐ LT [39]
- ☐ LA [40]
- ☐ LB [41]
- ☐ LC [42]
- ☐ LD [43]
- ☐ LE [44]
- ☐ LF [45]
- ☐ LG [46]
- ☐ RT [47]
- ☐ RA [48]
- ☐ RB [49]
- ☐ RC [50]
- ☐ RD [51]
- ☐ RE [52]
- ☐ RF [53]
- ☐ RG [54]

V3

ACRIN 6657 Extension

MRS Form: MRS Inter-regimen
MRS - 3

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

ACRIN Study **6657**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

MRS INTER-REGIMEN

10. Pre-scan calibration

Shimming: [55] O manual O automatic

Water Suppression: [56] O manual O automatic

11. Confidence in accurate reproduction of voxel placement *(check one):* [57]

Very Confident----------O **1** O **2** O **3** O **4** O **5**----------Not Confident

11a. Reasons for reduced confidence:
(select all that apply)

- ☐ Target lesion not clearly visualized [58]
- ☐ Lesion has changed in size and/or shape [59]
- ☐ Subject position is different [60]
- ☐ Clip artifact present [61]
- ☐ Other [62] _____

_____

_____

_____ [63]

12. Is the scanner and breast coil the same as was used for the baseline MRS exam? [67]

O No (Complete Q12a)
O Yes

12a. If no, specify system used

Specify, _____ [68]

COMMENTS: _____

_____

_____ [64]

_____ [65]
Signature of person responsible for the data

Date form completed ☐☐ - ☐☐ - ☐☐☐☐ (mm-dd-yyyy) [66]

V3 MRS Form - Completion Instructions

In accordance with protocol, four to five spectroscopy exams may be reported. Visit #3 (Inter-regimen Treatment visit), reported on the V3 form, must be performed within 12 weeks after completing treatment. This form is to be completed by the study radiologist during or very near to the actual acquisition of the data. Pretreatment baseline films (hard copy or online) with voxel positioning are required at time of study. The same magnet field strength and coil should be used at every imaging visit. Submit this form within two weeks of the MRS via the ACRIN website. Date must be in the mm/dd/yyyy format. Submit paper form only for revisions or corrections. **The V3 form must be submitted via the ACRIN website regardless of whether an MRS was performed.**

MRS TIME-POINT INFORMATION

1. Timepoint:

Mandatory. Record the appropriate response. The response to this question is mandatory and the default is set according to the form being completed; V3 = MRS 3 Inter-regimen Treatment.

QUESTION 2 DELETED FROM FORM.

3. Was MRS performed?

Mandatory. If the response is "Yes", skip Q3a and complete remaining questions. If the response is "No", **specify reason** in Q3a. Sign and date form on page 2.

4. Were baseline studies with voxel positioning used to determine MRS acquisition?

Mandatory. If the response is "No", specify reason in Q4a; skip Q4b. If the response is "Yes", indicate **"Which previous images were used for voxel placement"** in Q4b.

General

5. Date of MRS:

Mandatory. Record the date that the MRS was performed (date must not be in the future).

Phantom QC Measurement

8. Phantom scan performed within past 7 days?:

Mandatory. If the response is "Yes", skip Q8a and complete remaining questions. If the response is "No", specify reason in Q8a.

8b. Date of last phantom scan.

Mandatory. Record the date that the last phantom scan performed (date must not be in the future).

9. MRS Acquisition:

Mass Location: At least one choice must be selected in the Cranio-Caudal or Medio-Lateral view.

11. Confidence in accurate voxel placement: Provide confidence level.

11a. Reasons for reduced confidence:

Record the appropriate response(s). Select all that apply.

12. Is the scanner and breast coil the same as was used for the baseline MRS exam?

Mandatory. If the response is "No", specify system used in Q12a. *Please be persistent in using the same scanner and breast coil used in the baseline MRS exam.*

Signature of person responsible for data: Legible signature/name of the staff member responsible for Collating/reviewing the data and ensuring completion of the CRF (paper or web). If completing a web CRF only, without completing a paper CRF, the electronic summary must be printed and signed by the staff member responsible for the data. The RA's signature must be on the original document (whether paper or web).

Date form completed: Record the date the original CRF, whether paper or web, was completed. If completing a Paper CRF this refers to the date the data was originally recorded on the paper CRF; the date/time of web entry is automatically recorded by the database. If completing the web CRF only, without completing a paper CRF, this refers to the date the data was originally recorded in the web module.

Visit 4
MRI/MRS within 3-4 weeks after chemo and prior to Surgery

N4 ACRIN 6657 Extension Mammography Interpretation Form

ACRIN Study 6657

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

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

PRE-SURGERY

Instructions: In accordance with the protocol, two mammograms will be performed. The first mammogram, within 3 months prior to or 2 weeks after MRI-1 but before start of treatment. The second mammogram, after the final chemotherapy treatment and before surgery. This form is to be completed for each mammogram by the study radiologist. Report only clinically relevant findings. Report index lesion if visualized. When reporting index lesion, the index lesion corresponds to the tumor used to define participant eligibility. Submit this form within 2 weeks of each study mammogram via the ACRIN website. Submit paper form only for revisions or corrections.

1. Protocol Time Point [1]
- o Pre-surgery
  Anticipated surgery date

  _____-_____-_____ *(mm-dd-yyyy)* [2]

2. Date of Mammogram: _____-_____-_____ [4]
(mm-dd-yyyy)

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

4. Reader Name: _____ [6]

5. Reader ID: ☐☐☐☐☐☐☐ [7]

6. Clinically Relevant Lesion(s) Identified [8]
- o No *(proceed to question 15)*
- o Yes

7. Study Breast [9]
- o Right
- o Left
- o Bilateral

8. Density of Breast Parenchyma [10]
- o Mostly fat
- o Scattered fibroglandular densities
- o Heterogeneously dense
- o Extremely dense

12. Index Lesion Identified on Mammogram [17]
- o No
- o Yes

9. Clinically Relevant Mass(es) Identified [11]
- o No
- o Yes *(report in section A)*

Total Number ☐ [12]

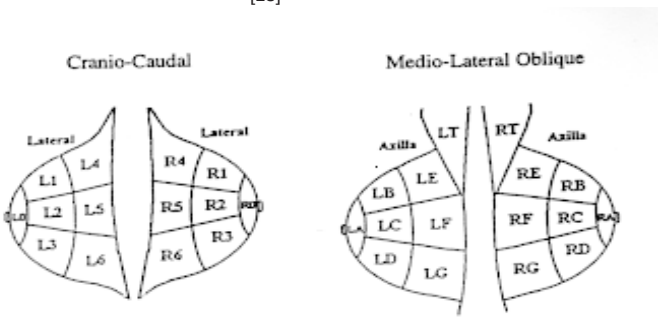
10. Remember to complete Clinically Relevant Calcification Cluster on page 3 - Section B

11. Remember to complete Clinically Relevant Architectural Distortions on page 5 - Section C

SECTION A: CLINICALLY RELEVANT MASSES

(Report index lesion if visualized. Report descriptive data for the three most prominent masses.)

Reporting Mass # ☐ [18]



Mass Location:

Cranio-Caudal *(select all that apply)*

☐	L0 [19]	☐	R0 [26]
☐	L1 [20]	☐	R1 [27]
☐	L2 [21]	☐	R2 [28]
☐	L3 [22]	☐	R3 [29]
☐	L4 [23]	☐	R4 [30]
☐	L5 [24]	☐	R5 [31]
☐	L6 [25]	☐	R6 [32]

Medio-Lateral *(select all that apply)*

☐	LT [33]	☐	RT [41]
☐	LA [34]	☐	RA [42]
☐	LB [35]	☐	RB [43]
☐	LC [36]	☐	RC [44]
☐	LD [37]	☐	RD [45]
☐	LE [38]	☐	RE [46]
☐	LF [39]	☐	RF [47]
☐	LG [40]	☐	RG [48]

Size of Mass *(record all three measurements)*

x = ☐☐☐ **mm** (medial-lateral) [49]

y = ☐☐☐ **mm** (superior-inferior) [50]

z = ☐☐☐ **mm** (anterior-posterior) [51]

Largest Dimension of Mass ☐☐☐ **mm** [52]

N4

ACRIN 6657 Extension
Mammography Interpretation Form

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

ACRIN Study **6657**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Mass Shape *(select one)* [53]
- o Round
- o Oval
- o Lobulated
- o Irregular

Mass Margins *(select one)* [54]
- o Circumscribed
- o Microlobulated
- o Obscured
- o Indistinct
- o Spiculated

Distance Between Ends of Spiculation
(answer if margin is spiculated)
└┴┴┘ **mm** [55]

Mass Density *(select one)* [56]
- o High
- o Equal
- o Low
- o Fat containing

Associated Features *(select all that apply)*
- ☐ Calcifications [57]
- ☐ Architectural distortions [58]
- ☐ Skin thickening [59]
- ☐ Solitary dilated duct [60]
- ☐ Multiple dilated ducts [61]
- ☐ None [62]

Mass Corresponds to Index Lesion [63]
- o No
- o Yes

Additional Masses [64]
- o No *(proceed to section B)*
- o Yes *(continue)*

Reporting Mass # └┴┘ [65]

Mass Location:
Cranio-Caudal *(select all that apply)*

☐	L0 [66]	☐	R0 [73]
☐	L1 [67]	☐	R1 [74]
☐	L2 [68]	☐	R2 [75]
☐	L3 [69]	☐	R3 [76]
☐	L4 [70]	☐	R4 [77]
☐	L5 [71]	☐	R5 [78]
☐	L6 [72]	☐	R6 [79]

PRE-SURGERY

Medio-Lateral *(select all that apply)*

☐	LT [80]	☐	RT [88]
☐	LA [81]	☐	RA [89]
☐	LB [82]	☐	RB [90]
☐	LC [83]	☐	RC [91]
☐	LD [84]	☐	RD [92]
☐	LE [85]	☐	RE [93]
☐	LF [86]	☐	RF [94]
☐	LG [87]	☐	RG [95]

Size of Mass *(record all three measurements)*
x = └┴┴┘**mm** (medial-lateral) [96]
y = └┴┴┘**mm** (superior-inferior) [97]
z = └┴┴┘**mm** (anterior-posterior) [98]

Largest Dimension of Mass └┴┴┘ **mm** [99]

Mass Shape *(select one)* [100]
- o Round
- o Oval
- o Lobulated
- o Irregular

Mass Margins *(select one)* [101]
- o Circumscribed
- o Microlobulated
- o Obscured
- o Indistinct
- o Spiculated

Distance Between Ends of Spiculation
(answer if margin is spiculated)
└┴┴┘ **mm** [102]

Mass Density *(select one)* [103]
- o High
- o Equal
- o Low
- o Fat containing

Associated Features *(select all that apply)*
- ☐ Calcifications [104]
- ☐ Architectural distortions [105]
- ☐ Skin thickening [106]
- ☐ Solitary dilated duct [107]
- ☐ Multiple dilated ducts [108]
- ☐ None [109]

Mass Corresponds to Index Lesion [110]
- o No
- o Yes

N4 **ACRIN 6657 Extension Mammography Interpretation Form**

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

ACRIN Study 6657

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Additional Masses [111]
- o No *(proceed to section B)*
- o Yes *(continue)*

Reporting Mass # ☐☐ [112]

Mass Location:

Cranio-Caudal *(select all that apply)*

☐	L0 [113]	☐	R0 [120]
☐	L1 [114]	☐	R1 [121]
☐	L2 [115]	☐	R2 [122]
☐	L3 [116]	☐	R3 [123]
☐	L4 [117]	☐	R4 [124]
☐	L5 [118]	☐	R5 [125]
☐	L6 [119]	☐	R6 [126]

Medio-Lateral *(select all that apply)*

☐	LT [127]	☐	RT [135]
☐	LA [128]	☐	RA [136]
☐	LB [129]	☐	RB [137]
☐	LC [130]	☐	RC [138]
☐	LD [131]	☐	RD [139]
☐	LE [132]	☐	RE [140]
☐	LF [133]	☐	RF [141]
☐	LG [134]	☐	RG [142]

Size of Mass *(record all three measurements)*

x = ☐☐☐**mm** (medial-lateral) [143]

y = ☐☐☐**mm** (superior-inferior) [144]

z = ☐☐☐**mm** (anterior-posterior) [145]

Largest Dimension of Mass ☐☐☐ **mm** [146]

Mass Shape *(select one)* [147]
- o Round
- o Oval
- o Lobulated
- o Irregular

Mass Margins *(select one)* [148]
- o Circumscribed
- o Microlobulated
- o Obscured
- o Indistinct
- o Spiculated

Distance Between Ends of Spiculation
(answer if margin is spiculated)

☐☐☐ **mm** [149]

Mass Density *(select one)* [150]
- o High
- o Equal
- o Low
- o Fat containing

PRE-SURGERY

Associated Features *(select all that apply)*
- ☐ Calcifications [151]
- ☐ Architectural distortions [152]
- ☐ Skin thickening [153]
- ☐ Solitary dilated duct [154]
- ☐ Multiple dilated ducts [155]
- ☐ None [156]

Mass Corresponds to Index Lesion [157]
- o No
- o Yes

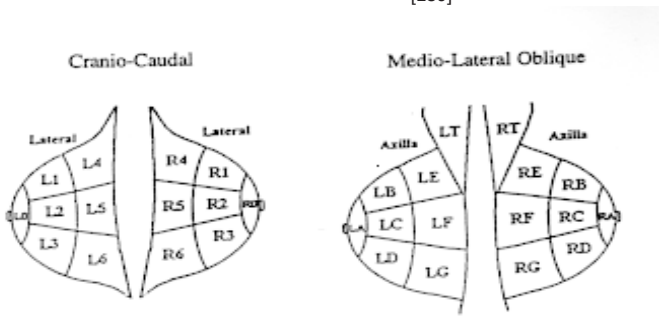
Additional Masses [158]
- o No
- o Yes

SECTION B: CLINICALLY RELEVANT CALCIFICATION CLUSTERS *(Report index lesion if visualized. Report descriptive data for the three most prominent calcification clusters.)*

