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

A C R I N

American College of Radiology Imaging Network Forms Index

ACRIN Study 6657

Form Version Date

Visit 1:	: Pre-Registration / Baseline Visit - Within 4 weeks prior to start of neoadjuvant treat	<u>tment</u>
A0 N1	Registration Eligibility Checklist	
T1 U1 V1	(within 3 months before or 2 weeks after entry MRI/MRS but before treatment start) MRI-1 Baseline/Pretreatment Form Ultrasound Interpretation Form MRS-1 Baseline/Pretreatment Form	09-10-07
	onal Visit (For 30 consented patient's ONLY): Within 72 hours post Baseline and prio chemotherapy	<u>r to</u>
TA VA	MRI-1.1 Additional Baseline / Pretreatment Reproducibility Form	
Visit 2:	: MRI/MRS within 20-28 or 48-96 hours post Baseline MRI/MRS	
T2 V2	MRI-2 Treatment Form	
Visit 3:	: MRI/MRS after Type 1 Chemotherapy	
T3 V3	MRI-3 MRI Inter-Regimen Treatment Form	
Visit 4:	: Within 3-4 weeks after final chemotherapy treatment and 1-2 weeks prior to Surg	ery
N4 T4	Mammography Interpretation Form	11-29-07
U4 V4 S4	Ultrasound Interpretation Form	01-09-09

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ACRIN Study 6657

Form Version <u>Version Date</u>

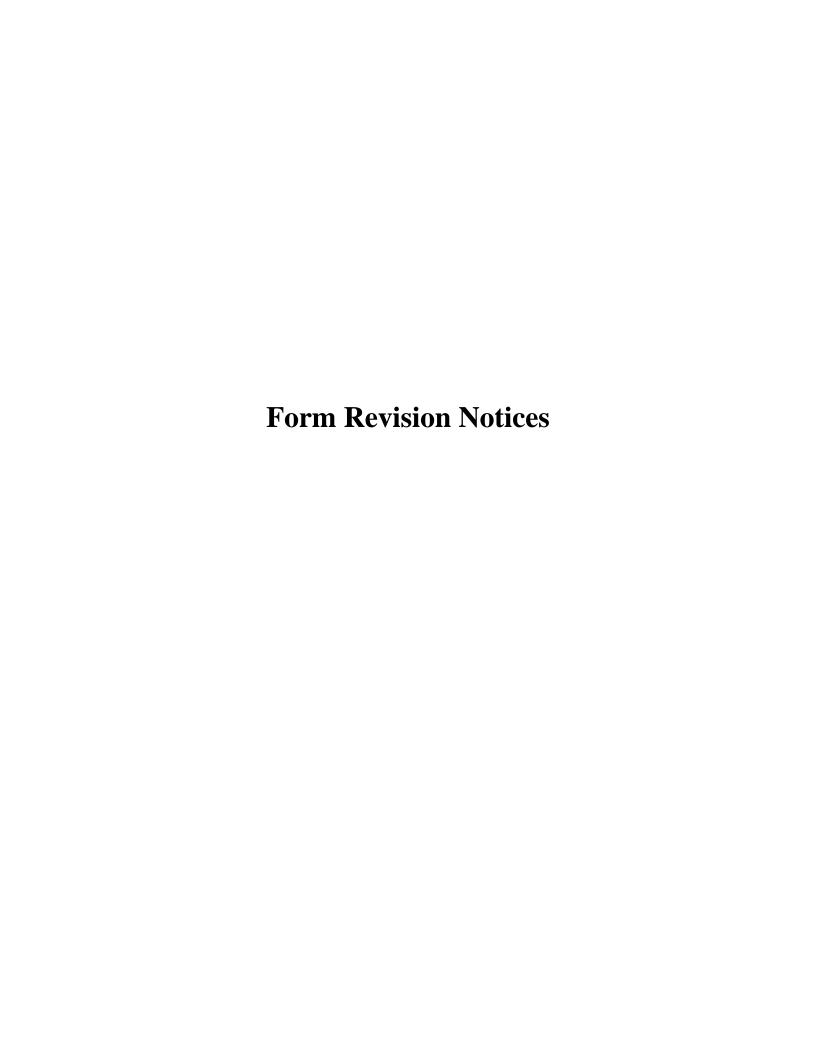
Supplemental MRI Form: Continued reporting of lesions not seen on Baseline (MRI-1)

Additional Forms

AE	ACRIN Adverse Event Form
PR	Protocol Variation Form
DS	End of Study Form
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.

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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.



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

<u>Description of revision:</u> 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



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.

Form Title: <u>V2 MRS Form:</u>

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.



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

Form Title: <u>AE – Adverse Events Form</u>

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.



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

 \triangleright 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

Version 1.1 mp: 07/23/2007



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 <u>December 12, 2007</u>
- ➤ 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

Version 1.1 mp: 07/23/2007

Visit 1

<u>Pre-Registration / Baseline Visit –</u> 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.

		Par	ient Initials	Case No.
	in the	owing questions will be asked at Study Registration event the website is down. Please retain source of tient file.		
		Name of institutional person registering this ca	ise? (initials only) [1]	
((Y) 2	 Has the Eligibility Checklist been completed? No Yes 	2]	
((Y) :	 3. Is the participant eligible for this study? [3] 1 No 2 Yes 		
	'	4. Date the study-specific Consent Form was sign	ed? (mm-dd-yyyy) (must be	prior to study entry) $_{[4]}$
	:	5. Participant Initials (Last, First) [5]		
	(6. Verifying Physician <i>(site PI)</i> _[6]		
		7. Participant's ID Number (Optional do not utiliz	e a medical record number o	r radiology assigned number) [7]
	;	8. Date of Birth (mm-dd-yyyy) [8]		
	:	9. Ethnic Category _[9]		
		1 Hispanic or Latino2 Not Hispanic of Latino9 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 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		

		ACRINStud	ly 6657
Re Re	evision	PLACE LABEL HERE	
		Institution	Institution No.
		Patient Initials	Case No.
(Y/N)	 15. Will any component of the participal 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-20) 20. Name of Medical Oncologist [20] 21. Is the participant enrolled in CALGI 1 No 2 Yes CALGB Protocol # [22] 	7] d-yyyy) _[19]	
(Y/N)	CALGB Case #		taxane based regimen
(N)	23. Is the participant pregnant? [25] 1 No 2 Yes		
(N)	 24. Are there any contraindications to the contraint of the contr		
(Y/N)	25. Was the participant's serum creating of registration? [30]1 No2 Yes	nine clearance > 30 mL/min within 2	28 days prior to or up to day
	Calculated serum creatinine cleara	nnce mL/min [33]	
DMMENTS:			
esearch Associate		Date for	

Registration / Eligibility

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

Registration / Eligibility

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.



ACRIN 6657 Extension Mammography Interpretation Form

	ACR	IN S	udy	66	57		
PI.A	CE	T.A	RF	T.	HE	R	FC.

PLACE LABEL HERE			
Institution	Institution No		
Participant Initials	Case No		
DDE TDE ATMENT			

If this is a revised or corrected form, please $\sqrt{\text{box.}}$

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.

	in 2 weeks of each study mammogram via the ACRIN website.					
1.	Protocol Time Point [1] o Pre-Treatment Anticipated Treatment start date	SECTION A: CLINICALLY R (Report index lesion if visualiz the three most prominent mas	zed. Report descriptive data for			
	(mm-dd-yyyy) _[2]	Reporting Mass # [18]				
2.	Date of Mammogram:	Cranio-Caudal	Medio-Lateral Oblique			
3.	Date of Interpretation:	Lateral L4 R4 R1	Azilla LT RT Azilla			
4.	Reader Name:	(us 1.2 1.5 R5 R2 R0)	LB RF RC RA			
5.	Reader ID: [7]	L5 L6 R6	LD LG RG RD			
6.	Clinically Relevant Lesion(s) Identified o No (proceed to question 15)		7 4			
	o Yes	Mass Location:				
7	Study Breast [9]	Cranio-Caudal (sele	ect all that apply)			
٠.	o Right	□ L0 _[19]	□ R0 _[26]			
	o Left	☐ ☐ [20]	K ₁₀₇₁			
	o Bilateral	□ L2 [21]	NZ _{[201}			
			K3 _{roo1}			
8.	Density of Breast Parenchyma [10]	L4 [23]	K4 ₁₀₀₁			
	o Mostly fat	L5 [24]				
	o Scattered fibroglandular densities	☐ L6 [25]	\square R6 $_{[32]}^{[31]}$			
	o Heterogeneously dense	Medio-Lateral (selec	Medio-Lateral (select all that apply)			
	o Extremely dense	□ LT _[33]	□ RT [41]			
40	In last to dear the CC at an Manager way	☐ LA [34]	□ RA [42]			
12.	Index Lesion Identified on Mammogram [17]					
	o No	☐ LC [35] ☐ LD resp	☐ RB [43] ☐ RC [44]			
	o Yes	□ □ 3/				
_			☐ RE [46]			
9.	Clinically Relevant Mass(es) Identified [11]		□ DE			
	o No	☐ LG [39]	☐ RG [47]			
	o Yes (report in section A)		d all three measurements)			
	Total Number [12]	x =mm (med	,			
10.	Remember to complete Clinically Relevant	1 1 1 1	erior-inferior) _[50]			
. ••	Calcification Cluster on page 3 - Section B	1 1 1 1	erior-posterior) [51]			
11.	Remember to complete Clinically Relevant Architectural Distortions on page 5 - Section C	Largest Dimension	of Mass mm _[52]			

N1	ACRIN 6657 Extension Mammography Interpretation Form
If this is a	revised or corrected form, please $\sqrt{\text{box.}}$
M 0 0 0	ass Shape (select one) [53] Round Oval Lobulated Irregular
	ass Margins (select one) [54] Circumscribed Microlobulated Obscured Indistinct Spiculated
	istance Between Ends of Spiculation Inswer if margin is spiculated)
M 0 0 0 0	ass Density (select one) [56] High Equal Low Fat containing
A 	Skin thickening [59]
M 0 0	ass Corresponds to Index Lesion [63] No Yes
A 0 0	dditional Masses _[64] No (proceed to section B) Yes (continue)
Reporting	g Mass # _[65]
	Ass Location: ranio-Caudal (select all that apply) L0 [66]

ACRIN Study 6657 PLACE LABEL HERE

Institution	Institution No.				
Participant Initials	Case No.				
PRE-TREATMENT					
Medio-Lateral (select al	l that apply)				
☐ LT [80] ☐ LA [81] ☐ LB [82] ☐ LC [83] ☐ LD [84] ☐ LE [85] ☐ LF [86] ☐ LG [87]	☐ RT [88] ☐ RA [89] ☐ RB [90] ☐ RC [91] ☐ RD [92] ☐ RE [93] ☐ RF [94] ☐ RG [95]				
Size of Mass (record all t	three measurements)				
x =mm (medial-ly =mm (superior z =mm (anterior-	-inferior) _[97] posterior) _[98]				
Largest Dimension of M	Mass mm _[99]				
Mass Shape (select one o Round o Oval o Lobulated o Irregular Mass Margins (select or o Circumscribed o Microlobulated o Obscured o Indistinct o Spiculated					
Distance Between Ends (answer if margin is spicu					
Mass Density (select one o High o Equal o Low o Fat containing	e) _[103]				
Associated Features (S	elect all that apply)				
☐ Calcifications [104] ☐ Architectural distortion ☐ Skin thickening [106] ☐ Solitary dilated ducts ☐ Multiple dilated ducts ☐ None [109]	107]				
Mass Corresponds to Ir	ndex Lesion [110]				
o No o Yes					

N1

ACRIN 6657 Extension **Mammography Interpretation Form** If this is a revised or corrected form, please $\sqrt{\text{box}}$. Additional Masses [111]
o No (proceed to section B) Yes (continue) Reporting Mass # _____ Mass Location: Cranio-Caudal (select all that apply) R0_[120] L0 [113] L1 [114] L2 [115] R1 R1 [121] R2 [122] L3 [116] L4 [147] R3 [122] R4 [123] R4 [124] R5 [125] [117] L5 [118] L6 [119] R6 [126] Medio-Lateral (select all that apply) RT_[135] LT [127] LA [127] LB [128] LC [129] LC [130] LD [131] LE [132] LF [133] RA [135] RB [136] RC [137] RC [138] RD [139] RE [140] RF [141] RG [142] П LF [133] LG [134] Size of Mass (record all three measurements) $\mathbf{x} =$ mm (medial-lateral) [143] y = mm (superior-inferior) $_{[144]}$ ____mm (anterior-posterior) [145] Largest Dimension of Mass _____ mm _ [146] Mass Shape (select one) [147] Round Oval 0 Lobulated Irregular Mass Margins (select one) [148] Circumscribed Microlobulated Obscured Indistinct Spiculated **Distance Between Ends of Spiculation** (answer if margin is spiculated) **」mm** _[149] Mass Density (select one) [150]

ACRIN Study 6657

PLACE LABEL HERE

Institution No. Institution Participant Initials _____ Case No.

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 $_{[157]}$

- Yes

Additional Masses [158]

- 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]

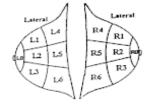
- Yes (report in section B)

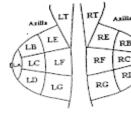
Total Number _____

Reporting Calcification Cluster#

Cranio-Caudal

Medio-Lateral Oblique





Calcification Location:

Cranio-Caudal (select all that apply)

R0 _[167] L0_[160] L1 [161] R1 [168] R2 [169] L2 [162] П R3 [170] R4 [171] R5 [172] R6 [173] L3 [163] L4 [164] L5 [165] L6 _[166] П

High

Equal Low

Fat containing

N1	ACRIN 6657 Extension Mammography Interpretation Form	
If this is a re	evised or corrected form, please $\sqrt{\text{box.}}$	
	Comparison of Calcification Cluster Color of the colo	R
	mm [190] prphology of Calcification: (select one) nign Appearing [191] Skin Calcifications Vascular Calcifications Coarse ("Pop-corn-like") Large Rod-like Round Lucent centered Eggshell or Rim Milk of Calcium Suture Dystrophic Punctate	
0	ermediate Concern Amorphous or Indistinct ther Probability Pleomorphic or Heterogenous (Granular)	
Cal 0 0 0 0 0 Cal Re 0 0 0	Fine, Linear, Branching (Casting) Icification Distribution (select one) Grouped/Clustered Linear Segmental Regional Diffuse/Scattered Icification Cluster Associated with Mass ported on This Form [193] No Yes, associated with previously identified mass # (#1-3) [194]	
0	Icification Cluster Corresponds to Index Lesion No Yes ditional Calcification Clusters No (proceed to section C) Yes (continue)	

ACRIN Study 6657 PLACE LABEL HERE				
Instituti	on	Ins	titution No	
Particip	oant Initials	Cas	se No	
	PRE-T	REATM	ENT	
eporting	g Calcification Cl	uster#	[197]	
	alcification Locat			
C	ranio-Caudal (se L0	elect all tha		
	[198]		R0 _[205] R1 _[205]	
	L2 [199]	П	R2 _[207]	
	L3 [201]		R3 [208]	
	L4 [202]		R4 [209]	
	L5 _[203]		R5 [210]	
	L6 [204]		R6 [211]	
M	edio-Lateral (sele	ect all that	apply)	
	LT _[212]		RT _[220]	
	LA [213]		[221]	
	LB _[214]		110 [222]	
	LC [215]		RC [223]	
	LD _[216]		RD [224] RE [225]	
	LF _[217]		RF [225]	
	L G [218]		PC [226]	
	argest Dimensior	of Calcif	[227]	or
		I OI Calcii	ication Glust	CI
	[228]			,
M Be	orphology of Cal enign Appearing	cification	: (select one) [229]
0	Skin Calcification	ns		
0	Vascular Calcifi			
0	Coarse ("Pop-co	orn-like")		
0	Large Rod-like			
0	Round Lucent centered	ı		
0	Eggshell or Rim	=		
0	Milk of Calcium			
0	Suture			
0	Dystrophic			
0	Punctate			
Int	termediate Concer	n		
0	Amorphous or Ir	ndistinct		
Hi	gher Probability			
0	Pleomorphic or I Fine, Linear, Bra	-	•)
Ca	alcification Distri	bution (s	elect one)	,
0	Grouped/Cluster	red	[230	J
0	Linear			
0	Segmental			
0	Regional			
0	Diffuse/Scattere	d		