Calcification Cluster(s) Identified [13]
- o No
- o Yes *(report in section B)*

Total Number ☐ [14]

Reporting Calcification Cluster# ☐ [159]



Calcification Location:

Cranio-Caudal *(select all that apply)*

☐	L0 [160]	☐	R0 [167]
☐	L1 [161]	☐	R1 [168]
☐	L2 [162]	☐	R2 [169]
☐	L3 [163]	☐	R3 [170]
☐	L4 [164]	☐	R4 [171]
☐	L5 [165]	☐	R5 [172]
☐	L6 [166]	☐	R6 [173]

N4 **ACRIN 6657 Extension Mammography Interpretation Form**

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

ACRIN Study 6657

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Medio-Lateral *(select all that apply)*

☐	LT [174]	☐	RT [182]
☐	LA [175]	☐	RA [183]
☐	LB [176]	☐	RB [184]
☐	LC [177]	☐	RC [185]
☐	LD [178]	☐	RD [186]
☐	LE [179]	☐	RE [187]
☐	LF [180]	☐	RF [188]
☐	LG [181]	☐	RG [189]

Largest Dimension of Calcification Cluster

⌊_⌊_⌊_ **mm** [190]

Morphology of Calcification: *(select one)*

Benign Appearing [191]

- o Skin Calcifications
- o Vascular Calcifications
- o Coarse ("Pop-corn-like")
- o Large Rod-like
- o Round
- o Lucent centered
- o Eggshell or Rim
- o Milk of Calcium
- o Suture
- o Dystrophic
- o Punctate

Intermediate Concern

- o Amorphous or Indistinct

Higher Probability

- o Pleomorphic or Heterogenous (Granular)
- o Fine, Linear, Branching (Casting)

Calcification Distribution *(select one)* [192]

- o Grouped/Clustered
- o Linear
- o Segmental
- o Regional
- o Diffuse/Scattered

Calcification Cluster Associated with Mass Reported on This Form [193]

- o No
- o Yes, associated with previously identified mass # ⌊_⌋ (#1-3) [194]

Calcification Cluster Corresponds to Index Lesion [195]

- o No
- o Yes

Additional Calcification Clusters [196]

- o No *(proceed to section C)*
- o Yes *(continue)*

PRE-SURGERY

Reporting Calcification Cluster# ⌊_⌋ [197]

Calcification Location:

Cranio-Caudal *(select all that apply)*

☐	L0 [198]	☐	R0 [205]
☐	L1 [199]	☐	R1 [206]
☐	L2 [200]	☐	R2 [207]
☐	L3 [201]	☐	R3 [208]
☐	L4 [202]	☐	R4 [209]
☐	L5 [203]	☐	R5 [210]
☐	L6 [204]	☐	R6 [211]

Medio-Lateral *(select all that apply)*

☐	LT [212]	☐	RT [220]
☐	LA [213]	☐	RA [221]
☐	LB [214]	☐	RB [222]
☐	LC [215]	☐	RC [223]
☐	LD [216]	☐	RD [224]
☐	LE [217]	☐	RE [225]
☐	LF [218]	☐	RF [226]
☐	LG [219]	☐	RG [227]

Largest Dimension of Calcification Cluster

⌊_⌊_⌊_ **mm** [228]

Morphology of Calcification: *(select one)* [229]

Benign Appearing

- o Skin Calcifications
- o Vascular Calcifications
- o Coarse ("Pop-corn-like")
- o Large Rod-like
- o Round
- o Lucent centered
- o Eggshell or Rim
- o Milk of Calcium
- o Suture
- o Dystrophic
- o Punctate

Intermediate Concern

- o Amorphous or Indistinct

Higher Probability

- o Pleomorphic or Heterogenous (Granular)
- o Fine, Linear, Branching (Casting)

Calcification Distribution *(select one)* [230]

- o Grouped/Clustered
- o Linear
- o Segmental
- o Regional
- o Diffuse/Scattered

N4

ACRIN 6657 Extension
Mammography Interpretation Form

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

ACRIN Study **6657**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Calcification Cluster Associated with Mass Reported on This Form [231]
- o No
- o Yes, associated with previously identified mass # ☐ (#1-3) [232]

Calcification Cluster Corresponds to Index Lesion [233]
- o No
- o Yes

Additional Calcification Clusters [234]
- o No *(proceed to section C)*
- o Yes *(continue)*

Reporting Calcification Cluster# ☐ [235]

Calcification Location:

Cranio-Caudal *(select all that apply)*

☐	L0 [236]	☐	R0 [243]
☐	L1 [237]	☐	R1 [244]
☐	L2 [238]	☐	R2 [245]
☐	L3 [239]	☐	R3 [246]
☐	L4 [240]	☐	R4 [247]
☐	L5 [241]	☐	R5 [248]
☐	L6 [242]	☐	R6 [249]

Medio-Lateral *(select all that apply)*

☐	LT [250]	☐	RT [258]
☐	LA [251]	☐	RA [259]
☐	LB [252]	☐	RB [260]
☐	LC [253]	☐	RC [261]
☐	LD [254]	☐	RD [262]
☐	LE [255]	☐	RE [263]
☐	LF [256]	☐	RF [264]
☐	LG [257]	☐	RG [265]

Largest Dimension of Calcification Cluster

☐☐☐ **mm** [266]

Morphology of Calcification: *(select one)* [267]

Benign Appearing
- o Skin Calcifications
- o Vascular Calcifications
- o Coarse ("Pop-corn-like")
- o Large Rod-like
- o Round
- o Lucent centered
- o Eggshell or Rim
- o Milk of Calcium
- o Suture
- o Dystrophic
- o Punctate

Intermediate Concern
- o Amorphous or Indistinct

Higher Probability
- o Pleomorphic or Heterogenous (Granular)
- o Fine, Linear, Branching (Casting)

PRE-SURGERY

Calcification Distribution *(select one)* [268]
- o Grouped/Clustered
- o Linear
- o Segmental
- o Regional
- o Diffuse/Scattered

Calcification Cluster Associated with Mass Reported on This Form [269]
- o No
- o Yes, associated with previously identified mass # ☐ (#1-3) [270]

Calcification Cluster Corresponds to Index Lesion [271]
- o No
- o Yes

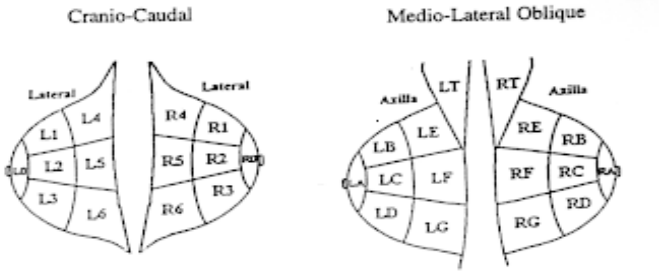
Additional Calcification Clusters [272]
- o No
- o Yes

SECTION C: CLINICALLY RELEVANT ARCHITECTURAL DISTORTIONS *(Report index lesion if visualized. Report descriptive data for the three most prominent architectural distortions.)*

Architectural Distortion(s) Identified [15]
- o No
- o Yes *(report in section C)*

Total Number ☐ [16]

Reporting Architectural Distortion # ☐ [273]



Architectural Distortion Location:

Cranio-Caudal *(select all that apply)*

☐	L0 [274]	☐	R0 [281]
☐	L1 [275]	☐	R1 [282]
☐	L2 [276]	☐	R2 [283]
☐	L3 [277]	☐	R3 [284]
☐	L4 [278]	☐	R4 [285]
☐	L5 [279]	☐	R5 [286]
☐	L6 [280]	☐	R6 [287]

N4 **ACRIN 6657 Extension Mammography Interpretation Form**

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

ACRIN Study 6657

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Medio-Lateral *(select all that apply)*

☐	LT [288]	☐	RT [296]
☐	LA [289]	☐	RA [297]
☐	LB [290]	☐	RB [298]
☐	LC [291]	☐	RC [299]
☐	LD [292]	☐	RD [300]
☐	LE [293]	☐	RE [301]
☐	LF [294]	☐	RF [302]
☐	LG [295]	☐	RG [303]

Largest Dimension of Architectural Distortion

|_|_|_| **mm** [304]

Architectural Distortion Associated with Mass Reported on This Form [305]

o No
o Yes, associated with previously identified mass # |_| (#1-3) [306]

Architectural Distortion Corresponds to Index Lesion [307]

o No
o Yes

Additional Architectural Distortions [308]

o No *(proceed to question 13)*
o Yes *(continue)*

Reporting Architectural Distortion # |_| [309]

Architectural Distortion Location: Cranio-Caudal *(select all that apply)*

☐	L0 [310]	☐	R0 [317]
☐	L1 [311]	☐	R1 [318]
☐	L2 [312]	☐	R2 [319]
☐	L3 [313]	☐	R3 [320]
☐	L4 [314]	☐	R4 [321]
☐	L5 [315]	☐	R5 [322]
☐	L6 [316]	☐	R6 [323]

Medio-Lateral *(select all that apply)*

☐	LT [324]	☐	RT [332]
☐	LA [325]	☐	RA [333]
☐	LB [326]	☐	RB [334]
☐	LC [327]	☐	RC [335]
☐	LD [328]	☐	RD [336]
☐	LE [329]	☐	RE [337]
☐	LF [330]	☐	RF [338]
☐	LG [331]	☐	RG [339]

Largest Dimension of Architectural Distortion

|_|_|_| **mm** [340]

PRE-SURGERY

Architectural Distortion Associated with Mass Reported on This Form [341]

o No
o Yes, associated with previously identified mass # |_| (#1-3) [342]

Architectural Distortion Corresponds to Index Lesion [343]

o No
o Yes

Additional Architectural Distortions [344]

o No *(proceed to question 13)*
o Yes *(continue)*

Reporting Architectural Distortion # |_| [345]

Architectural Distortion Location: Cranio-Caudal *(select all that apply)*

☐	L0 [346]	☐	R0 [353]
☐	L1 [347]	☐	R1 [354]
☐	L2 [348]	☐	R2 [355]
☐	L3 [349]	☐	R3 [356]
☐	L4 [350]	☐	R4 [357]
☐	L5 [351]	☐	R5 [358]
☐	L6 [352]	☐	R6 [359]

Medio-Lateral *(select all that apply)*

☐	LT [360]	☐	RT [368]
☐	LA [361]	☐	RA [369]
☐	LB [362]	☐	RB [370]
☐	LC [363]	☐	RC [371]
☐	LD [364]	☐	RD [372]
☐	LE [365]	☐	RE [373]
☐	LF [366]	☐	RF [374]
☐	LG [367]	☐	RG [375]

Largest Dimension of Architectural Distortion

|_|_|_| **mm** [376]

Architectural Distortion Associated with Mass Reported on This Form [377]

o No
o Yes, associated with previously identified mass # |_| (#1-3) [378]

Architectural Distortion Corresponds to Index Lesion [379]

o No
o Yes

N4 **ACRIN 6657 Extension Mammography Interpretation Form**

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

ACRIN Study **6657**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

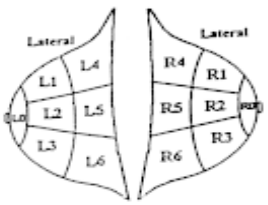
Additional Architectural Distortions [380]
- o No
- o Yes

13. Special Cases [381]
- o No *(proceed to question 14)*
- o Yes *(report special cases below)*

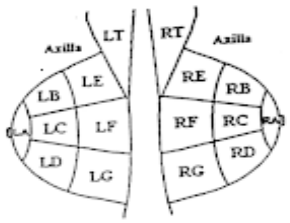
Indicate Special Cases *(select all that apply)*
- ☐ Intramammary Lymph Node [382]
- ☐ Asymmetric Breast Tissue [383]
- ☐ Focal Asymmetric Density [384]

14. Full Extent of Disease
(spanning all disease present)

Cranio-Caudal

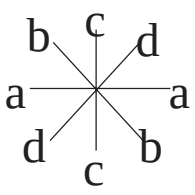


Medio-Lateral Oblique



Direction for Longest Diameter Measurement
(refer to above diagrams - use same direction for all mammograms) [385]
- o Cranio-caudal
- o Medio-lateral

PRE-SURGERY



Orientation of Longest Diameter Measurement
(refer to above diagrams - use same orientation for all mammograms) [386]
- o a
- o b
- o c
- o d

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** [387]

15. BIRADS Lexicon [388]
- o Category 1 Negative
- o Category 2 Benign Finding
- o Category 3 Probably Benign Finding – Short interval follow-up suggested
- o Category 4 Suspicious Abnormality – Biopsy should be considered
- o Category 5 Highly Suggestive of Malignancy – Appropriate action should be taken

COMMENTS: _____

_____ [389]

_____
Radiologist Signature
(radiologist must sign either the completed paper form or the completed/printed web form)

_____ [390]
Signature of person responsible for data

_____-_____-**2 0 0**___ [391]
Date form completed (mm-dd-yyyy)

_____ [392]
Signature of person entering data onto web

N4 Mammography Interpretation Form - Completion Instructions

In accordance with the protocol, two mammograms will be performed. The second mammogram, reported on the N4 form, must be performed after the final chemotherapy treatment and before surgery. This form is to be completed by the study radiologist. Report only clinically relevant findings. Report index lesion if visualized. When reporting index lesion, the index lesion corresponds to the tumor used to define participant eligibility. Date must be in the mm/dd/yyyy format. Submit this form within 2 weeks of the study mammogram via the ACRIN website. Submit paper form only for revisions or corrections.

TIME-POINT INFORMATION

1. Protocol imaging time point:

Record the appropriate response. The response to this question is mandatory and the default is set according to the form being completed; N4 – Pre-Surgery Form.

2. Date of Mammogram:

Mandatory. Record the date that the mammogram was performed (date must not be in the future).

3. Date of Interpretation:

Mandatory. Record the date that the mammogram was interpreted by the radiologist (date must not be in the future).

5. Reader ID:

This 7 alphanumeric character user specific Id is required.

6. Clinically Relevant Lesion(s) Identified?

Response to this question is mandatory. If clinically relevant lesion(s) were identified, complete question 6 through the remainder of the form. If clinically relevant lesion(s) were not identified, skip to question 15 and complete the remainder of the form.

12. Index Lesion Identified on Mammogram

Question 12 has been moved to correspond with the data entry screen. If the response is “Yes”, indicate which mass(es), calcification cluster(s), and/or architectural distortion(s) correspond to index lesion when completing remainder of the form.

9. Clinically Relevant Mass(es) Identified?

Response to this question is mandatory. If clinically relevant mass(es) were identified, complete Section A. Indicate total number of clinically relevant masses (1-10). If clinically relevant mass(es) were not identified, skip to Section B.

10. Remember to complete Clinically Relevant Calcification Cluster on page 3 - Section B.

This is an important reminder to the radiologist to complete Section B.

11. Remember to complete Clinically Relevant Architectural Distortions on page 5 - Section C.

This is an important reminder to the radiologist to complete Section C.

Section A: Clinically Relevant Masses

Report index lesion if visualized. Complete this section if there are clinically relevant masses to report. Provide descriptive data for up to three of the most prominent masses.

Mass Location: For each reported mass, at least one choice must be selected in the Cranio-Caudal or Medio-Lateral view.

Size of Mass: At least one of x, y, or z must be greater than 0.

Largest Dimension of Mass: Record the largest of "Size of Mass" (x, y, or z) therefore, the "Largest Dimension of Mass" must equal x, y, or z.

Mass Corresponds to Index lesion: A "Yes" response is allowed only if the response to Q12 "Index Lesion Identified on Mammogram" equals "Yes".

Additional Masses: If the response is "No" for this or any additional Mass being reported in this section, skip to section B on page 3. If the response is "Yes" for this or any other additional mass, complete responses are required for each relevant mass.

Section B: Clinically Relevant Calcifications Clusters

Calcification Cluster(s) Identified?

Response to this question is mandatory. If clinically relevant calcifications cluster(s) were identified, complete Section B. Indicate total number of clinically relevant calcifications clusters (1-10). If clinically relevant calcifications cluster(s) were not identified, skip to Section C.

Calcification Location: For each reported calcification cluster, at least one choice must be selected in the Cranio-Caudal or Medio-Lateral view.

Calcification Cluster Associated with Mass Reported on This Form: If "Yes", identify which mass (in Section A) calcification cluster is associated with – mass number 1, 2 or 3.

Calcification Cluster Corresponds to Index lesion: "Yes" response is allowed only if the response to Q12 "Index Lesion Identified on Mammogram" equals "Yes".

Additional Calcification Clusters: If the response is "No" for this or any additional Calcification Cluster being reported in this section, skip to section C on page 5. If the response is "Yes" for this or any other additional calcification cluster, complete responses are required for each relevant calcification cluster.

Section C: Clinically Relevant Architectural Distortions

Architectural Distortion(s) Identified?

Response to this question is mandatory. If clinically relevant architectural distortion(s) were identified, complete Section C. Indicate total number of clinically relevant architectural distortion(s) (1-10). If clinically relevant architectural distortion(s) were not identified, skip to Question 13.

Architectural Distortion Location: For each reported architectural distortion, at least one choice must be selected in the Cranio-Caudal or Medio-Lateral view.

Architectural Distortion Associated with Mass Reported on This Form: If "Yes", identify which mass (in Section A) architectural distortion is associated with – mass number 1, 2 or 3.

Architectural Distortion Corresponds to Index lesion: "Yes" response is allowed only if the response to Q12 "Index Lesion Identified on Mammogram" equals "Yes".

Additional Architectural Distortions: If the response is "No" for this or any additional architectural distortion being reported in this section, skip to question 13. If the response is "Yes" for this or any other additional architectural distortion, complete responses are required for each relevant architectural distortion.

14. Full Extent of Disease:

Direction for Longest Diameter Measurement: Either the Cranio-Caudal or the Medio-Lateral Oblique diagram must be selected. The same direction must be used for each mammogram.

Orientation of Longest Diameter Measurement: Indicate the direction (a, b, c, or d) of orientation. The same direction must be used for each mammogram.

Radiologist Signature: Legible signature of the Radiologist. If completing a web CRF only, without completing a paper CRF, the electronic summary must be printed and signed by the Radiologist. The Radiologist's signature must be on the original document (whether paper or web).

Signature of person responsible for data: Legible signature/name of the staff member responsible for Collating/reviewing the data and ensuring completion of the CRF (paper or web). If completing a web CRF only, without completing a paper CRF, the electronic summary must be printed and signed by the staff member responsible for the data. The RA's signature must be on the original document (whether paper or web).

Date form completed: Record the date the original CRF, whether paper or web, was completed. If completing a Paper CRF this refers to the date the data was originally recorded on the paper CRF; the date/time of web entry is automatically recorded by the database. If completing the web CRF only, without completing a paper CRF, this refers to the date the data was originally recorded in the web module.

Signature of person entering data onto web: Record the signature/name of the staff member submitting the Data on-line. If completing a web CRF only, without completing a paper CRF, the electronic summary must be printed and signed by the staff member entering the data onto the web.

T4

ACRIN 6657 Extension
MRI Form: Pre-Surgery MRI 4

ACRIN Study 6657 Case #

PLACE LABEL HERE

Institution Institution No.

Participant's Initials Participant's I.D. No.

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

PRE-SURGERY

Instructions: In accordance with the protocol, each participant will receive three or four MRI exams. MRI-4 must be performed 3-4 weeks after chemo and prior to surgery. This form is to be completed by the study radiologist and used for treatment reproducibility MR Imaging only. When reporting index lesion, the index lesion corresponds to the tumor used to define participant eligibility. To enable lesion tracking from T1, use the T4 to report on all lesions documented on the T1 form, use the same lesion category and number assignment. Submit this form within 2 weeks of MRI via the ACRIN website. Submit a paper form for the data corrections only.

1. Protocol Time Point [1]
- o Pre-Surgery

1a. Was MRI performed? [407]
- o No* (complete Q1b, then sign and date form)
- o Yes (proceed to Q2 and continue with form)

1b. *If No, provide reason: [408]
- o Scheduling problem
- o Equipment failure
- o Participant refusal
- o Medical reason
- o Injection site complications
- o Claustrophobia
- o Participant withdrew consent
- o Progressive disease
- o Participant death
- o Other, specify: _____ [409]
- o Unknown

2. Date of MRI ____ - ____ - **20**____ (mm-dd-yyyy) [3]

3. Date of Interpretation ____ - ____ - **20**____ [4]
(mm-dd-yyyy)

4. Reader Name: _____ [5]

5. Reader ID: ____|____|____|____|____|____|____|____ [6]

6. Patient Weight (kgs) ____|____|____ [7]

7. Total Amount of Gadolinium Injected (cc) ____|____ [8]

8. Were Clinically Relevant Enhancing Lesion(s) Identified [9]
- o No *(sign and date form)*
- o Yes

Complete For Study Breast Only

9. Study Breast [10]
- o Right
- o Left

10. Density of Breast Parenchyma
(same as identified in (T1) baseline)) [11]
- o Mostly fat
- o Scattered fibroglandular tissue
- o Heterogeneously dense
- o Extremely dense

11a. Were Clinically Relevant Mass(es) Identified on the Baseline (T1 Form) [12]
- o No
- o Yes *(report in Section A)*

Total Number ____ [13] (enter same response from T1 Q11a)

11b. Are New Masses now seen that were not seen on Baseline [362]
- o No
- o Yes *(report on supplemental TS form)*

12a. Were Clinically Relevant Regional Enhancements Identified on the baseline (T1 Form) [14]
- o No
- o Yes *(report in Section B)*

Total Number ____ [15] (enter same response from T1 Q12a)

12b. Are New Regional Enhancements now seen that were not seen on Baseline [387]
- o No
- o Yes *(report on supplemental TS form)*

13. Index Lesion Identified on this MRI Exam [16]
- o No
- o Yes

*** Please remember to complete page 8**

T4

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

ACRIN Study 6657 Case #

PLACE LABEL HERE

Institution Institution No.

Participant's Initials Participant's I.D. No.

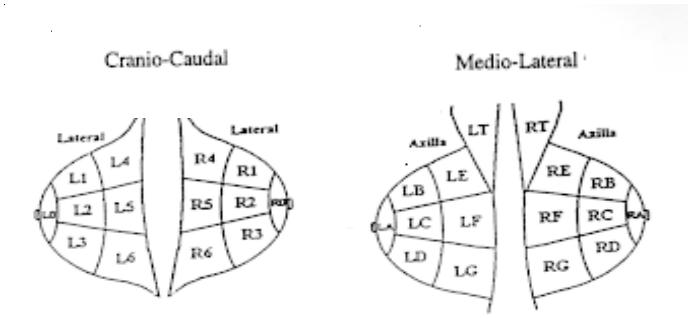
PRE-SURGERY

Section A: Masses

All masses documented on the T1 Form must be reported in this section. If new masses are now present, report on the supplemental TS Form.

1. Is the lesion identified as Mass #1 on the T1 Form still visible? [338]

- o No (skip 1a-1i)
- o Yes (complete 1a-1i)
- o Not Applicable



1a. Location:

Cranio-Caudal *(select all that apply)*

☐ L0 [18]	☐ R0 [25]
☐ L1 [19]	☐ R1 [26]
☐ L2 [20]	☐ R2 [27]
☐ L3 [21]	☐ R3 [28]
☐ L4 [22]	☐ R4 [29]
☐ L5 [23]	☐ R5 [30]
☐ L6 [24]	☐ R6 [31]

Medio-Lateral *(select all that apply)*

☐ LT [32]	☐ RT [40]
☐ LA [33]	☐ RA [41]
☐ LB [34]	☐ RB [42]
☐ LC [35]	☐ RC [43]
☐ LD [36]	☐ RD [44]
☐ LE [37]	☐ RE [45]
☐ LF [38]	☐ RF [46]
☐ LG [39]	☐ RG [47]

1b. Size *(record all three measurements [0 = not seen])*

x = ___ **mm** (medial-lateral) [48]

y = ___ **mm** (superior-inferior) [49]

z = ___ **mm** (anterior-posterior) [50]

1c. Shape/Margin *(select one)* [51]

- o Smooth round
- o Smooth oval
- o Lobulated
- o Irregular
- o Spiculated
- o No longer a mass

1d. Internal Enhancement *(select one)* [52]

- o Homogeneous confluent
- o Heterogeneous
- o Rim enhanced
- o Centrally enhanced
- o Dark septation(s)
- o Enhancing septation(s)
- o No longer a mass

1e. T2 Appearance *(select one)* [53]

- o Hyperintense to surrounding breast tissue
- o Hypointense to surrounding breast tissue
- o Isointense to surrounding breast tissue
- o Unable to evaluate

1f. Degree of Enhancement

(characterize by strongest degree seen) [54]

- o Minimal
- o Moderate
- o Marked

1g. Enhancement Pattern

(characterize by strongest pattern seen) [55]

- o Gradual
- o Sustained
- o Washout

1h. Series and Image Number of Representative Slices *(list up to 3)*

Series ___ : [339] **Image #** ___ [340]

Series ___ : [341] **Image #** ___ [342]

Series ___ : [343] **Image #** ___ [344]

1i. Corresponds to Index Lesion [56]

- o No
- o Yes

COMMENTS: _____

_____

_____

_____ [345]

T4

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

ACRIN Study 6657 Case #

PLACE LABEL HERE

Institution Institution No.

Participant's Initials Participant's I.D. No.

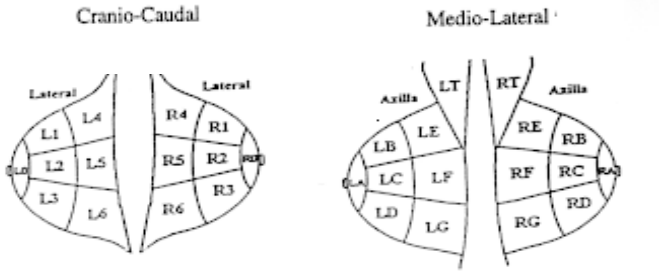
PRE-SURGERY

Section A: Masses

All masses documented on the T1 Form must be reported in this section. If new masses are now present, report on the supplemental TS Form.

2. Is the lesion identified as Mass #2 on the T1 Form still visible? [346]

- o No (skip 2a-2i)
- o Yes (complete 2a-2i)
- o Not Applicable



2a. Location:

Cranio-Caudal *(select all that apply)*

☐ L0 [59]	☐ R0 [66]
☐ L1 [60]	☐ R1 [67]
☐ L2 [61]	☐ R2 [68]
☐ L3 [62]	☐ R3 [69]
☐ L4 [63]	☐ R4 [70]
☐ L5 [64]	☐ R5 [71]
☐ L6 [65]	☐ R6 [72]

Medio-Lateral *(select all that apply)*

☐ LT [73]	☐ RT [81]
☐ LA [74]	☐ RA [82]
☐ LB [75]	☐ RB [83]
☐ LC [76]	☐ RC [84]
☐ LD [77]	☐ RD [85]
☐ LE [78]	☐ RE [86]
☐ LF [79]	☐ RF [87]
☐ LG [80]	☐ RG [88]

2b. Size *(record all three measurements [0 = not seen])*

x = ___ **mm** (medial-lateral) [89]

y = ___ **mm** (superior-inferior) [90]

z = ___ **mm** (anterior-posterior) [91]

2c. Shape/Margin *(select one)* [92]

- o Smooth round
- o Smooth oval
- o Lobulated
- o Irregular
- o Spiculated
- o No longer a mass

2d. Internal Enhancement *(select one)* [93]

- o Homogeneous confluent
- o Heterogeneous
- o Rim enhanced
- o Centrally enhanced
- o Dark septation(s)
- o Enhancing septation(s)
- o No longer a mass

2e. T2 Appearance *(select one)* [94]

- o Hyperintense to surrounding breast tissue
- o Hypointense to surrounding breast tissue
- o Isointense to surrounding breast tissue
- o Unable to evaluate

2f. Degree of Enhancement

(characterize by strongest degree seen) [95]

- o Minimal
- o Moderate
- o Marked

2g. Enhancement Pattern

(characterize by strongest pattern seen) [96]

- o Gradual
- o Sustained
- o Washout

2h. Series and Image Number of Representative Slices *(list up to 3)*

Series ___ : [347] **Image #** ___ [348]

Series ___ : [349] **Image #** ___ [350]

Series ___ : [351] **Image #** ___ [352]

2i. Corresponds to Index Lesion [97]

- o No
- o Yes

COMMENTS: _____

_____

_____

_____ [353]

T4

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

ACRIN Study 6657 Case #

PLACE LABEL HERE

Institution Institution No.