		r	N		1	_
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					C	a

ACRIN 6657 Extension

Mammography Interpretation Form	ACRIN Study 6657 PLACE LABEL HERE		
If this is a revised or corrected form, please √box.	Institution Institution No		
it tills is a revised of corrected form, please V box.	Participant Initials Case No		
Calcification Cluster Associated with Mass Reported on This Form [231]	PRE-TREATMENT		
o No o Yes, associated with previously identified mass # [] (#1-3) [232] Calcification Cluster Corresponds to Index Lesion [233] o No	Calcification Distribution (select one) [268] o Grouped/Clustered o Linear o Segmental o Regional o Diffuse/Scattered		
o Yes Additional Calcification Clusters o No (proceed to section C) o Yes (continue) Reporting Calcification Cluster#	Calcification Cluster Associated with Mass Reported on This Form [269] o No o Yes, associated with previously identified mass # [41-3] [270]		
Calcification Location: Cranio-Caudal (select all that apply)	Calcification Cluster Corresponds to Index Lesion [271]		
□ 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]	o No o Yes Additional Calcification Clusters [272] o No o Yes SECTIONC: CLINICALLY RELEVANT ARCHITECTURAL DISTORTIONS (Report index lesion if visualized. Report descriptive data for the three most prominent architectural distortions.) Architectural Distortion(s) Identified [15]		
$\begin{array}{c cccc} & LD & [254] & & & & & & & & \\ & LE & [255] & & & & & & \\ & LF & [256] & & & & & & \\ & LG & [257] & & & & & & \\ & & & & & & \\ & & & & & $	o No o Yes (report in section C) Total Number [
Largest Dimension of Calcification Cluster	Reporting Architectural Distortion # [273]		
Morphology of Calcification: (select one) [267]	Cranio-Caudal Medio-Lateral Oblique		
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	Lateral R4 R1 R5 R2 R2 R5 R6 R3 R6 R6 R6 R6 R6 R6		
o Milk of Calcium o Suture o Dystrophic o Punctate	Architectural Distortion Location: Cranio-Caudal (select all that apply)		
Intermediate Concern	$\begin{array}{c cccc} & & \square & & \text{L1}_{[275]} & & \square & & \text{R1}_{[282]} \\ & \square & & \text{L2}_{[276]} & & \square & & \text{R2}_{[283]} \end{array}$		
o Amorphous or Indistinct Higher Probability o Pleomorphic or Heterogenous (Granular)	□ L3 [276] □ R3 [284] □ L4 [278] □ R4 [285] □ L5 [279] □ R5 [286]		
o Fine, Linear, Branching (Casting)			

N 1

ACRIN 6657 Extension

Mammography Interpretation Form If this is a revised or corrected form, please $\sqrt{\text{box}}$. Medio-Lateral (select all that apply) LT [288] RT_[296] RA [297] LA [289] LA [288]

LB [290]

LC [291]

LD [292]

LE [293] RB [298] RC [299] LD [292] LE [293] LF [294] RD [300] RE [301] RF [302] [294] [302] RG [303] LG [295] **Largest Dimension of Architectural Distortion** _____ **mm** [304] **Architectural Distortion Associated with Mass** Reported on This Form $_{[305]}$ Yes, associated with previously identified mass # [__] (#1-3) [306] **Architectural Distortion Corresponds to Index** Lesion [307] No o Yes Additional Architectural Distortions [308] o No (proceed to question 13) o Yes (continue) **Architectural Distortion Location:** Cranio-Caudal (select all that apply) R0_[317] L0_[310] R1 [318] R2 [319] R3 [320] R4 [321] R5 [322] R6 [323] L6 [316] Medio-Lateral (select all that apply) RT_[332] LT_[324] RA [333] LA [325] RB [334] RC [335] LB [326] LC [327] RD [336] RE [337] RF [338] RG [339] LD [328] LE [329] LF [330] LG [331]

Largest Dimension of Architectural Distortion

ACRIN Study 6657

PLACE LABEL HERE				
Institution		_ Institut	ion No	
Participant	Initials	_ Case N	lo	
	PRE-TRE	ATMEN	T	
Architectural Distortion Associated with Mas Reported on This Form o No o Yes, associated with previously identified mass # (#1-3) [342]				
Ar Le o o	chitectural Distort esion _[343] No Yes	tion Corre	esponds to Index	
A 0 0 0	dditional Architect No (proceed to qu Yes (continue)	ural Disto uestion 13	ortions _[344] 3)	
Reporting	Architectural Dis	tortion #	[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	LA [361] LB [362] LC [363] LD [364] LE [365] LF [366] LG [367] argest Dimension of	□ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □	RA [369] RB [370] RC [371] RD [372] RE [373] RF [374] RG [375]	

____ **mm** _[376]

Architectural Distortion Associated with Mass Reported on This Form $_{[377]}$

- No
- Yes, associated with previously identified mass # [___] (#1-3) [378]

Architectural Distortion Corresponds to Index Lesion [379]

- No
- Yes

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

N1

ACRIN 6657 Extension Mammography Interpretation Form

If this is a revised or corrected form, please $\sqrt{\text{box.}}$

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)

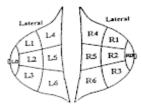
- ☐ Intramammary Lymph Node [382]
- ☐ Asymmetric Breast Tissue [383]
- ☐ Focal Asymmetric Density [384]

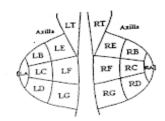
14. Full Extent of Disease

(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

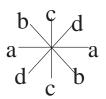
ACRIN Study 6657

PLACE LABEL HERE

Institution _____ Institution No. ____

Participant Initials _____ Case No. _

PRE-TREATMENT



Orientation of Longest Diameter Measurement

(refer to above diagrams - use same orientation for all mammograms) $_{\mbox{\tiny 13861}}$

- 0 8
- o b
- o C
- 0

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]

- 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 o	r the completed/printed	web form)
Signature of person responsible for data	[390]	2 0 0
Signature of person entering data onto web	[392]	

Visit 1 – Pre-Registration / Baseline Visit (within 3 months before or 2 weeks after entry MRI but before treatment start)

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.

Visit 1 – Pre-Registration / Baseline Visit (within 3 months before or 2 weeks after entry MRI but before treatment start)

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.

Visit 1 – Pre-Registration / Baseline Visit (within 3 months before or 2 weeks after entry MRI but before treatment start)

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".

Visit 1 – Pre-Registration / Baseline Visit (within 3 months before or 2 weeks after entry MRI but before treatment start)

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]	Complete For Study Breast Only
O Baseline / Pre-Treatment		
	O Baseline / Fre freatment	
	1a. Was MRI performed? [407]	9. Study Breast [10]
	O No* (complete Q1b, then sign and date form)	O Right
	O Yes (proceed to Q2 and continue with form)	O Left
	o res (proceed to Q2 and continue with form)	0 2010
	1b. *If No, provide reason: [408]	10. Density of Breast Parenchyma [11]
	O Scheduling problem	O Mostly fat
	O Equipment failure	O Scattered fibroglandular tissue
	O Participant refusal	O Heterogeneously dense
	O Medical reason	O Extremely dense
	O Injection site complications	
		11. Index Lesion Identified on this MRI Exam [16]
	O Claustrophobia	O No
	O Practicipant withdrew consent	O Yes
	O Progressive disease	
	O Participant death	12. Were Clinically Relevant Mass(es) Identified $_{[12]}$
	O Other, specify:	O No
	[409]	O Yes (report in Section A)
	O Unknown	
		Total Number _[13]
2.	Date of MRI 20 (mm-dd-yyyy) [3]	[]
		13. Remember to complete clinically revelant regional
3.	Date of Interpretation 20 _[4]	enhancements located on page 5 - Section B
	(mm-dd-yyyy)	
4.	Reader Name:	
5.	Reader ID:	
	[o]	
6	Patient Weight (kgs)	
0.	Patient Weight (kgs) [7]	
	6a. Patient Height (cm)	
7.	Total Amount of Gadolinium Injected (cc)	
	[o]	
8. Were Clinically Relevant Enhancing Lesion(s) Identified [9]		
O No (sign and date form)		
	O Yes	