Participant's Initials Participant's I.D. No.

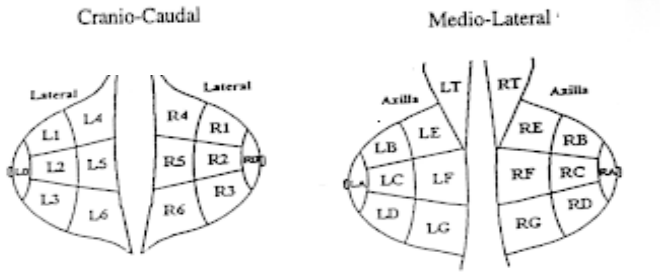
PRE-SURGERY

Section A: Masses

All masses documented on the T1 Form must be reported in this section. If new masses are now present, report on the supplemental TS Form.

3. Is the lesion identified as Mass #3 on the T1 Form still visible? [354]

- o No (skip 3a-3i)
- o Yes (complete 3a-3i)
- o Not Applicable



3a. Location:

Cranio-Caudal *(select all that apply)*

☐ L0 [100]	☐ R0 [107]
☐ L1 [101]	☐ R1 [108]
☐ L2 [102]	☐ R2 [109]
☐ L3 [103]	☐ R3 [110]
☐ L4 [104]	☐ R4 [111]
☐ L5 [105]	☐ R5 [112]
☐ L6 [106]	☐ R6 [113]

Medio-Lateral *(select all that apply)*

☐ LT [114]	☐ RT [122]
☐ LA [115]	☐ RA [123]
☐ LB [116]	☐ RB [124]
☐ LC [117]	☐ RC [125]
☐ LD [118]	☐ RD [126]
☐ LE [119]	☐ RE [127]
☐ LF [120]	☐ RF [128]
☐ LG [121]	☐ RG [129]

3b. Size *(record all three measurements [0 = not seen])*

x = ___ **mm** (medial-lateral) [130]

y = ___ **mm** (superior-inferior) [131]

z = ___ **mm** (anterior-posterior) [132]

3c. Shape/Margin *(select one)* [133]

- o Smooth round
- o Smooth oval
- o Lobulated
- o Irregular
- o Spiculated
- o No longer a mass

3d. Internal Enhancement *(select one)* [134]

- o Homogeneous confluent
- o Heterogeneous
- o Rim enhanced
- o Centrally enhanced
- o Dark septation(s)
- o Enhancing septation(s)
- o No longer a mass

3e. T2 Appearance *(select one)* [135]

- o Hyperintense to surrounding breast tissue
- o Hypointense to surrounding breast tissue
- o Isointense to surrounding breast tissue
- o Unable to evaluate

3f. Degree of Enhancement

(characterize by strongest degree seen) [136]

- o Minimal
- o Moderate
- o Marked

3g. Enhancement Pattern

(characterize by strongest pattern seen) [137]

- o Gradual
- o Sustained
- o Washout

3h. Series and Image Number of Representative Slices *(list up to 3)*

Series ___ : [355] **Image #** ___ [356]

Series ___ : [357] **Image #** ___ [358]

Series ___ : [359] **Image #** ___ [360]

3i. Corresponds to Index Lesion [138]

- o No
- o Yes

COMMENTS: _____

_____

_____

_____ [361]

T4 If this is a revised or corrected form, please √box. ☐

ACRIN Study 6657 Case #

PLACE LABEL HERE

Institution Institution No.

Participant's Initials Participant's I.D. No.

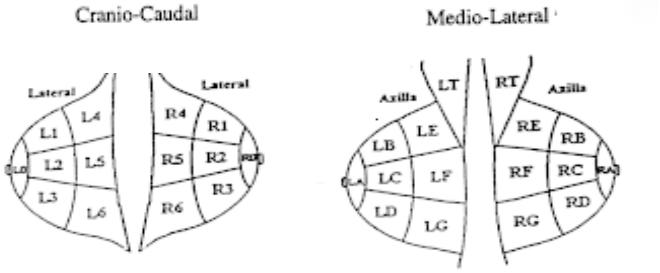
PRE-SURGERY

Section B: Regional Enhancements

All regional enhancements documented on the T1 Form must be reported in this section. If new regional enhancements are now present, report on the supplemental TS Form.

1. Is the lesion identified as Regional Enhancement #1 from the T1 Form still visible? [363]

- o No (skip 1a-1i)
- o Yes (complete 1a-1i)
- o Not Applicable



1a. Location:

Cranio-Caudal *(select all that apply)*

☐	L0 [141]	☐	R0 [148]
☐	L1 [142]	☐	R1 [149]
☐	L2 [143]	☐	R2 [150]
☐	L3 [144]	☐	R3 [151]
☐	L4 [145]	☐	R4 [152]
☐	L5 [146]	☐	R5 [153]
☐	L6 [147]	☐	R6 [154]

Medio-Lateral *(select all that apply)*

☐	LT [155]	☐	RT [163]
☐	LA [156]	☐	RA [164]
☐	LB [157]	☐	RB [165]
☐	LC [158]	☐	RC [166]
☐	LD [159]	☐	RD [167]
☐	LE [160]	☐	RE [168]
☐	LF [161]	☐	RF [169]
☐	LG [162]	☐	RG [170]

1b. Largest Dimension

|_|_|_| **mm** [171]

1c. Distribution Subtype *(select one)* [172]

- o Diffuse non-specific
- o Linear non-specific
- o Linear ductal: Smooth
- o Linear ductal: Irregular
- o Linear ductal: Clumped
- o Segmental
- o Regional
- o Diffuse patchy

1d. Internal Enhancement *(select one)* [173]

- o Homogeneous confluent
- o Heterogeneous non-specific
- o Heterogeneous stippled, punctate
- o Heterogeneous clumped
- o Septal, dendritic
- o Asymmetric
- o Symmetric
- o Not applicable

1e. T2 Appearance *(select one)* [174]

- o Hyperintense to surrounding breast tissue
- o Hypointense to surrounding breast tissue
- o Isointense to surrounding breast tissue
- o Unable to evaluate

1f. Degree of Enhancement

(characterize by strongest degree seen) [175]

- o Minimal
- o Moderate
- o Marked

1g. Enhancement Pattern

(characterize by strongest pattern seen) [176]

- o Gradual
- o Sustained
- o Washout

1h. Series and Image Number of Representative Slices *(list up to 3)*

Series |_|_|: [364] **Image #** |_|_|_| [365]

Series |_|_|: [366] **Image #** |_|_|_| [367]

Series |_|_|: [368] **Image #** |_|_|_| [369]

1i. Corresponds to Index Lesion [177]

- o No
- o Yes

COMMENTS: _____

_____

_____

_____ [370]

T4

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

ACRIN Study 6657 Case #

PLACE LABEL HERE

Institution Institution No.

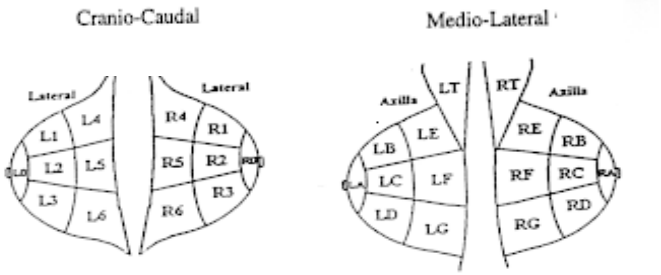
Participant's Initials Participant's I.D. No.

Section B: Regional Enhancements

All regional enhancements documented on the T1 Form must be reported in this section. If new regional enhancements are now present, report on the supplemental TS Form.

2. Is the lesion identified as Regional Enhancement #2 on the T1 Form still visible? [371]

- o No (skip 2a-2i)
- o Yes (complete 2a-2i)
- o Not Appliable



2a. Location:

Cranio-Caudal *(select all that apply)*

☐ L0	[180]	☐ R0	[187]
☐ L1	[181]	☐ R1	[188]
☐ L2	[182]	☐ R2	[189]
☐ L3	[183]	☐ R3	[190]
☐ L4	[184]	☐ R4	[191]
☐ L5	[185]	☐ R5	[192]
☐ L6	[186]	☐ R6	[193]

Medio-Lateral *(select all that apply)*

☐ LT	[194]	☐ RT	[202]
☐ LA	[195]	☐ RA	[203]
☐ LB	[196]	☐ RB	[204]
☐ LC	[197]	☐ RC	[205]
☐ LD	[198]	☐ RD	[206]
☐ LE	[199]	☐ RE	[207]
☐ LF	[200]	☐ RF	[208]
☐ LG	[201]	☐ RG	[209]

2b. Largest Dimension

___ ___ ___ **mm** [210]

2c. Distribution Subtype *(select one)* [211]

- o Diffuse non-specific
- o Linear non-specific
- o Linear ductal: Smooth
- o Linear ductal: Irregular
- o Linear ductal: Clumped
- o Segmental
- o Regional
- o Diffuse patchy

PRE-SURGERY

2d. Internal Enhancement *(select one)* [212]

- o Homogeneous confluent
- o Heterogeneous non-specific
- o Heterogeneous stippled, punctate
- o Heterogeneous clumped
- o Septal, dendritic
- o Asymmetric
- o Symmetric
- o Not applicable

2e. T2 Appearance *(select one)* [213]

- o Hyperintense to surrounding breast tissue
- o Hypointense to surrounding breast tissue
- o Isointense to surrounding breast tissue
- o Unable to evaluate

2f. Degree of Enhancement

(characterize by strongest degree seen) [214]

- o Minimal
- o Moderate
- o Marked

2g. Enhancement Pattern

(characterize by strongest pattern seen) [215]

- o Gradual
- o Sustained
- o Washout

2h. Series and Image Number of Representative Slices *(list up to 3)*

Series ___ ___ : [372] **Image #** ___ ___ ___ [373]

Series ___ ___ : [374] **Image #** ___ ___ ___ [375]

Series ___ ___ : [376] **Image #** ___ ___ ___ [377]

2i. Corresponds to Index Lesion [216]

- o No
- o Yes

COMMENTS: _____

_____

_____

_____ [378]

T4

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

ACRIN Study 6657 Case #

PLACE LABEL HERE

Institution Institution No.

Participant's Initials Participant's I.D. No.

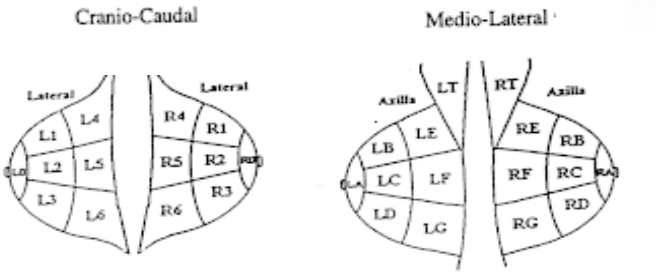
PRE-SURGERY

Section B: Regional Enhancements

All regional enhancements documented on the T1 Form must be reported in this section. If new regional enhancements are now present, report on the supplemental TS Form.

3. Is the lesion identified as Regional Enhancement #3 on the T1 Form still visible? [379]

- o No (skip 3a-3i)
- o Yes (complete 3a-3i)
- o Not Applicable



3a. Location:

Cranio-Caudal *(select all that apply)*

☐ L0	[219]	☐ R0	[226]
☐ L1	[220]	☐ R1	[227]
☐ L2	[221]	☐ R2	[228]
☐ L3	[222]	☐ R3	[229]
☐ L4	[223]	☐ R4	[230]
☐ L5	[224]	☐ R5	[231]
☐ L6	[225]	☐ R6	[232]

Medio-Lateral *(select all that apply)*

☐ LT	[233]	☐ RT	[241]
☐ LA	[234]	☐ RA	[242]
☐ LB	[235]	☐ RB	[243]
☐ LC	[236]	☐ RC	[244]
☐ LD	[237]	☐ RD	[245]
☐ LE	[238]	☐ RE	[246]
☐ LF	[239]	☐ RF	[247]
☐ LG	[240]	☐ RG	[248]

3b. Largest Dimension

|___|___|___| **mm** [249]

3c. Distribution Subtype *(select one)* [250]

- o Diffuse non-specific
- o Linear non-specific
- o Linear ductal: Smooth
- o Linear ductal: Irregular
- o Linear ductal: Clumped
- o Segmental
- o Regional
- o Diffuse patchy

3d. Internal Enhancement *(select one)* [251]

- o Homogeneous confluent
- o Heterogeneous non-specific
- o Heterogeneous stippled, punctate
- o Heterogeneous clumped
- o Septal, dendritic
- o Asymmetric
- o Symmetric
- o Not applicable

3e. T2 Appearance *(select one)* [252]

- o Hyperintense to surrounding breast tissue
- o Hypointense to surrounding breast tissue
- o Isointense to surrounding breast tissue
- o Unable to evaluate

3f. Degree of Enhancement

(characterize by strongest degree seen) [253]

- o Minimal
- o Moderate
- o Marked

3g. Enhancement Pattern

(characterize by strongest pattern seen) [254]

- o Gradual
- o Sustained
- o Washout

3h. Series and Image Number of Representative Slices *(list up to 3)*

Series |___|___| : [380] **Image #** |___|___|___| [381]

Series |___|___| : [382] **Image #** |___|___|___| [383]

Series |___|___| : [384] **Image #** |___|___|___| [385]

3i. Corresponds to Index Lesion [255]

- o No
- o Yes

COMMENTS: _____

_____

_____

_____ [386]

ACRIN Study 6657 Case #

PLACE LABEL HERE

Institution Institution No.

Participant's Initials Participant's I.D. No.

PRE-SURGERY

14. Other Multi-focality *(select all that apply)*

- ☐ Other masses [257]
- ☐ Other regional enhancements [258]
- ☐ Diffuse enhancement(s) [259]
- ☐ Scattered, stippled enhancement(s) [260]
- ☐ Not applicable/None [261]

15. Other Findings [262]

- o No *(proceed to question 16)*
- o Yes *(continue, characterize other findings)*

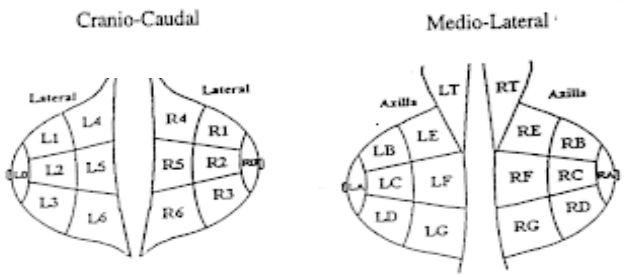
Characterization of Other Findings

(select all that apply)

- ☐ Nipple retraction [263]
- ☐ Nipple invasion [264]
- ☐ Pectoralis muscle invasion [265]
- ☐ Pre-contrast high duct signal [266]
- ☐ Skin thickening (focal) [267]
- ☐ Skin thickening (diffuse) [268]
- ☐ Skin invasion [269]
- ☐ Edema [270]
- ☐ Lymph Adenopathy [271]
- ☐ Hematoma/blood [272]
- ☐ Abnormal signal void [273]
- ☐ Cyst(s) [274]
- ☐ Other [388] _____ [389]

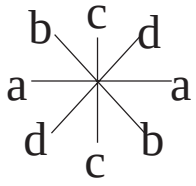
16. Full Extent of Disease

If any new lesions were identified, report description data on the TS form but include these when determining the full extent of disease below.



Direction for Longest Diameter Measurement
(indicate which diagram above was used to determine measurement direction) [275]

- o cranial - caudal
- o medio-lateral



Orientation of Longest Diameter Measurement
(indicate the orientation used to determine measurement direction) [276]

- o a
- o b
- o c
- o d

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** [277]

T4

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

ACRIN Study 6657 Case #

PLACE LABEL HERE

Institution Institution No.

Participant's Initials Participant's I.D. No.

PRE-SURGERY

17. TFQ Staging Classification

***T** (select one – size of dominant lesion only)* [278]

- O T0 No primary
- O Tis In Situ
- O T1a <5 mm
- O T1b 5-9 mm
- O T1c 10-20 mm
- O T2 21-50 mm
- O T3 >50 mm
- O T4a chest wall
- O T4b skin
- O T4c chest wall and skin
- O T4d inflammatory

F *(select one – size of full extent of disease)* [279]

- O F0 no other area of suspicious enhancement
- O F1 ≤10mm
- O F2 11-20 mm
- O F3 21-30 mm
- O F4 31-40 mm
- O F5 41-50 mm
- O F6 51-60 mm
- O F7 61-70 mm
- O F8 71-80 mm
- O F9 81-90 mm
- O F10 91-100 mm
- O FX >100 mm, please record

size ___ mm. [280]

Q *(select one - number of quadrants involved)* [281]

- O Q0 no quadrant of suspicious enhancement
- O Q1 one quadrant of suspicious enhancement
- O Q2 two quadrants of suspicious enhancement
- O Q3 three quadrants of suspicious enhancement
- O Q4 four quadrants of suspicious enhancement

18. Total number of masses seen on this exam ___ [405]

19. Total number of regional enhancements seen on this exam ___ [406]

COMMENTS: _____

_____ **[282]**

_____

Radiologist Signature

(radiologist must sign either the completed paper form or the completed/printed web form)

_____ **[283]**

Signature of person responsible for data

_____ **[285]**

Signature of person entering data onto web

_____ - _____ - **20**_____ **[284]**

Date form completed (mm-dd-yyyy)

*** Please remember to complete page 8**

T4 MRI Pre-Surgery Form - Completion Instructions

MRI-4, Pre-Surgery MRI, must be performed within 3-4 weeks after chemotherapy and prior to surgery. This form is to be completed by the study radiologist and used for treatment MR Imaging only. Report only clinically relevant findings (up to 3 masses and/or 3 regional enhancements) for the study breast only. Report index lesion if visualized. When reporting index lesion, the index lesion corresponds to the tumor used to define participant eligibility. To enable lesion tracking from T1, use the T4 to report on all lesions documented on the T1 form; use the same lesion category and number assignment. Date must be in the mm/dd/yyyy format. Submit this form within 2 weeks of the MRI via the ACRIN website. Submit paper form only for revisions or corrections. Please remember to complete page 8.

MRI TIME-POINT INFORMATION

1. Protocol imaging time point:

Record the appropriate response. The response to this question is mandatory and the default is set according to MRI 4 – Pre-Surgery.

1a. Was MRS performed?

Mandatory. If the response is "Yes", skip Q1b and complete remaining questions. If the response is "No", specify reason in Q1b. Sign and date form on page 2.

2. Date of MRI:

Mandatory. Record the date that the MRI was performed (date must not be in the future).

3. Date of Interpretation:

Mandatory. Record the date the MRI was interpreted by the radiologist. Date must not be prior to the Date of MRI or a future date.

5. Reader ID:

This 7 alphanumeric character user specific Id is required.

8. Were Clinically Relevant Enhancing Lesion(s) Identified?

Response to this question is mandatory. If clinically relevant enhancing lesion(s) were identified, complete question 9 through the remainder of the form. If clinically relevant enhancing lesion(s) were not identified, sign and date form.

11a. Were Clinically Relevant Mass(es) Identified on Baseline (T1)?

Response to this question is mandatory. If clinically relevant mass(es) were identified, complete Section A. Indicate total number of clinically relevant masses (1-10); the total number of masses must equal the response to question 12 on the T1 form. Provide descriptive data for up to three of the most prominent masses. If clinically relevant mass(es) were not identified, skip to Section B.

11b. Are new masses now seen that were not seen on Baseline?

Response to this question is mandatory. If the response is "Yes," a TS form will be generated to the calendar. Information regarding new mass(es) must be reported on the TS.

12a. Were Clinically Relevant Regional Enhancements Identified on Baseline (T1)?

Response to this question is mandatory. If clinically relevant regional enhancement(s) were identified, complete Section B. Indicate total number of clinically relevant regional enhancements (1-10); the total number of Clinically Relevant Regional Enhancements must equal the response in Section B, question 1, of the T1 form. Provide descriptive data for up to three of the most prominent masses. If clinically relevant regional enhancement(s) were not identified, skip to Section C.

12b. Are new regional enhancements now seen that were not seen on Baseline?

Response to this question is mandatory. If the response is "Yes," a TS form will be generated to the calendar. Information regarding the new regional enhancement(s) must be reported on the TS.

Section A: Masses

Report index lesion if visualized. Complete this section if there are clinically relevant masses to report. All masses documented on the T1 Form must be reported in this section. If new masses are now present, report on the supplemental TS Form.

Is the lesion identified as Mass #__ on the T1 Form still visible?

If the response is "No" for mass #1, skip to "Comments". If the response is "No" for mass #2, skip to mass #3. If the response is "Yes" for this or any additional mass being reported in section A, complete the remainder of the section. The response of "Not Applicable" may not be selected.

a. Mass Location: For each reported mass, at least one choice must be selected in the Cranio-Caudal or Medio-Lateral view.

b. Size of Mass: At least one of x, y, or z must be greater than 0.

h. Series and Image Number of Representative Slices: If unknown, enter 99 for series and 999 for Image #.

i. Corresponds to Index lesion: A "Yes" response is allowed only if the response to Q13 "Index Lesion Identified on this MRI Exam" equals "Yes".

Section B: Regional Enhancements

Report index lesion if visualized. Complete this section if there are regional enhancements masses to report. All regional enhancements documented on the T1 Form must be reported in this section. If new regional enhancements are now present, report on the supplemental TS Form.

Is the lesion identified as Regional Enhancements #__ on the T1 Form still visible?

If the response is "No" for regional enhancement #1, skip to "Comments". If the response is "No" for regional enhancement #2, skip to regional enhancement #3. If the response is "Yes" for this or any additional regional enhancement being reported in section A, complete the remainder of the section. The response of "Not Applicable" may not be selected.

a. Regional Enhancement Location: For each reported regional enhancement, at least one choice must be selected in the Cranio-Caudal or Medio-Lateral view.

h. Series and Image Number of Representative Slices: If unknown, enter 99 for series and 999 for Image #.

i. Mass Corresponds to Index lesion: A "Yes" response is allowed only if the response to Q13 "Index Lesion Identified on this MRI Exam" equals "Yes".

Section C: Other Findings

14. Other Multi-focality: Record the appropriate response(s). Select all that apply.

15. Other Findings: If the response is "No", skip to Question 16. If the response is "Yes", provide a **"Characterization of Other Findings"** by checking each of the characteristics that apply.

16. Full Extent of Disease (spanning all disease present)**:**

If any new lesions were identified, report description data on the TS form but include these when determining the full extent of disease below.

Direction for Longest Diameter Measurement: Either the Cranio-Caudal or the Medio-Lateral Oblique diagram must be selected. Indicate which diagram was used to determine measurement direction for the MRI. The direction used on the T1 **must** be used for subsequent MRIs.

Orientation of Longest Diameter Measurement: Indicate the direction (a, b, c, or d) of orientation. The same direction must be used for each MRI. The direction used on the T1 **must** be used for subsequent MRIs.

18. Total number of masses seen on this exam: Indicate the total number of masses, both old and new, that were seen on this exam.

19. Total number of regional enhancements seen on this exam: Indicate the total number of regional enhancements, both old and new, that were seen on this exam.

Radiologist Signature: Legible signature of the Radiologist. If completing a web CRF only, without completing a paper CRF, the electronic summary must be printed and signed by the Radiologist. The Radiologist's signature must be on the original document (whether paper or web).

Signature of person responsible for data: Legible signature/name of the staff member responsible for Collating/reviewing the data and ensuring completion of the CRF (paper or web). If completing a web CRF only, without completing a paper CRF, the electronic summary must be printed and signed by the staff member responsible for the data. The RA's signature must be on the original document (whether paper or web).

Date form completed: Record the date the original CRF, whether paper or web, was completed. Date must not be prior to "Date of MRI." If completing a Paper CRF this refers to the date the data was originally recorded on the paper CRF; the date/time of web entry is automatically recorded by the database. If completing the web CRF only, without completing a paper CRF, this refers to the date the data was originally recorded in the web module.

Signature of person entering data onto web: Record the signature/name of the staff member submitting the Data on-line. If completing a web CRF only, without completing a paper CRF, the electronic summary must be printed and signed by the staff member entering the data onto the web.

U4 ACRIN 6657 Extension Ultrasound Interpretation Form

ACRIN Study 6657

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

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

PRE-SURGERY

Instructions: In accordance with protocol, two optional diagnostic ultrasound exams may be reported. This form is to be completed by the study radiologist if a diagnostic ultrasound is performed. Report only ultrasound exams corresponding to the last MRI exam. Please report characteristics of the index lesion only. The index lesion corresponds to the tumor used to define participant eligibility. Submit this form within two weeks of each ultrasound via the ACRIN website. Submit paper form only for revisions or corrections. **Do not submit this form if a diagnostic ultrasound was not performed.**

1. Protocol Time Point [1]
- o Pre-surgery

2. Date of Ultrasound ☐☐-☐☐-☐☐☐☐ (mm-dd-yyyy) [2]

3. Date of Interpretation ☐☐-☐☐-☐☐☐☐ [3]
(mm-dd-yyyy)

4. Reader Name: _____ [4]

5. Reader ID: ☐☐☐☐☐☐ [5]

6. Study Breast [6]
- o Right
- o Left
- o Bilateral

7. Clinically Relevant Lesion(s) Identified [7]
- o No *(sign and date form)*
- o Yes

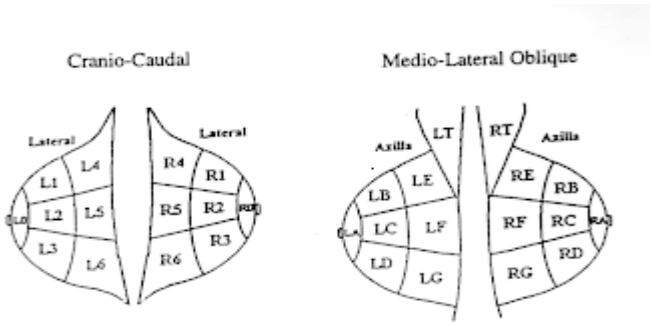
8. Total Number of Clinically Relevant Lesions ☐☐ [8]

9. Index Lesion Identified on Ultrasound [9]
- o No *(sign and date form)*
- o Yes

10. Doppler Characteristics [10]
- o Not applicable
- o Hypervascular
- o Hypovascular

11. Characterize the Index Lesion [11]
- o Cystic
- o Solid
- o Other, specify_____ [12]
- o Unknown

INDEX LESION:
(The index lesion corresponds to the tumor used to define participant eligibility.)