(—					
	$\boxed{1}$ If this is a revised or corrected form, please $\sqrt{\sf box}$.	ACR	RIN Study 6657	Case #	
	The state of the s		PLACE LA	ABEL HERE	
	ection A: Clinically Relevant Masses	Insti	tution	Institution No.	
	port on the study breast only. Report descriptive data for up to three	Parti	icipant's Initials	Participant's I.D. No.	
	asses. If more than three masses are present, report only the three	l uiti	-		
	ost prominent to include the index lesion, if visualized.		BASELINE/F	PRE-TREATMENT	
1.	Reporting Mass # 1	1e.	T2 Appearance (se		
·	Cranio-Caudal Medio-Lateral		O Hypointense to O Isointense to s	o surrounding breast tissue o surrounding breast tissue surrounding breast tissue	
	Lateral Axilla LT RT Axilla	1f.	O Unable to evalu		
	L1 L5 R5 R2 P0 LB LE RE RB			rongest degree seen) _[54]	
	L3 L6 R6 R3 CLC LF RF RC CO		O Moderate O Marked		
		1g.	Enhancement Patte		
1a.	Location:		O Gradual	ongest pattern seen) [55]	
	Cranio-Caudal (select all that apply) ☐ L0 [19] ☐ R0 [25]		O Sustained		
	\Box I1 \Box \Box R1 \Box		O Washout		
	$\Box 12^{[19]} \qquad \Box R2^{[20]}$				
	\square L3 $^{[20]}_{[21]}$ \square R3 $^{[27]}_{[28]}$	1h.		Number of Representative	
	□ L4 _[22] □ R4 _[29]		Slices (list up to 3)		
	\sqcup L5 _[23] \sqcup R5 _[30]				1
	☐ L6 [24] ☐ R6 [31]		Series:	[339] Image #	^{_]} [340
	Medio-Lateral (select all that apply) ☐ LT rest ☐ RT rest		Series :	[341] Image #] [342
	☐ LA [33] ☐ RA [40] ☐ LB [34] ☐ RB [43]		Series :	[343] Image #	_ _{[344}
	$\Box \Box C^{[34]} \qquad \Box BC^{[42]}$				٠
	[35][43]	1i.	Corresponds to Inc	dex Lesion _[56]	
	☐ LD [36] ☐ RD [44] ☐ LE [37] ☐ RE [45]		O No O Yes (skip Q1j)		
			O Tes (skip QTJ)		
	$\Box \ LF_{[38]} \ \Box \ RG_{[46]}^{[46]}$	1j.	Has this been inder	pendently biopsied? [393]	
1b.	Size (record all three measurements [0 = not seen])	',	o No	[393]	
			o Yes		
	x = mm (medial-lateral) [48]		o Don't know		
	y = mm (superior-inferior) [49]	Comr	ments about this mass	s:	
	z = mm (anterior-posterior) _[50]				
1c.	Shape/Margin (select one) [51] O Smooth round				
	O Smooth oval				
	O Lobulated				⁻ [345
	O Irregular				ر٥٠٠٥
	O Spiculated				
1d.	Internal Enhancement (select one) [52]	1k.	Additional Masses	[394]	
	O Homogeneous confluent		o No o Yes		
	O Heterogeneous		0 162		
	O Rim enhanced				
	O Centrally enhanced	If no	additional masses	s to report complete pag	e 5
	O Dark septation(s) O Enhancing septation(s)			oport oompiete pag	J J
1	= -inianonig ooptation(o)	1			

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. Reporting Mass # 2	$\boxed{1}$ If this is a revised or corrected form, please $\sqrt{\text{box}}$.	ACRIN Study 6657	Case #
BASELINE/PRE-TREATMENT	Report on the study breast only. Report descriptive data for up to three	Institution	Institution No.
2. Reporting Mass # 2		Participant's Initials	Participant's I.D. No.
Cranio Caudal Medio-Lateral Medio-	most prominent to include the index lesion, if visualized.	BASELINE/F	PRE-TREATMENT
2a. Location: Cranio-Caudal (select all that apply)	Cranio-Caudal Medio-Lateral Lateral LT RT Azilla R4 R1 L5 R5 R2 R0 L6 R6 R3 LC LF R6 R0 RD	O Hyperintense to O Hypointense to O Isointense to si O Unable to evalu 2f. Degree of Enhance (characterize by stro O Minimal O Moderate O Marked	o surrounding breast tissue surrounding breast tissue urrounding breast tissue urrounding breast tissue ate ment ongest degree seen) [95]
L4	Cranio-Caudal (select all that apply) □ L0 [59] □ R0 [66] □ L1 [60] □ R1 [67] □ L2 [61] □ R2 [68]	(characterize by stro O Gradual O Sustained O Washout	ongest pattern seen) [96]
LT RA RA	$ \begin{array}{c cccc} & L4 & [62] & & & R4 & [69] \\ & L5 & [64] & & & R5 & [71] \\ & L6 & [65] & & & R6 & [72] \end{array} $	Slices (list up to 3) Series :	[347] Image #
2b. Size (record all three measurements [0 = not seen]) x =	□ LT □ RT [81] □ LA [74] □ RA [82] □ LB [75] □ RB [83] □ LC [76] □ RC [84] □ LD [77] □ RD [85] □ LE [78] □ RE [86]	Series : 2i. Corresponds to Ind O No O Yes (Skip Q2j) 2j. Has this been indep	[352] Image # [352] [352] [352] [352]
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	x = mm (medial-lateral) [89]	O Yes	
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		Comments about this mass	:
O Homogeneous confluent O Heterogeneous O Rim enhanced	O Smooth round O Smooth oval O Lobulated O Irregular		[353]
O Dark septation(s) * If no additional masses to report complete page of the	O Homogeneous confluent O Heterogeneous O Rim enhanced O Centrally enhanced O Dark septation(s)	O No O Yes	

$\boxed{1}$ If this is a revised or corrected form, please $\sqrt{\text{box}}$.	ACRIN Study 6657 Case #
	PLACE LABEL HERE
Section A: Clinically Relevant Masses	Institution Institution No.
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	Participant's Initials Participant's I.D. No.
most prominent to include the index lesion, if visualized.	BASELINE/PRE-TREATMENT
3. Reporting Mass # 3 [99] Cranio-Caudal Medio-Lateral	3e. T2 Appearance (select one) [135] O Hyperintense to surrounding breast tissue O Hypointense to surrounding breast tissue O Isointense to surrounding breast tissue
Lateral R4 R1 R5 R2 R5 R3 R6 R3 R6 R3 R6 R6 R7 R6 R7 R6 R7 R7	O Unable to evaluate 3f. Degree of Enhancement (characterize by strongest degree seen) O Minimal O Moderate O Marked
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 [112]	3g. Enhancement Pattern (characterize by strongest pattern seen) O Gradual O Sustained O Washout 3h. Series and Image Number of Representative Slices (list up to 3)
Medio-Lateral (select all that apply) LT [114]	Series : [355] Image # [356] Series : [357] Image # [356] Series : [357] Image # [356] Series : [359] Image # [366] 3i. Corresponds to Index Lesion [138] O No O Yes (Skip Q3j) 3j. Has this been independently biopsied? [397]
3b. Size (record all three measurements [0 = not seen]) x = mm (medial-lateral) [130] y = mm (superior-inferior) [131] z = mm (anterior-posterior) [132]	O No O Yes O Don't know Comments about this mass:
3c. Shape/Margin (select one) [133] O Smooth round O Smooth oval O Lobulated O Irregular O Spiculated	3k. Additional Masses [398]
3d. Internal Enhancement (select one) O Homogeneous confluent O Heterogeneous O Rim enhanced O Centrally enhanced O Dark septation(s) O Enhancing septation(s)	O No O Yes * Remember to complete Section B - Clinically Relevant Regional Enhancements on page 5

$\boxed{1}$ If this is a revised or corrected form, please $\sqrt{\text{box}}$.	ACRIN Study 6657 Case #
	PLACE LABEL HERE
<u>Section B:</u> Clinically Relevant Regional Enhancements Report on the study breast only. Report descriptive data for up to three	Institution Institution No.
regional enhancements. If more than three are present, report only the	
three most prominent to include the index lesion, if visualized.	BASELINE/PRE-TREATMENT
1. Were Clinically Relevant Regional Enhancements Identified [14] O No O Yes (report in Section B) Total Number [15] Reporting Regional Enhancement # 1 [140] Cranio-Caudal	1e. T2 Appearance (select one) 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) O Minimal O Moderate O Marked 1g. Enhancement Pattern (characterize by strongest pattern seen) O Gradual O Sustained O Washout 1h. Series and Image Number of Representative Slices (list up to 3) Series : [364] Image # [367] Series : [366] Image # [367] Series : [368] Image # [369] 1i. Corresponds to Index Lesion O No O Yes (Skip Q1j) 1j. Has this been independently biopsied? [399] O No O Yes
	O Don't know
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	Comments about this regional enhancement:
O Regional	
O Diffuse patchy 1d. Internal Enhancement (select one) O Homogeneous confluent O Heterogeneous non-specific O Heterogeneous stippled, punctate O Heterogeneous clumped O Septal, dendritic O Asymmetric	1k. Additional Regional Enhancements [400] O No O Yes * If no additional Clinically Relevant Regional Enhancements to report complete
O Symmetric	page 8 - Section C
O Not applicable	1 - 3