Index Lesion Location:

Cranio-Caudal *(select all that apply)*

☐	L0 [13]	☐	R0 [20]
☐	L1 [14]	☐	R1 [21]
☐	L2 [15]	☐	R2 [22]
☐	L3 [16]	☐	R3 [23]
☐	L4 [17]	☐	R4 [24]
☐	L5 [18]	☐	R5 [25]
☐	L6 [19]	☐	R6 [26]

Medio-Lateral *(select all that apply)*

☐	LT [27]	☐	RT [35]
☐	LA [28]	☐	RA [36]
☐	LB [29]	☐	RB [37]
☐	LC [30]	☐	RC [38]
☐	LD [31]	☐	RD [39]
☐	LE [32]	☐	RE [40]
☐	LF [33]	☐	RF [41]
☐	LG [34]	☐	RG [42]

Size of Index Lesion

x = ☐☐☐**mm** (medial-lateral) [43]

y = ☐☐☐**mm** (superior-inferior) [44]

z = ☐☐☐**mm** (anterior-posterior) [45]

Largest Dimension of Index Lesion

☐☐☐**mm** [46]

U4

ACRIN 6657 Extension
Ultrasound Interpretation Form

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

ACRIN Study **6657**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

PRE-SURGERY

Homogeneity of Index Lesion *(select one)* [47]
- o Homogeneous
- o Heterogeneous without cysts
- o Heterogeneous with cysts

Echogenicity of Index Lesion *(select one)* [48]
- o Hypoechoic
- o Isoechoic
- o Hyperechoic

Border of Index Lesion *(select one)* [49]
- o Smooth
- o Spiculated
- o Lobular
- o Irregular
- o Other, specify, _____ [50]

COMMENTS: _____

_____ [51]

_____

Radiologist Signature
(radiologist must sign either the completed paper form or the completed/printed web form)

_____ [52]
Signature of person responsible for data

_____ [54]
Signature of person entering data onto web

_____-_____-**2 0 0**___ [53]
Date form completed (mm-dd-yyyy)

U4 Ultrasound Interpretation Forms - Completion Instructions

In accordance with protocol, two optional diagnostic ultrasound exams may be reported. The second ultrasound, reported on U4, must be performed after the final chemotherapy treatment and before surgery. This form is to be completed by the study radiologist if a diagnostic ultrasound is performed. Report only the ultrasound exam corresponding to the last MRI exam on the U4 form. Please report characteristics of the index lesion only. The index lesion corresponds to the tumor used to define participant eligibility. Submit this form within two weeks of ultrasound via the ACRIN website. Date must be in the mm/dd/yyyy format. Submit paper form only for revisions or corrections. **Do not submit this form if a diagnostic ultrasound was not performed. Please submit a General Communication Memo indicating that the ultrasound was not performed and the U1 will not be submitted.**

TIME-POINT INFORMATION

1. Protocol imaging time point:

Record the appropriate response. The response to this question is mandatory and the default is set according to the form being completed; U4 – Pre-Surgery Form.

2. Date of Ultrasound:

Mandatory. Record the date that the ultrasound was performed (date must not be in the future).

3. Date of Interpretation:

Mandatory. Record the date that the ultrasound was interpreted by the radiologist (date must not be in the future).

5. Reader ID:

This 7 alphanumeric character user specific Id is required.

7. Clinically Relevant Lesion(s) Identified?

Response to this question is mandatory. If clinically relevant lesion(s) were identified, complete question 7 through the remainder of the form. If clinically relevant lesion(s) were not identified, skip to bottom of page 2 and sign and date form.

9. Index Lesion Identified on Ultrasound

Response to this question is mandatory. If index lesion(s) were identified, complete question 9 through the remainder of the form. If index lesion(s) were not identified, skip to bottom of page 2 and sign and date form.

Index Lesion:

Report index lesion if visualized. Complete this section if there are clinically relevant lesions to report. Provide descriptive data for the most prominent lesion.

Index Lesion Location: At least one choice must be selected in the Cranio-Caudal or Medio-Lateral view.

Size of Index Lesion: At least one of x, y, or z must be greater than 0.

Largest Dimension of Index Lesion: Record the largest of "Size of Mass" (x, y, or z) therefore, the "Largest Dimension of Mass" must equal x, y, or z.

Radiologist Signature: Legible signature of the Radiologist. If completing a web CRF only, without completing a paper CRF, the electronic summary must be printed and signed by the Radiologist. The Radiologist's signature must be on the original document (whether paper or web).

Signature of person responsible for data: Legible signature/name of the staff member responsible for Collating/reviewing the data and ensuring completion of the CRF (paper or web). If completing a web CRF only, without completing a paper CRF, the electronic summary must be printed and signed by the staff member responsible for the data. The RA's signature must be on the original document (whether paper or web).

Date form completed: Record the date the original CRF, whether paper or web, was completed. If completing a Paper CRF this refers to the date the data was originally recorded on the paper CRF; the date/time of web entry is automatically recorded by the database. If completing the web CRF only, without completing a paper CRF, this refers to the date the data was originally recorded in the web module.

Signature of person entering data onto web: Record the signature/name of the staff member submitting the Data on-line. If completing a web CRF only, without completing a paper CRF, the electronic summary must be printed and signed by the staff member entering the data onto the web.

V4

ACRIN 6657 Extension

MRS Form: Pre-Surgery
MRS - 4

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

ACRIN Study **6657**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

PRE-SURGERY

INSTRUCTIONS: This is to be filled out during or very near to the actual acquisition of the data. Pretreatment baseline films (hard copy or online) with voxel positioning are required at time of study. Same magnet field strength and coil should be used at every imaging visit.

1. Timepoint [1]
- O MRS 4 Pre-Surgery

3. Was MRS performed? [4]
- O 1 No (if no, complete Q3a, sign and date form)
- O 2 Yes (If yes, continue with form)

3a. If no, specify reason: [5]
- O 1 No time
- O 2 Technical Problem
- O 88 Other, specify _____ [6]

4. Were baseline studies with voxel positioning used to determine MRS asquisition? [7]
- O 1 No (Complete Q4a)
- O 2 Yes (If yes, complete Q4b)

4a. If no, specify reason:

Specify, _____ [8]

4b. Which previous images were used for voxel placement?

MRI -1: ☐ hardcopy [9] ☐ online [10]

MRI - 1.1: ☐ hardcopy [11] ☐ online [12]

MRI -2: ☐ hardcopy [13] ☐ online [14]

General

5. Date of MRI ☐☐-☐☐-☐☐☐☐ *(mm-dd-yyyy)* [17]

6. Magnet field strength [18]
- O 1 1.5
- O 2 3
- O 88 Other, specify _____ [19]

7. Person responsible for voxel placement: [20] *(select one)*
- O 1 MR Technologist
- O 2 Research Associate
- O 3 Nurse
- O 4 PI Radiologist
- O 5 Physician
- O 88 Other personnel (specify):

_____ [21]

Phantom QC Measurement

8. Phantom scan performed within past 7 days? [22]
- O 1 No (If no, complete Q8a)
- O 2 Yes

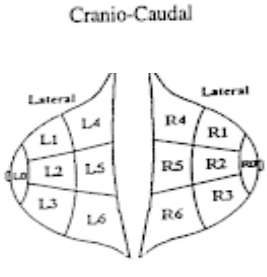
8a. If no, specify reason:

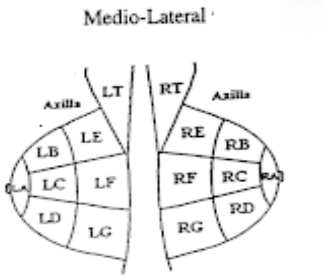
Specify, _____ [23]

8b. Date of last phantom scan

☐☐-☐☐-☐☐☐☐ [24]
(mm-dd-yyyy)

9. MRS Acquisition





Cranio-Caudal *(select all that apply)*

- ☐ L0 [25]
- ☐ L1 [26]
- ☐ L2 [27]
- ☐ L3 [28]
- ☐ L4 [29]
- ☐ L5 [30]
- ☐ L6 [31]
- ☐ R0 [32]
- ☐ R1 [33]
- ☐ R2 [34]
- ☐ R3 [35]
- ☐ R4 [36]
- ☐ R5 [37]
- ☐ R6 [38]

Medio-Lateral *(select all that apply)*

- ☐ LT [39]
- ☐ LA [40]
- ☐ LB [41]
- ☐ LC [42]
- ☐ LD [43]
- ☐ LE [44]
- ☐ LF [45]
- ☐ LG [46]
- ☐ RT [47]
- ☐ RA [48]
- ☐ RB [49]
- ☐ RC [50]
- ☐ RD [51]
- ☐ RE [52]
- ☐ RF [53]
- ☐ RG [54]

V4

ACRIN 6657 Extension

MRS Form: Pre-Surgery
MRS - 4

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

ACRIN Study **6657**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

PRE-SURGERY

10. Pre-scan calibration

Shimming: [55] O manual O automatic

Water Suppression: [56] O manual O automatic

11. Confidence in accurate reproduction of voxel placement *(check one):* [57]

Very Confident---------- O **1** O **2** O **3** O **4** O **5**----------Not Confident

11a. Reasons for reduced confidence:
(select all that apply)

- ☐ Target lesion not clearly visualized [58]
- ☐ Lesion has changed in size and/or shape [59]
- ☐ Subject position is different [60]
- ☐ Clip artifact present [61]
- ☐ Other [62] _____

_____

_____

_____ [63]

12. Is the scanner and breast coil the same as was used for the baseline MRS exam? [67]

O No (Complete Q12a)
O Yes

12a. If no, specify system used

Specify, _____ [68]

COMMENTS: _____

_____

_____ [64]

_____ [65]
Signature of person responsible for the data

Date form completed ☐☐ - ☐☐ - ☐☐☐☐ (mm-dd-yyyy) [66]

V4 MRS Form - Completion Instructions

In accordance with protocol, four to five spectroscopy exams may be reported. Visit #4 (Pre-surgery visit), reported on the V4 form, must be performed within 3-4 weeks after chemo and prior to Surgery. This form is to be completed by the study radiologist during or very near to the actual acquisition of the data. Pretreatment baseline films (hard copy or online) with voxel positioning are required at time of study. The same magnet field strength and coil should be used at every imaging visit. Submit this form within two weeks of the MRS via the ACRIN website. Date must be in the mm/dd/yyyy format. Submit paper form only for revisions or corrections. **The V4 form must be submitted via the ACRIN website regardless of whether an MRS was performed.**

MRS TIME-POINT INFORMATION

1. Timepoint:

Mandatory. Record the appropriate response. The response to this question is mandatory and the default is set according to the form being completed; V4 = MRS 4 Pre-Surgery.

QUESTION 2 DELETED FROM FORM.

3. Was MRS performed?

Mandatory. If the response is "Yes", skip Q3a and complete remaining questions. If the response is "No", **specify reason** in Q3a. Sign and date form on page 2.

4. Were baseline studies with voxel positioning used to determine MRS acquisition?

Mandatory. If the response is "No", specify reason in Q4a; skip Q4b. If the response is "Yes", indicate **"Which previous images were used for voxel placement"** in Q4b.

General

5. Date of MRS:

Mandatory. Record the date that the MRS was performed (date must not be in the future).

Phantom QC Measurement

8. Phantom scan performed within past 7 days?:

Mandatory. If the response is "Yes", skip Q8a and complete remaining questions. If the response is "No", specify reason in Q8a.

8b. Date of last phantom scan.

Mandatory. Record the date that the last phantom scan performed (date must not be in the future).

9. MRS Acquisition:

Mass Location: At least one choice must be selected in the Cranio-Caudal or Medio-Lateral view.

11. Confidence in accurate voxel placement: Provide confidence level.

11a. Reasons for reduced confidence:

Record the appropriate response(s). Select all that apply.

12. Is the scanner and breast coil the same as was used for the baseline MRS exam?

Mandatory. If the response is "No", specify system used in Q12a. *Please be persistent in using the same scanner and breast coil used in the baseline MRS exam.*

Signature of person responsible for data: Legible signature/name of the staff member responsible for Collating/reviewing the data and ensuring completion of the CRF (paper or web). If completing a web CRF only, without completing a paper CRF, the electronic summary must be printed and signed by the staff member responsible for the data. The RA's signature must be on the original document (whether paper or web).

Date form completed: Record the date the original CRF, whether paper or web, was completed. If completing a Paper CRF this refers to the date the data was originally recorded on the paper CRF; the date/time of web entry is automatically recorded by the database. If completing the web CRF only, without completing a paper CRF, this refers to the date the data was originally recorded in the web module.

S4

ACRIN 6657 Extension Surgical Pathology Form

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

ACRIN Study 6657

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

SURGERY

Instructions: To be completed by the ACRIN Research Associate based on the CALGB Post-Surgery Summary Form (C-911) and/or surgical pathology reports. Submit this form within 2 weeks of surgery via the ACRIN website. Submit paper form only for revisions or corrections.

POST-CHEMOTHERAPY SURGERY

1. Most extensive primary surgery [1]
- o Partial mastectomy/lumpectomy/excisional biopsy
- o Mastectomy, NOS

2. Date of most extensive primary surgery [2]
|_|_|-|_|_|-|_|_|_|_| mm/dd/yyyy

3. Specimen laterality [3]
- o Left
- o Right
- o Unknown

4. If breast-conserving surgery was not performed, indicate principal reason: [4]
- o Multicentric disease
- o Inflammatory disease
- o Diffuse microcalcifications
- o Patient choice/family history
- o Institutional norm
- o Specific anatomy of primary
- o Other, specify:_____ [5]

PATHOLOGY: ASSESSMENT OF DUCTAL CARCINOMA IN SITU (DCIS)

5. Is DCIS present? [6]
- o No *(proceed to question 6)*
- o Yes *(complete A-D)*

A. Is DCIS present with invasive cancer? [7]
- o No
- o Yes

B. Pathologic primary tumor size, if pure DCIS
|_|_|_| **mm** [8]

C. Histologic type *(select all that apply)*
- ☐ Comedo [9]
- ☐ Solid [10]
- ☐ Cribriform [11]
- ☐ Micropapillary [12]
- ☐ Clinging [13]
- ☐ Apocrine [14]
- ☐ Intra-cystic (encysted papillary) [15]
- ☐ Papillary carcinoma in situ (papillary) [16]
- ☐ Other, [17] specify:_____ [18]

D. Nuclear grade (mark highest grade) [19]
- o Grade I (low)
- o Grade II (intermediate)
- o Grade III (high)

PATHOLOGY: ASSESSMENT OF INVASIVE TUMOR

6. Is there residual invasive carcinoma in the breast? [20]
- o No *(proceed to question 7)*
- o Yes *(complete A-H)*

A. Pathologic primary tumor size, Gross
|_|_|_| **mm** [21]

B. Pathologic primary tumor size, Microscopic
|_|_|_| **mm** [22]

C. Were there additional foci of invasive cancer? [23]
- o No
- o Yes, complete below:

Lesion # 1 |_|_|_| Pathologic tumor size (mm), Gross [24]
|_|_|_| Pathologic tumor size (mm), Microscopic [25]
Lesion # 2 |_|_|_| Pathologic tumor size (mm), Gross [26]
|_|_|_| Pathologic tumor size (mm), Microscopic [27]

D. Histologic type [28]
- o Ductal carcinoma
- o Lobular carcinoma
- o Mixed ductal/lobular carcinoma
- o Other, specify:_____ [29]

E. Nuclear grade (highest grade) [30]
- o Grade I (low, 1 pt)
- o Grade II (intermediate, 2 pts)
- o Grade III (high, 3 pts)

F. Mitotic count [31]
- o 1
- o 2
- o 3
- o Indeterminate

S4 **ACRIN 6657 Extension Surgical Pathology Form**

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

ACRIN Study 6657

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

G. Architecture (tubule formation) [32]
- o 1
- o 2
- o 3
- o Indeterminate

H. Combined histologic grade (according to SBR/ Elston classification) [33]
- o Grade I (low)
- o Grade II (intermediate)
- o Grade III (high)
- o Unknown

PATHOLOGY: ASSESSMENT OF LYMPH NODES

7. Was sentinel node sampling performed? [34]
- o No
- o Yes *(complete A-C)*
- o Unknown

A. Number of sentinel nodes examined: ☐☐ [35]

B. Total number of positive sentinel nodes: ☐☐ [36]

C. Diameter of largest positive sentinel lymph node, if applicable

☐☐☐ **mm** [37]

8. Was axillary dissection performed? [38]
- o No
- o Yes *(complete A-C)*
- o Unknown

A. Number of lymph nodes examined: ☐☐ [39]

B. Total number of positive lymph nodes: ☐☐ [40]

C. Diameter of largest positive axillary lymph node, if applicable

☐☐☐ **mm** [41]

SURGERY

PATHOLOGY: DISEASE STAGING

9. T stage, pathologic [42]
- o T0
- o Tis
- o T1mic
- o T1a
- o T1b
- o T1c
- o T2
- o T3
- o T4
- o T4a chest wall
- o T4b skin
- o T4c chest wall and skin
- o T4d inflammatory
- o TX

10. N stage, pathologic [43]
- o N0
- o N1
- o N1a
- o N1b
- o N1bi
- o N1bii
- o N1biii
- o N1biv
- o N2
- o N3
- o NX

11. M stage, pathologic [44]
- o M0
- o M1
- o MX

12. Stage grouping [45]
- o 0
- o I
- o IIA
- o IIB
- o IIIA
- o IIIB
- o IV

COMMENTS: _____ [46]

_____ [47]
Signature of person responsible for data

_____ [49]
Signature of person entering data onto web

_____-_____-**2 0 0**___ [48]
Date form completed (mm-dd-yyyy)

S4 Surgical Pathology Form - Completion Instructions

The S4 – Surgical Pathology Form must be completed by the ACRIN Research Associate based on the CALGB Post-Surgery Summary Form (C-911) and/or surgical pathology reports. Submit this form within 2 weeks of surgery via the ACRIN website. Submit paper form only for revisions or corrections.

POST-CHEMOTHERAPY SURGERY

1. Most extensive primary surgery:

Record the appropriate response. The response to this question is mandatory.

2. Date of most extensive primary surgery:

Mandatory. Record the date that the most extensive primary surgery was performed (date must not be in the future).

3. Specimen laterality:

Mandatory.

4. If breast-conserving surgery was not performed, indicate principal reason:

Mandatory. One response required. If "Other, specify" is selected, a response must be keyed-in.

PATHOLOGY: ASSESSMENT OF DUCTAL CARCINOMA IN SITU (DCIS)

5. Is DCIS present?

Mandatory. If the response is "No", skip to Q6 and complete remaining questions. If the response is "Yes", complete questions 5A-D.

5B. Pathologic primary tumor size, if pure DCIS: Response required only if DCIS is pure. Response to Q5A must = "No".

5C. Histologic type: Provide response by checking each Histologic type that applies.

PATHOLOGY: ASSESSMENT OF INVASIVE TUMOR

6. Is there residual invasive carcinoma in the breast?

Mandatory. If the response is "No", skip to Q7 and complete remaining questions. If the response is "Yes", complete questions 6A-H.

6C. Were there additional foci of invasive cancer?

Mandatory. If "No", skip to Q6D. If "Yes", indicate gross and microscopic pathologic tumor sizes in Lesions #1 and 2 if more than one lesion.

PATHOLOGY: ASSESSMENT OF LYMPH NODES

7. Was sentinel node sampling performed?

Mandatory. If the response is "No" or "Unknown", skip to Q8 and complete remaining questions. If the response is "Yes", complete questions 7A-C.

8. Was axillary dissection performed?

Mandatory. If the response is "No" or "Unknown", skip to Q9. If the response is "Yes", complete questions 8A-C.

Signature of person responsible for data: Legible signature/name of the staff member responsible for Collating/reviewing the data and ensuring completion of the CRF (paper or web). If completing a web CRF only, without completing a paper CRF, the electronic summary must be printed and signed by the staff member responsible for the data. The RA's signature must be on the original document (whether paper or web).

Date form completed: Record the date the original CRF, whether paper or web, was completed. Date must not be prior to "Date of MRI." If completing a Paper CRF this refers to the date the data was originally recorded on the paper CRF; the date/time of web entry is automatically recorded by the database. If completing the web CRF only, without completing a paper CRF, this refers to the date the data was originally recorded in the web module.

Signature of person entering data onto web: Record the signature/name of the staff member submitting the Data on-line. If completing a web CRF only, without completing a paper CRF, the electronic summary must be printed and signed by the staff member entering the data onto the web.

Supplemental MRI Form

Continued reporting of lesions not seen on Baseline MRI/MRS

TS

ACRIN 6657 Extension Supplemental MRI Form

ACRIN Study 6657 Case #

PLACE LABEL HERE

Institution Institution No.

Participant's Initials Participant's I.D. No.

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

SUPPLEMENTAL MRI FORM

Instructions: This form is a supplement to the TA, T2, T3, and T4 Forms. Record data for new, study breast, lesions (lesions not seen on MRI-1). Continue to follow and report on this lesion(s) on subsequent MRI exams. Please enter the data via the web. Submit only revisions to this form to ACRIN Data Management via mail or fax (215) 717-0936.

1. **Date of MRI** _____ - _____ - **20** _____ (mm-dd-yyyy) [1]

2. ☐ **Total number of new masses not previously seen / reported** [2]

3. ☐ **Total number of regional enhancements not previously seen / reported** [3]

Reader ID: ☐☐☐☐☐☐☐☐ [4]

COMMENTS: _____

_____

_____ [5]

_____

Radiologist Signature
(radiologist must sign either the completed paper form or the completed/printed web form)

_____ [6]
Signature of person responsible for data

_____ - _____ - **20**_____ [7]
Date form completed (mm-dd-yyyy)

_____ [8]
Signature of person entering data onto web

TS Supplemental MRI Form - Completion Instructions

This form is a supplement to the TA, T2, T3, and T4 Forms. This form is to be completed by the study radiologist. Record data for new study breast lesions (lesions not seen on MRI-1). Continue to follow and report on this lesion(s) on subsequent MRI exams. Please enter the data via the web. Date must be in the mm/dd/yyyy format. Submit this form within 2 weeks of MRI via the ACRIN website. Submit paper form only for revisions or corrections.

1. Date of MRI:
Mandatory. Record the date that the MRI was performed (date must not be in the future).

2. Total number of new masses not previously seen / reported:
Indicate the total number of new masses that were seen on this exam.

3. Total number of regional enhancements not previously seen / reported:
Indicate the total number of regional enhancements that were seen on this exam.

Radiologist Signature: Legible signature of the Radiologist. If completing a web CRF only, without completing a paper CRF, the electronic summary must be printed and signed by the Radiologist. The Radiologist's signature must be on the original document (whether paper or web).

Signature of person responsible for data: Legible signature/name of the staff member responsible for Collating/reviewing the data and ensuring completion of the CRF (paper or web). If completing a web CRF only, without completing a paper CRF, the electronic summary must be printed and signed by the staff member responsible for the data. The RA's signature must be on the original document (whether paper or web).

Date form completed: Record the date the original CRF, whether paper or web, was completed. Date must not be prior to "Date of MRI." If completing a Paper CRF this refers to the date the data was originally recorded on the paper CRF; the date/time of web entry is automatically recorded by the database. If completing the web CRF only, without completing a paper CRF, this refers to the date the data was originally recorded in the web module.

Signature of person entering data onto web: Record the signature/name of the staff member submitting the Data on-line. If completing a web CRF only, without completing a paper CRF, the electronic summary must be printed and signed by the staff member entering the data onto the web.

6657 Additional Forms

AE

ACRIN Adverse Event Form
ACRIN 6657 Extension
MRI Evaluation of Stage III Breast Patients

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

ACRIN Study 6657 Case #

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

All Adverse Events (AEs) and Serious Adverse Events (SAEs) as defined in the protocol require routine reporting via web entry of the AE CRF. Only one AE is captured per form. For further instructions in completing the form, please refer to the AE completion instructions. Please note that source documentation (ACRIN AE log, ACRIN AE CRF, printed AE web confirmation, or participant's chart) must have the investigator's signature. For AE reporting requirements, please refer to the AE reporting section of the protocol. Contact ACRIN's AE coordinator for any questions.

AE Description _____ [1, 2]

AE Short Name (online look-up) _____ [3]

Grade [4]	Attribution [5]	Expectedness [6]	Serious AE? [42]	Expedited Report Submitted [7]	Action Taken (mark ☒ all that apply)	Outcome [9]	Date of AE Onset and Resolution (mm-dd-yyyy); mark ☒ the box "ongoing" if the AE is ongoing at the time of report
O Mild O Moderate O Severe O Life threatening or disabling O Fatal	O Unrelated O Unlikely O Possible O Probable O Definite	O Expected O Unexpected	O No O Yes	O No O Yes	☐ None [43] ☐ Medication therapy [44] ☐ Procedure [45] ☐ Hospitalization [46] ☐ Other [47]	O Recovered O Improved O Ongoing O Death O Unknown	Start date: ____ - ____ - ____ [10] Resolution date: ____ - ____ - ____ [11] ☐ Ongoing [12]

Comments: _____ [37], [38]

Additional AEs to report? [39]
- O No
- O Yes (Please complete an additional AE form)

Was the AE assessed, reviewed and signed by the investigator? [40]
- O No
- O Yes

____-____-____ [41]
Date form completed (mm-dd-yyyy)

_____ [50]
Investigator's initials

Investigator's signature _____ *(for external use only)*

AE Form Completion Instructions

An adverse event (AE) form is to be completed for each reportable AE that occurs during the study. The adverse event reporting section of the protocol will specify reporting requirements. This form should be submitted via the ACRIN data center at www.acrin.org. All available dates should be reported as MM-DD-YYYY. Code all questions unless otherwise specified; do not leave mandatory questions blank. Instructions are provided below for all questions that are not self-explanatory. If further clarification is required for any question on the form, please contact the ACRIN AE Coordinator.

If revisions are required, a paper case report form (CRF) must be submitted. Refer to the general form completion instructions for additional details. Please use Good Clinical Practice (GCP) in making data corrections; a single line should be drawn through the incorrect data with your initials and the date. Please note that when revising the AE form, the investigator must also initial and date any revisions.

AE Description: A 200 character field is provided to allow for adequate adverse event description. Please include the investigator's determination of what the AE is related to.

Note: On the paper AE form, you may notice the following "[1, 2]" which represents element numbers. Each question on the form is stored in ACRIN's database as an element number. Element 2 is no longer active as the character length has increased to 200 from the former version which captured 60 characters in elements 1 and 2.

AE Short Name: This field requires an online look-up into the National Cancer Institute's (NCI) Common Toxicology Criteria for Adverse Events (CTCAE) data table.

1. Select the blue 'Adverse Event' button next to the "AE Short Name (online look-up)" field.
2. You will then be taken to another page with three fields:
    a. Category: (Required to search for appropriate short name and code)

    This is also known as the System Organ Class (SOC) within the CTCAE version 4.0. You MUST select a category in order to proceed. If you are having difficulty finding the appropriate category, you can search the electronic PDF of the CTCAE version 4.0 or contact ACRIN's AE Coordinator.

    b. Code Description: (Optional to search will narrow down the choices) you can filter further by entering partial term and or the entire term;

    OR

    c. MedDRA Term: (Optional to search will narrow down the choices) you can filter further by entering partial term and or the entire term.
3. To search select the blue 'Retrieve' button to obtain a list of code descriptions.
4. Review the code description and MedDRA term and select the appropriate code number of the reported AE.
5. Once selected, MedDRA code number will be populated in the AE Short Name field. The MedDRA term will be displayed in red to the right of the AE Short Name field on the web entry screen when you are returned to the form.