T	1 If this is a revised or corrected form, please $\sqrt{\sf box}$.	AC	RIN Study 6657	Case #
			PLACE L	ABEL HERE
<u>Section B:</u> Clinically Relevant Regional Enhancements Report on the study breast only. Report descriptive data for up to three			titution	Institution No.
	al enhancements. If more than three are present, report only the	Par	ticipant's Initials	Participant's I.D. No.
three most prominent to include the index lesion, if visualized.		BASELINE/PRE-TREATMENT		
1	Cranio-Caudal Medio-Lateral Lateral Asilla LT RE RB RS R2 R0 L3 L6 R6 R3 Location:	2e. 2f.	O Hypointense to sur O Isointense to sur O Unable to evalua Degree of Enhance (characterize by stro O Minimal O Moderate O Marked	surrounding breast tissue surrounding breast tissue rounding breast tissue teement engest degree seen) [214]
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] □ RE [207] □ LE [199] □ RF [208] □ LG [201] □ RG [209]	2g. 2h.	O Gradual O Sustained O Washout Series and Image Slices (list up to 3) Series : [3 Series : [3 Corresponds to Ind O No O Yes (Skip Q2j)	Number of Representative Image #
2b.	Largest Dimension	2j.	Has this been indepe O No O Yes O Don't know	ndently biopsied? [401]
2c.	Distribution Subtype (select one) 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	Con		onal enhancement: [378]
2d.	Internal Enhancement (select one) O Homogeneous confluent O Heterogeneous non-specific O Heterogeneous stippled, punctate O Heterogeneous clumped O Septal, dendritic O Asymmetric	2k. *		nically Relevant Regional
	O Symmetric			to report complete
	O Not applicable		page 8	- Section C

$\boxed{1}$ If this is a revised or corrected form, please $\sqrt{\text{box}}$.	ACRIN Study 6657 Case #
in the to a revised of corrected form, product $\sqrt{500.0}$	PLACE LABEL HERE
Section B: Clinically Relevant Regional Enhancements Report on the study breast only. Report descriptive data for up to three	Institution Institution No. Participant's Initials Participant's I.D. No.
regional enhancements. If more than three are present, report only the three most prominent to include the index lesion, if visualized.	BASELINE/PRE-TREATMENT
3a. Location: Cranio-Caudal Medio-Lateral RR RI RS R2 RS R2 RS R2 RS R2 RS R	3e. T2 Appearance (select one) 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) O Minimal O Moderate O Marked 3g. Enhancement Pattern (characterize by strongest pattern seen) 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 O No O Yes (Skip Q3j)
3b. Largest Dimension	3j. Has this been independently biopsied? [403] O No O Yes O Don't know
O Diffuse non-specific U Linear non-specific U Linear ductal: Smooth U Linear ductal: Irregular U Linear ductal: Clumped U Segmental U Regional U Diffuse patchy	Comments about this regional enhancement:
3d. Internal Enhancement (select one) O Homogeneous confluent O Heterogeneous non-specific O Heterogeneous stippled, punctate O Heterogeneous clumped O Septal, dendritic O Asymmetric O Symmetric O Not applicable	3k. Additional Regional Enhancements [404] O No O Yes * Remember to complete page 8 - Section C

If this is a revised or corrected form, please $\sqrt{\text{box}}$.

Case #

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]

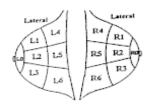
☐ Cyst(s) [274]

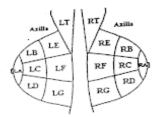
Other [388]

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

Cranio-Caudal

Medio-Lateral





Direction for Longest Diameter Measurement

(indicate which diagram above was used to determine measurement direction) [275]

cranial - caudal

medio-lateral

ACRIN Study 6657

PLACE LABEL HERE

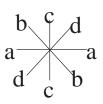
Institution

Institution No.

Participant's Initials

Participant's I.D. No.

BASELINE/PRE-TREATMENT



Orientation of Longest Diameter Measurement

(indicate the orientation used to determine measurement direction) [276]

 \circ

0 b

0 С

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

0 Tis In Situ

<5 mm T1a

 \circ T1b 5-9 mm 0 T1c 10-20 mm

O T2 21-50 mm

O T3 $>50 \,\mathrm{mm}$

0 T4a chest wall

0 T4b

chest wall and skin T4c 0

O T4d inflammatory

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

O F0 no other area of suspicious enhancement

≤10mm 0 F1

O F2 11-20 mm

0 F3 21-30 mm

0 F4 31-40 mm

0 F5 41-50 mm 0 F6 51-60 mm

O F7 61-70 mm

O F8 71-80 mm

0 F9 81-90 mm

O F10 91-100 mm

O FX >100 mm, please record

∫ mm. _[280]

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

no quadrant of suspicious enhancement O Q0

one quadrant of suspicious enhancement O Q1

O Q2 two quadrants of suspicious enhancement

O Q3 three quadrants of suspicious enhancement

four quadrants of suspicious enhancement

$\overbrace{1}$ If this is a revised or corrected form, please $\sqrt{\text{box}}$.	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 partic O No O Yes	cipate in the additional MRI [392]
COMMENTS:		[282]
Radiologist Signature (radiologist must sign either the completed paper form or the comp		
Signature of person responsible for data	[—] [283]	
Signature of person entering data onto web	[285] Date f	orm completed (mm-dd-yyyy)
* Please remember com	plete page 8 - Section	on C

"Copyright 2007" ACRIN 6657 T1 12-11-07 9 of 9

Visit 1 – Pre-Registration / Baseline Visit

(within 4 weeks prior to start of neoadjuvant treatment)

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.

Visit 1 - Pre-Registration / Baseline Visit

(within 4 weeks prior to start of neoadjuvant treatment)

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.
- 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.

Visit 1 – Pre-Registration / Baseline Visit

(within 4 weeks prior to start of neoadjuvant treatment)

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.
- 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.

Visit 1 - Pre-Registration / Baseline Visit

(within 4 weeks prior to start of neoadjuvant treatment)

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.

ACRIN 6657 Extension	AODINO	GGE7				
Ultrasound Interpretation Form	ACRIN Study 6657 PLACE LABEL HERE					
	Institution	Institution No				
If this is a revised or corrected form, please $\sqrt{\text{box.}}$	Participant Initials	Case No				
	PRE-TR	EATMENT				
Instructions: In accordance with protocol, two optional diagnostic ultrasoration and in a diagnostic ultrasound is performed. Report only ultrasound the index lesion only. The index lesion corresponds to the tumor used to dultrasound via the ACRIN website. Submit paper form only for revisions on the performed.	exams corresponding to the first MRI efine participant eligibility. Submit thi	exam. Please report characteristics of s form within two weeks of each				
Protocol Time Point [1] Pre-treatment	INDEX LESION: (The index lesion correspondent control of the index lesion)	onds to the tumor used to define				
2. Date of Ultrasound (mm-dd-yyyy) [2		Medio-Lateral Oblique				
3. Date of Interpretation (mm-dd-yyyy) [3]	Lateral R4 R1	Axilla LT RT Axilla RE RB				
4. Reader Name:[4]	L3 L6 R6 R3	LC LF RF RC CO				
5. Reader ID: [5]		7 7				
6. Study Breast [6]	Index Lesion L Cranio-Caudal	ocation: (select all that apply)				
o Right	□ L0 _[13]	□ R0 _[20]				
o Left o Bilateral	☐ L1 [14] ☐ L2 [15]	☐ R1 [21] ☐ R2 [22]				
o bilateral		\square R2 $_{[22]}$ \square R3 $_{[23]}$				
7. Clinically Relevant Lesion(s) Identified [7]		□ R4 [24]				
o No (sign and date form)	☐ L5 [18] ☐ L6 [19]	☐ R5 [25] ☐ R6 [26]				
o Yes		(select all that apply)				
	☐ LT [27]	□ RT [35]				
8. Total Number of Clinically Relevant Lesions [8]	☐ LA [28]	☐ RA [36]				
		☐ RC [37]				
9. Index Lesion Identified on Ultrasound [9]		□ RD [39]				
No (sign and date form)Yes	☐ LE [32] ☐ LF [33]	☐ RE [40] ☐ RF [41]				
	☐ LG [33]	☐ RG [41]				
10. Doppler Characteristics [10]	Size of Index L					

- o Not applicable
- o Hypervascular
- o Hypovascular
- 11. Characterize the Index Lesion $_{[11]}$
 - o Cystic
 - o Solid

 - o Unknown

•		OI IIIGOX EGGIOII
		mm (medial-lateral) _[43]
У	' =	mm (superior-inferior) [44]
Z	: =	mm (anterior-posterior) [45]

Largest Dimension of Index Lesion

mm	[46]
----	------

	U1
--	----

TJ1	ACRIN 6657 Extension Ultrasound Interpretation Form	ACRIN Study 6657 PLACE LABEL HERE			
	Oltrasound Interpretation Form				
If this is a rev	vised or corrected form, please $\sqrt{\text{box.}}$	Institution	Institution No		
11 11113 13 4 16	vised of corrected form, please v box.	Participant Initials	Case No		
		PRE	-TREATMENT		
Н	omogeneity of Index Lesion (select one) [47]				
0	Homogeneous				
0	Heterogeneous without cysts				
0	Heterogeneous with cysts				
Ed	chogenicity of Index Lesion (select one) [48]				
0	Hypoechoic				
0	Isoechoic				
0	Hyperechoic				
В	order of Index Lesion (select one) [49]				
0	Smooth				
0	Spiculated				
0	Lobular				
0	Irregular Other, specify,				
0	Other, specily,				
COMMENTS	:				
COMMENTO					
			[51		
Radiologist	Signature	_			
	must sign either the completed paper form or the co	ompleted/printed web form)			
Signatura	f person responsible for data	— _[52]			
orginature 0	i personi responsibile foi data				
			200		
Signature of	f person entering data onto web	— [54] Date 1	form completed (mm-dd-yyyy) [53]		

Visit 1 - Pre-Registration / Baseline Visit (4 weeks prior to start of neoadjuvant treatment)

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.

Visit 1 - Pre-Registration / Baseline Visit (4 weeks prior to start of neoadjuvant treatment)

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.

ACRIN - 6657 COMPLETION INSTRUCTIONS Visit 1 – Pre-Registration / Baseline Visit (4 weeks prior to start of neoadjuvant treatment)

$\mathbf{V1}$

ACRIN 6657 Extension

MRS Form: Baseline / Pre-Treatment MRS - 1

	′	
If this is a revised or corrected form, please $\sqrt{}$	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.

311	oulu L	oe us	sed at every imaging visit.	
1.	Time		nt [1] S 1 Baseline Pre-Treatment	
3.	Ο	1	S performed? [4] No (if no, complete Q3a, sign and date form) Yes (If yes, continue with form)	
	3a.		o, specify reason: [5] O 1 No time O 2 Technical Problem O 88 Other, specify	
Ge	enera	al		
4.	Date	of N	MRI . (mm-dd-yyyy) [17]	
5.	Mag	net f	ield strength _[18]	
		1		
		2		
	O	88	Other, specify[19]	
6.	Pers (sele	on r	esponsible for voxel placement: [20]	
			MR Technologist	
			Research Associate	
	0	3	Nurse PI Radiologist	
			Physician	
			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,	
Opcony,	[23]

Medio-Lateral

Medio-Lateral

(select all that apply)

7b. Date of last phantom scan

		_			_					
(mm-dd-yyyy)								[24		

8. MRS Acquisition

Cranio-Caudal

Lateral R4 R1 1.2 L5 R5 R2 sup 1.3 L6 R6 R3	Asilla LT RT Asilla RE RB RF RC RD LG RG RD
L1 L4 R4 R1 12 L5 R5 R2 R01 L3 R3	LB LE RE RB LC LF RF RC LD RD

Cranio-Caudal (select all that apply)

□ L0 _[25]	☐ R0 _[32]	☐ LT _[39]	☐ RT _[47]
☐ L1 [26]	☐ R1 [33]	☐ LA [40]	☐ RA [48]
☐ L2 _[27]	☐ R2 _[34]	☐ LB _[41]	☐ RB [49]
☐ L3 _[28]	☐ R3 _[35]	☐ LC _[42]	\square RC _[50]
☐ L4 _[29]	☐ R4 _[36]	☐ LD _[43]	\square RD _[51]
☐ L5 [30]	☐ R5 _[37]	☐ LE _[44]	☐ RE _[52]
□ L6 _[31]	☐ R6 _[38]	☐ LF _[45]	\square RF _[53]
		☐ LG _[46]	☐ RG _[54]

|V1|

ACRIN 6657 Extension

MRS Form: Baseline / Pre-Treatment MRS - 1

If this is a revised or corrected form, please $\sqrt{\text{box}}$.

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	7]
	Very Confident	O 5Not Confident
	10a. Reasons for reduced confidence: (select all that apply)	
	☐ Target lesion not clearly visualized [58]	
	☐ Clip artifact present [61] ☐ Other [62]	
		[63]
201	MMFNTS:	
COI	MMENTS:	
		[64]
Siar	nature of person responsible for the data	Date form completed (mm-dd-yyyy) [66]
oigi	action of potoon responsible for the data	

Visit 1 – Baseline / Pre-Treatment Visit (within 4 weeks prior to start of neoadjuvant treatment)

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).

Page 1 of 2

Visit 1 – Baseline / Pre-Treatment Visit (within 4 weeks prior to start of neoadjuvant treatment)

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

Complete For Study Breast Only

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.

	Protect Time Point	
1.	Protocol Time Point [1]	
o MRI1.1 Additional Baseline / Pre-Treatment reproducibility		
		9. Study Breast (Same as identified in Baseline (T1 form)) [10]
	A - West MDI and source 10	O Right
	1a. Was MRI performed? [407]	O Left
	O No* (complete Q1b, then sign and date form)	
	O Yes (proceed to Q2 and continue with form)	10. Density of Breast Parenchyma [11]
		O Mostly fat
	1b. *If No, provide reason: [408]	O Scattered fibroglandular tissue
	O Scheduling problem	O Heterogeneously dense
	O Equipment failure	O Extremely dense
	O Participant refusal	
	O Medical reason	11a. Were Clinically Relevant Mass(es) Identified
	O Injection site complications	on Baseline (T1) _[12]
	O Claustrophobia	O No
	•	O Yes (report in Section A)
	O Participant withdrew consent	
	O Progressive disease	Total Number (enter same response from T1 Q11a)
	O Participant death	(13)
	O Other, specify:	11b. Are New masses now seen that were
		not seen on Baseline [362]
	[409]	O No
	O Unknown	O Yes (report on supplemental TS form)
	20	
2.	Date of MRI 20 (mm-dd-yyyy) [3]	12a. Were Clinically Relevant Regional Enhancements
		Identified on Baseline (T1) [14]
3.	Date of Interpretation 20 _[4]	O No
	(mm-dd-yyyy)	O Yes (report in Section B)
	(),,,,,	
4.	Reader Name:[5]	Total Number (enter same response from T1 Q12a)
	[0]	[10]
5.	Reader ID:	12b. Are New Regional Enhancements now seen
	[6]	that were not seen on baseline [387]
6	Patient Weight (kgs)	O No
0.	Patient Weight (kgs) [7]	O Yes (report on supplemental TS form)
_		
7.	Total Amount of Gadolinium Injected (cc) [8]	13. Index Lesion Identified on this MRI Exam [16]
		O No
8.	Were Clinically Relevant Enhancing Lesion(s) Identified [9]	O Yes
	O No (sign and date form)	
	O Yes	
		* Please remember to complete page 8

$\stackrel{\frown}{}$ If this is a revised or corrected form, please $\sqrt{\sf box}$.	ACRIN Study 6657 Case #
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.	Institution Institution No. Participant's Initials Participant's I.D. No. ADDITIONAL BASELINE/PRE-TREATMENT
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 Cranio-Caudal Medio-Lateral Lateral Lateral	 Internal Enhancement (select one) o Homogeneous confluent o Heterogeneous o Rim enhanced o Centrally enhanced o Dark septation(s) o Enhancing septation(s) o No longer a mass T2 Appearance (select one) o Hyperintense to surrounding breast tissue o Hypointense to surrounding breast tissue o Isointense to surrounding breast tissue o Unable to evaluate Degree of Enhancement (characterize by strongest degree seen) o Minimal o Moderate o Marked
Location: Cranio-Caudal (select all that apply) □ L0 [18] □ R0 [25] □ L1 [19] □ R2 [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] □ LA [33] □ RB [41] □ LB [34] □ RC [43] □ LD [36] □ RC [43] □ LD [36] □ RE [45] □ LE [37] □ RE [45] □ LF [38] □ RF [46] □ LG [39] □ RG [47]	1g. Enhancement Pattern (characterize by strongest pattern seen) o Gradual o Sustained o Washout 1h. Series and Image Number of Representative Slices (list up to 3) Series : [339] Image # [34 Series : [341] Image # [34 Series : [343] Image # [34 Ii. Corresponds to Index Lesion [56] o No o Yes 1j. Has this been independently biopsied? [393]
1b. Size (record all three measurements [0 = not seen]) $x = $	o No o Yes 1k. Additional Masses [394] o No o Yes
z = mm (anterior-posterior) [50] 1c. Shape/Margin (select one) [51] o Smooth round o Smooth oval o Lobulated o Irregular o Spiculated	COMMENTS:

o No longer a mass

[345]

	$\overline{\Gamma}$ If this is a re
All	ection A: Masses masses documented ction. If new masses a Form.
2.	Is the lesion identificatill visible? [346] o No (skip 2a-2j) o Yes (complete 2o Not Applicable
	Cranio-Caudal
	Lateral R4 L1 L4 R4 R5 L5 R5 L6 R6
2a.	Location: Cranio-Caudal

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

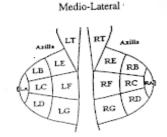
Masses

documented on the T1 Form must be reported in this w masses are now present, report on the supplemental

sion identified as Mass #2 on the T1 Form ole?_[346]