In the event that a paper AE form is completed and sent to ACRIN Data Management for entry, please document the appropriate AE short name from the CTCAE. If you have question about which short name is applicable, please contact ACRIN's AE coordinator for assistance.

Grade: Select the investigator-determined grade based on the National Cancer Institute's (NCI) Common Toxicology Criteria for Adverse Events (CTCAE). If the AE worsens (e.g. Grade 2 (moderate) to Grade 3 (severe), a new AE form must be completed.

Grade 1 = Mild
Grade 2 = Moderate
Grade 3 = Severe
Grade 4 = Life threatening or disabling
Grade 5 = Fatal

Attribution: Select the investigator-determined relationship of the AE to the study.

Expectedness: Expected AEs are listed in section 9.5, 9.6, 9.7, 9.8, and 9.9 of the protocol, informed consent or the investigator's brochure. Unexpected AEs refers to an adverse event that has not been previously observed.

Serious AE: A serious adverse event (SAE) is defined as any untoward medical occurrence that:

- results in death, or
- is life-threatening (at the time of the event), or
- requires inpatient hospitalization or prolongation of an existing hospitalization, or
- results in persistent or significant disability or incapacity, or
- is a congenital anomaly/birth defect.

Expedited Report Submitted: Refer to 9.11 of the protocol for information on what events require expedited reporting.

Action Taken: Select all actions taken; if 'None' is selected, no other boxes may be marked. If "Other" is selected, please provide details in the comments section.

Outcome: Select the patient's outcome. If 'Ongoing' is selected, the AE 'Resolution Date' should be blank and the 'Ongoing?' box must be marked. Please note that "ongoing" AEs will be queried by ACRIN until resolution is reached. Once additional information for an AE is obtained, ACRIN must be notified and the AE form must be updated accordingly. If an expedited report was submitted, this will also need to be updated accordingly.

Start Date & Resolution Date: These dates are mandatory unless the stop date is ongoing. In the event that the start date and/or resolution date are unknown and/or partial dates, sites are required to document the reason for the date omission(s) and any details (e.g. partial dates or estimated dates) in the comments section. Please note that sites will be queried if dates are inconsistent or if adequate details are not provided in the comments section. Once additional information for an AE is obtained, ACRIN must be notified and the AE form must be updated accordingly. If an expedited report was submitted, this will also need to be updated accordingly.

Comments: The comment field is provided for sites to document relevant clinical or study notations, etc. The comments section is not intended for "actionable" information you need to relate to data management (DM) and is not intended for data analysis. Comments should be limited to 200 characters.

Additional AEs to report: Only one adverse event is captured per form. If there are multiple events to report, select 'Yes' and an additional AE form will be populated to the patient calendar.

Was the AE assessed, reviewed, and signed by the investigator?: This question eliminates the need for entering the investigator's name into the database. However if a paper form is completed (e.g. for revision purposes, a down web system or if the AE form is used as a source document), the investigator's signature on the paper form is required.

Investigator's initials: Enter the initials [e.g. John Smith: JS] of the investigator responsible for assessing, reviewing and signing off on the AE.

Investigator's Signature (for external use only): The field is available for the site PI to sign off in the event that the site completes a paper AE form. The information from this field will not be entered into the ACRIN's database. PI sign off is captured by question "Was the AE assessed, reviewed and signed by the investigator?"

IMPORTANT: Please note that source documentation (ACRIN AE log, ACRIN AE CRF, printed web confirmation or participant's chart) must have the investigator's signature.

PR

ACRIN 6657
Protocol Variation Form

ACRIN Study **6657**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Instructions: In the instance a protocol requirement is not met please record the necessary information below. Complete a separate form for each case and for each instance. Retain the form in the case study file. Fax a copy to ACRIN Headquarters at (215) 717-0936. Data Management will note this information in the database to prevent multiple queries.

1. Check The Protocol Event Being Reported: (report only one per form)

- ☐ Ineligible participant registered
- ☐ Participant completed study activity before signing consent
- ☐ Participant withdrew study consent, provide documentation
- ☐ MRI not performed per protocol specified time point (specify MRI by circling number 1, 2, 3, 4)
- ☐ MRI not performed per protocol specified imaging parameters (specify MRI by circling number 1, 2, 3, 4)
- ☐ Mammogram not performed per protocol specified time point (specify mammo by circling number 1, 2)
- ☐ Other, specify _____

2. Describe The Protocol Event Reported Above:

_____ ____-____-200

Signature of Person Responsible for Data

Date form completed (mm-dd-yyyy)

PR completion guidelines

The PR Form is used to report protocol deviations to ACRIN. Each organization may also have separate reporting requirements for protocol deviations, follow your IRB guidelines. The PR form should be completed by the study site when/if a protocol deviation is discovered. A GCM for suppression of forms is not required when reporting protocol deviations, the PR will serve as the suppression trigger (as appropriate). Complete a separate PR Form for each case and for each deviation. Retain the form in the case study file and fax/mail a copy to ACRIN Headquarters at (215) 717-0936. A completed ACRIN Case Specific Label should be affixed to the PR Form. In lieu of a label, the Participants Initials, Case Number, Institution Number, and Institution Name can be recorded in the space provided. Contact ACRIN DM for any questions regarding the PR Form.

END OF STUDY INFORMATION

1. Check The Protocol Event Being Reported: Required data element. Place a mark in the box to the left of the protocol deviation being reported. Report only one protocol deviation (check only one box) per PR Form.

Ineligible participant registered. Select this response when it is discovered that an erroneous randomization occurred, that is, randomization of an individual who did not meet eligibility criteria at the time of randomization. Eligibility is established at the time of randomization based on the protocol-specified inclusion/exclusion criteria. Please reference the protocol for inclusion/exclusion criteria.

Participant completed study activity before signing consent. Select this response when it is discovered that a participant completed a study activity before signing a consent form.

Participant withdrew study consent, provide documentation. Document this event on the DS Form.

MRI not performed per protocol specified timepoint. Select this response when it is discovered that a participant did not receive an imaging examination or the MRI was performed outside of the specified timepoint. The imaging window should be closed before reporting this deviation. **Circle the appropriate MRI timepoint.** ACRIN DM will suppress the screening forms and images once the PR Form has been processed; *no GCM is required*. **The T and V form for the missed timepoint will not be suppressed and must be completed via the web.**

MRI not performed per protocol specified imaging parameters. Select this response when it is discovered that the imaging parameters were not strictly adhered to. **Circle the appropriate MRI timepoint.**

Mammogram not performed per protocol specified timepoint. Select this response when it is discovered that a participant did not receive a mammogram or the mammogram was performed outside of the specified timepoint. The mammography window should be closed before reporting this deviation. **Circle the appropriate mammography timepoint.** ACRIN DM will suppress the mammography forms and images once the PR Form has been processed; *no GCM is required*.

Other, specify. Select this response if there is a violation of the study protocol. In the event that another type of violation/deviation from the protocol occurs, please specify the type of occurrence on this part of the form. In the event that you still have questions regarding the type of violation please contact an ACRIN data manager prior to submitting the form.

2. **Describe The protocol Event Reported Above:** Required data element, 60-character limit. Provide a description of the protocol deviation. The description should include the following elements:
   - How the protocol deviation was discovered
   - How the protocol deviation occurred
   - Ramifications for the participant

   One of the purposes of this form is to differentiate between types of "randomized ineligibles." If the protocol deviation being described is a randomized ineligible, the description should also include details that specify the type of randomized ineligible, as described below:
   - Participant was randomized in error.
   - Participant was randomized appropriately based on information provided at the time of randomization, but it was discovered after randomization that the information provided was verifiably incorrect.

Signature of person responsible for data:

Legible signature/name of the staff member responsible for collating / reviewing the data and ensuring completion of the CRF (paper or web). If completing a web CRF only, without completing a paper CRF, the electronic summary must be printed and signed by the staff member responsible for the data. The Research Associate's (RA) signature must be on the original document (whether paper or web).

Date form completed:

Record the date the PR form was completed. If completing a paper CRF this refers to the date the data was originally recorded on the paper CRF; the date/time of web entry is automatically recorded by the database. If completing the web CRF only, without completing a paper CRF, this refers to the date the data was originally recorded in the web module.

DS

ACRIN 6657 Extension
MRI Evaluation of Stage III Breast Patients
End of Study Form

ACRIN Study **6657**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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

END OF STUDY FORM

Instructions: For each registered participant, please submit this form within two (2) weeks of study completion or premature discontinuation, including death.

1. End of Study status: [1]

- O 1 Protocol specific criteria and follow-up complete (sign and date form)
- O 2 Premature discontinuation (complete Q2 and Q2a)
- O 3 Participant death (skip to Q3 and Q3a)

2. Date of premature discontinuation: _____-_____-_____ *(mm/dd/yyyy)* [2]

2a. Primary reason for premature discontinuation: *(check only one)* [3]

- O Adverse events/side effect/complications (also specify on the Adverse Event form)
- O Participant explicitly withdraws study consent/authorizations
- O Protocol violation
- O Did not meet baseline criteria
- O Lost to follow-up (unable to obtain contact with the participant during the prescribed protocol intervals)
- O Unsatisfactory therapeutic effect
- O Abnormal laboratory value(s)
- O Investigator decision (specify reason below)
- O Other (specify reason below)

Specify reason: _____ [4]

3. Date of death _____-_____-_____ *(mm/dd/yyyy)* [5]

3a. Cause of death [6]

- O Disease Progression
- O Other _____ *(specify cause of death)* [7]

COMMENTS: _____

_____

_____ [8]

_____ [9]
Signature of person responsible for the data

_____ - _____ - _____ [10]
Date form completed (mm-dd-yyyy)

_____ [11]
Signature of person entering data onto the web

ACRIN - 6657 FORM COMPLETION INSTRUCTIONS

END OF STUDY

DS Completion Instructions

A DS Form is required for each participant on the ACRIN 6657 study. This form documents when a patient goes off study for any reason and should be submitted via the ACRIN data center at www.acrin.org within two weeks of study completion, premature discontinuation, or patient death.

All available dates should be reported as MM-DD-YYYY. Code all questions unless otherwise specified; do not leave mandatory questions blank. Please note that online logic requires dates to be after 09/01/2007 but no later than current date.

Instructions are provided below. If further clarification is required for any question on the form, please contact the ACRIN Data Management Center.

1 End of Study status: Only one reason should be selected per patient and it must be the primary reason for off-study status (for example, if the patient is taken off-study for disease progression and then dies, 'premature discontinuation' should be selected).
(1) Protocol specific criteria and follow-up complete: should only be selected if the patient has completed all required protocol imaging. If option 1 is selected, sign and date form.
(2) Premature discontinuation: should be selected for any other reason besides patient death. If option 2 is selected, Q2 and 2a must be completed; Q3 and 3a must be left blank.
(3) Participant death: if this is selected, skip Q2 and 2a and answer Q3 and 3a.

2 Date of premature discontinuation: Please note that all patients prematurely discontinued from this study must receive a final MRI scan after protocol treatment has been terminated; this scan may be done any time after discontinuation of treatment, but ideally should be done within one month. The date of discontinuation from the ACRIN study should be the date of this final scan, not the date the patient was taken off RTOG protocol treatment.

2a Primary reason for premature discontinuation: Please choose the primary reason that a patient is discontinuing the protocol treatment, then sign and date form.
(1) Adverse events/side effect/complications: if this option is selected, complete aAE form must be completed[1].
(2) Participant explicitly withdraws study consent/authorization
(3) Protocol violation
(4) Did not meet baseline criteria
(5) Lost to follow-up
(6) Unsatisfactory Therapeutic Effect: Select this option if the patient is taken off protocol treatment due to disease progression.
(7) Abnormal laboratory value(s)
(8) Investigator decision: Investigator's reason for premature discontinuation must be specified.
(9)
(10) Other: Other reason for premature discontinuation must be specified.

3 Date of death: Please specify the date of patient's death in mm/dd/yyyy format.

3a Cause of death:
(1) Disease Progression: This option should only be selected if the death was directly related to the protocol-type disease.
(2) Other: Record any other cause of death.

Comments: The comment field is an optional field provided for site use (relevant clinical or study notations, etc.) and/or reference for data related questions. The comment section is not intended for "actionable" information you need to relate to DM and is not intended for data analysis. Comments should be limited to 60 characters.

Signature of person responsible for data: Legible signature/name of the person responsible for collating/reviewing the data and ensuring completion of the CRF.

[1]Imaging related AE's must be reported to ACRIN via the AE form.

ACRIN

GENERAL COMMUNICATION MEMO/REPLY TO FORMS DUE REQUEST

INSTRUCTIONS: Use this memo
- To communicate the unavailability of a required calendar item.
- To inform us that a participant has expired and you are awaiting details.
- To communicate information about the case that cannot be reported on a form. **Note**: A narrative will not be accepted in lieu of a form.

Use a separate form for each case.

Be sure to properly identify the study, case, the form your explanation refers to, and the calendar due date.
A **case specific label** can be affixed within the section below for convenience and study / case identification.

From Institution # / Name: _____ Forms Due Request Date _____

ACRIN Protocol # _____ Case # _____ Participant Initials / ID _____

Data Item	Data Collection Calendar Due Date	Assessment / Imaging Date Recorded on Form by Institution	Comment / Explanation
☐ Initial evaluation form	_____	_____	_____
☐ Imaging Form (specify)	_____	_____	_____
☐ Biopsy Form	_____	_____	_____
☐ Follow-up Form	_____	_____	_____
☐ Image Reports	_____	_____	_____
☐ Image(s)	_____	_____	_____
Other (specify)			
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

_____ Research Associate _____ Date 04 / 04