- skip 2a-2j)
- (complete 2a-2k)
- Applicable

R2



2a.	Location:		
	0		

Cranio-Caudal	(select all that apply,

	I a [59]	D4 [00]
	L1 [60] L2 [61] L3 [62] L4 [63] L5 [64] L6 [65]	R1 [67] R2 [68] R3 [69] R4 [70] R5 [71] R6 [72]
	12 [00]	P2 [0/]
ш	LE [61]	1881
П	13 [8.1]	R3 [60]
	[62]	[69]
Ш	L4 ;;	R4 :;
	[63]	D [/0]
Ш	L5 1641	K5 ₁₇₄₁
	16 [04]	De [, i]
ш	LO _[65]	rο _[72]
	[OO]	[, -]

Medio-Lateral (select all that apply)

(coroct an triat appro
□ RT [81] □ RA [82] □ RB [83] □ RC [84] □ RD [85] □ RE [86] □ RF [87] □ RG [88]
☐ RB [OZ]
☐ RD [84]
□ RF [85]
□ RE [86]
□ RG [87]
□ KG _[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]

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

- Smooth round
- Smooth oval
- 0 Lobulated
- Irregular 0
- Spiculated 0
- No longer a mass

ACRIN Study 6657

Case #

PLACE LABEL HERE

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

ADDITIONAL BASELINE/PRE-TREATMENT

2d.	Internal Enhancement	(select	one)	[93
				100

- Homogeneous confluent 0
- Heterogeneous 0
- Rim enhanced
- Centrally enhanced
- Dark septation(s)
- Enhancing septation(s)
- No longer a mass

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

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

Degree of Enhancement 2f.

(characterize by strongest degree seen) [95]

- Minimal
- Moderate 0
- Marked

2g. **Enhancement Pattern**

(characterize by strongest pattern seen) [96]

- Gradual
- Sustained
- Washout

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

Series : [347]	Image #
Series : [349]	Image # [350]
Series : [351]	Image #

2i. Corresponds to Index Lesion [97]

- No
- Yes

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

- o No
- o Yes

Additional Masses [396] 2k.

- o No
- o Yes

COMMENTS:_			

[353]

$\overline{\mathbf{TA}}$ If this is a revised or corrected form, please $\sqrt{\mathtt{box}}$.
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
Cranio-Caudal Medio-Lateral
Lateral R4 R1 R5 R2 R0 L5 R6 R3 R6 R3 LT RT Axilla LT RT Axilla LT RE RB RF RC RA RF RC RA RG RD RG RD
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] □ RF [127] □ LF [120] □ RF [128] □ LG [121] □ RG [129]
3b. Size (record all three measurements [0 = not seen])
x = mm (medial-lateral) (120)

mm (superior-inferior) [131]

mm (anterior-posterior) [132]

Shape/Margin (select one) [133]

Smooth round Smooth oval Lobulated

No longer a mass

Irregular Spiculated

Tartic	cipant's Initials Participant's I.D. No.
ADD	DITIONAL BASELINE/PRE-TREATMEN
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) 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 # Series : [357] Image # Series : [359] Image #
3i.	Corresponds to Index Lesion [138] o No o Yes
3ј.	Has this been independently biopsied? [397] o No o Yes
3k.	Additional Masses [398] o No o Yes

ACRIN Study 6657

Institution

Case #

Institution No.

PLACE LABEL HERE

0

0

3с.

[361]

$\overline{\mathbf{TA}}$ If this is a revised or corrected form, please \sqrt{box} .	ACRIN Study 6657 Case #
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.	Institution Institution No. Participant's Initials Participant's I.D. No. ADDITIONAL BASELINE/PRE-TREATMENT
1. Is the lesion identified as Regional Enhancement #1 from the T1 Form still visible? O No (skip 1a-1j) O Yes (complete 1a-1k) O Not Applicable Cranio-Caudal Medio-Lateral Lateral Lateral Reg RB Re	 1d. Internal Enhancement (select one) Homogeneous confluent Heterogeneous non-specific Heterogeneous stippled, punctate Heterogeneous clumped Septal, dendritic Asymmetric Symmetric Not applicable 1e. T2 Appearance (select one) [174] Hyperintense to surrounding breast tissue Hypointense to surrounding breast tissue Isointense to surrounding breast tissue Unable to evaluate 1f. Degree of Enhancement
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]	(characterize by strongest degree seen) o Minimal o Moderate o Marked 1g. Enhancement Pattern (characterize by strongest pattern seen) o Gradual
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]	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]
1b. Largest Dimension	1i. Corresponds to Index Lesion [177] o No o Yes
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	1j. Has this been independently biopsied? [399] o No o Yes 1k. Additional Regional Enhancements [400] o No o Yes

COMMENTS:

[—] [370]

$\overline{\mathbf{TA}}$ If this is a revised or corrected form, please \sqrt{box} .	ACRIN Study 6657	Case #
	PLACE L	ABEL HERE
Section B: Regional Enhancements All regional enhancements documented on the T1 Form must be	Institution	Institution No.
reported in this section. If new regional enhancements are now		Participant's I.D. No.
present, report on the supplemental TS Form.	ADDITIONAL BASE	LINE/PRE-TREATMENT
2. Is the lesion identified as Regional Enhancement #2 on the T1 Form still visible? O No (skip 2a-2j) O Yes (complete 2a-2k) O Not Appliable Cranio-Caudal Medio-Lateral Axilla LT RE RB RF RC LS RG RB RG RB RG RB	o Homogeneous of Heterogeneous of Heterogeneous of Heterogeneous of Heterogeneous of Septal, dendrition of Asymmetric of Symmetric of Not applicable 2e. T2 Appearance (see of Hyperintense to of Hypointense to see of Hyp	non-specific stippled, punctate clumped s lect one) [213] surrounding breast tissue surrounding breast tissue rrounding breast tissue
2a. Location: Cranio-Caudal (select all that apply) L0 [180]	o Minimal o Moderate o Marked 2g. Enhancement Patt (characterize by stro o Gradual o Sustained	ongest degree seen) _[214]
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]	Slices (list up to 3) Series : [3	Number of Representative [372] Image # [373] [374] Image # [375]

☐ LA [194] ☐ LB [196]	☐ RA [202] ☐ RB [204]	2h.	Slices (list up to 3)
☐ LC [197] ☐ LD [198]	☐ RC [205] ☐ RD [206]		Series : [372] Image # [373]
LE [199] LF [200] LG [201]	☐ RE [207] ☐ RF [208]		Series : [374] Image # [375]
☐ LG [201]	☐ RG [208]		Series : [376] Image # [377]
Largest Dimens	ion	2i	Corresponds to Index Lesion

2i.	Co	rresponds to Index Lesion [216]
	0	No
	0	Yes

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

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

COMMENTS:_			

[378]

2b.

2c.

0

0

0

mm _[210]

Distribution Subtype (select one) [211]

o Diffuse non-specific

Segmental

Diffuse patchy

Regional

Linear non-specific

Linear ductal: Smooth Linear ductal: Irregular Linear ductal: Clumped

	If this is a revised or corrected form, please $\sqrt{\text{box.}}$	ACRIN Study 6657 Case #	
		PLACE LABEL HERE	
	tion B: Regional Enhancements	Institution Institution No.	
	egional enhancements documented on the T1 Form must be	Participant's Initials Participant's I.D. No.	
	rted in this section. If new regional enhancements are now ent, report on the supplemental TS Form.	ADDITIONAL BASELINE/PRE-TREATMEN	T
(Is the lesion identified as Regional Enhancement #3 on the T1 Form still visible? O No (skip 3a-3j) O Yes (complete 3a-3k) O Not Applicable Cranio-Caudal Medio-Lateral Lateral La	3d. Internal Enhancement (select one) 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	
За.	Location: Cranio-Caudal (select all that apply) □ L0 □ □ R0 □ [226] □ L1 □ □ R1 □ [227] □ L2 □ □ R2 □ [228] □ L3 □ □ R3 □ [229] □ L4 □ R4	3f. Degree of Enhancement (characterize by strongest degree seen) o Minimal o Moderate o Marked	
	□ L5 [223] □ R5 [230] □ L5 [224] □ R6 [231] □ L6 [225] □ R6 [232] Medio-Lateral (select all that apply) □ LT □ RT □ RA [241] □ LA [234] □ RA [242]	 (characterize by strongest pattern seen) [254] o Gradual o Sustained o Washout 3h. Series and Image Number of Representative	
	□ LB [235] □ RB [243] □ LC [236] □ RC [244] □ LD [237] □ RD [245] □ LE [238] □ RE [246] □ LF [239] □ RF [247] □ LG [240] □ RG [248]	Slices (list up to 3) Series : [380] Image # [380] [380]	33]
3b.	Largest Dimension	[304] - [30	[5]
3c.	Distribution Subtype (select one) [250]	3i. Corresponds to Index Lesion [255] o No o Yes	
	o Diffuse non-specific	3j. Has this been independently biopsied? [403]	
	o Linear non-specific	o No	
	o Linear ductal: Smooth	o Yes	
	o Linear ductal: Irregular o Linear ductal: Clumped o Segmental o Regional o Diffuse patchy	3k. Additional Regional Enhancements [404] o No o Yes	

COMMENTS:____

	Γ If this is a revised or corrected form, please $\sqrt{\sf box}$.	AC	CRIN Study 6657		Case #
14.	Other Multi-focality (select all that apply)		PLAC	E LABEI	HERE
	☐ Other masses [257]	Ins	stitution		Institution No.
	Other regional enhancements [258]	Pa	rticipant's Initials		Participant's I.D. No.
	☐ Diffuse enhancement(s) [258]		<u> </u>		
	☐ Scattered, stippled enhancement(s) [260]	AD	DITIONALB	ASELINE/	PRE-TREATMENT
	☐ Not applicable/None [261]				
15.			_		tent of Disease all disease present,
	O No (proceed to question 16)				OCIS foci, even if there
	O Yes (continue, characterize other findings)		is normal tissu		
	Characterization of Other Findings			_ mm _[277]	
	(select all that apply)	4			
	☐ Nipple retraction [263]	17. 1	FQ Staging Class		
	☐ Nipple invasion [264]		T (select one	size of domir	nant lesion only) _[278]
	☐ Pectoralis muscle invasion [265]			rimary	
	☐ Pre-contrast high duct signal _[266]		O Tis In Sit O T1a <5 m		
	☐ Skin thickening (focal) [267]		O T1b 5-9 n	nm	
	☐ Skin thickening (diffuse) [268]		O T1c 10-20 O T2 21-50	0 mm 0 mm	
	☐ Skin invasion _[269]		O T3 >50r		
	☐ Edema _[270]			t wall	
	☐ Lymph Adenopathy [271]		O T4b skin O T4c ches	at wall and skin	
	☐ Hematoma/blood [272] ☐ Abnormal signal void [273]		O T4d inflar	mmatory	
	☐ Cyst(s) [274]		F (select one -	- size of full ex	tent of disease) [279]
	Other		O F0 no othe		ous enhancement
16			O F1 ≤10m O F2 11-20	nm 0 mm	
16.	Full Extent of Disease (spanning all disease present) If any new lesions were identified, report description data			0 mm	
	on the TS form but include these when determining the full			0 mm	
	extent of disease below.			0 mm 0 mm	
	Cranio-Caudal Medio-Lateral			0 mm	
	(1) J			0 mm 0 mm	
	Lateral Axilla LT RT Axilla			00 mm	
	Li La Ra Ri LE RE RB		O FX >100) mm, please reco	1
	LE LF RF RC MA		size		」mm. _[280]
	L3 L6 R6 R3 LD RD		Q (select one	- number of qu	adrants involved) [281]
	LG RG				spicious enhancement
	, ,				uspicious enhancement
	Direction for Longest Diameter Measurement				suspicious enhancement f suspicious enhancement
	(indicate which diagram above was used to				suspicious enhancement
	determine measurement direction) [275] O cranial - caudal	18 N	Aornhologic Patte	ern Classificati	ion of Dominant Lesion [391]
	O medio-lateral				vith well-defined margin
	h ¢ d				well-defined margin
	u				rregular margins -
	a a		with nodula		rregular margins -
	d h		without nod		regular margins
	G C			ead; streaming	
	Orientation of Longest Diameter Measurement	10 7	Total number of n	naeses seen o	n this exam
	(indicate the orientation used to determine				[405]
	measurement direction) [276]		Total number of re	1 1	cements
	O a O b	s	seen on this exan	n _{[40}	06]
	0 0				

O d

If this is a revised or corrected form, please $\sqrt{\text{box.}}$	ACRIN Study 6657	Case # ABEL HERE
	Institution Participant's Initials	Institution No. Participant's I.D. No.
		·
COMMENTS:		
		[282]
Radiologist Signature (radiologist must sign either the completed paper form or the com	— pleted/printed web form)	
Signature of person responsible for data	[283]	
Signature of person entering data onto web	— _[285] — — - Date form	completed (mm-dd-yyyy)
* Please remember	to complete page 8	

Visit 1.1 - Additional Baseline / Pre-Treatment Reproducibility Visit

(within 72 hours post Baseline)

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.

Visit 1.1 - Additional Baseline / Pre-Treatment Reproducibility Visit

(within 72 hours post Baseline)

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.

Visit 1.1 - Additional Baseline / Pre-Treatment Reproducibility Visit

(within 72 hours post Baseline)

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

Visit 1.1 - Additional Baseline / Pre-Treatment Reproducibility Visit

(within 72 hours post Baseline)

- 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.

Visit 1.1 – Additional Baseline / Pre-Treatment Reproducibility Visit

(within 72 hours post Baseline)

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).

Visit 1.1 – Additional Baseline / Pre-Treatment Reproducibility Visit

(within 72 hours post Baseline)

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.



ACRIN 6657 Extension

ACRIN Study 6657

MRS Form: Additional Baseline / Pre-Treatment Reproducibility	PLACE LABEL HERE Institution Institution No			
MRS 1.1	Participant Initials Case No			
If this is a revised or corrected form, please $\sqrt{\text{box.}}$				
	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.				
Timepoint [1] O MRS 1.1 Additional Baseline / Pre-Treatment reproducibility	7. Person responsible for voxel placement: [20] (select one) O 1 MR Technologist O 2 Research Associate			
 Was MRS performed? [4] O 1 No (if no, complete Q3a, sign and date form) O 2 Yes (If yes, continue with form) 	O 3 Nurse O 4 PI Radiologist O 5 Physician O 88 Other personnel (specify):			
3a. If no, specify reason: [5] O 1 No time O 2 Technical Problem O 88 Other, specify	Phantom QC Measurement			
4. Were baseline studies with voxel positioning used to determine MRS asquisition? [7]	8. Phantom scan performed within past 7 days? O 1 No (If no, complete Q8a) O 2 Yes			
O 1 No (Complete Q4a) O 2 Yes (If yes, complete Q4b)	8a. If no, specify reason: Specify,			
4a. If no, specify reason: Specify,	8b. Date of last phantom scan			
4b. Which previous images were used for voxel placement?	(mm-dd-yyyy) 9. MRS Acquisition			
MRI-1: □ hardcopy _[9] □ online _[10]	Cranio-Caudal Medio-Lateral			
General	Lateral Azilla LT RT Azilla R4 R1 LE RE RB			
 5. Date of MRI (mm-dd-yyyy) (17) 6. Magnet field strength (18) 	LB LS R5 R2 R5 R5 R5 R5 R5 R5 R6 R5			
O 1 1.5 O 2 3 O 88 Other, specify[19]	Cranio-Caudal Medio-Lateral (select all that apply) (select all that apply)			
	\square LO $_{[25]}$ \square RO $_{[32]}$ \square LT $_{[39]}$ \square RT $_{[47]}$			

☐ L1 _[26]

☐ L2 [27]

☐ L3 [28]

☐ L4 [29]

☐ L5 [30]

☐ L6 [31]

☐ R1 _[33]

☐ R2 [34]

☐ R3 [35]

☐ R4 _[36]

☐ R5 [37]

☐ R6 [38]

☐ LA _[40]

☐ LB [41]

☐ LC [42]

☐ LD [43]

☐ LE _[44]

☐ LF _[45] ☐ LG [46] ☐ 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 $\sqrt{\text{box}}$.

ACRIN Study 6657

PLACE LABEL HERE

Institution	_ Institution No
Participant Initials	Case No

	ADDITIONAL BASELINE/PRE-TREATMENT
0. Pre-scan calibration	
Shimming: [55] O manual O automatic	
Water Suppression: [56] O manual O automatic	
1. Confidence in accurate reproduction of voxel placement (ch	eck one): [57]
Very Confident	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]
2. 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,	
COMMENTS:	
	[64]
	to form completed
	te form completed (mm-dd-yyyy) _{[6}

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).

Visit 1.1 - Additional Baseline / Pre-Treatment Reproducibility Visit

(within 72 hours post Baseline)

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

		/	
f 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

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.

O Injection site complications O Claustrophobia O Participant withdrew consent O Progressive disease O Participant death O Other, specify: O Unknown Baseline (T1 Form) [12] O No O Yes (report in Section A) Total Number I [13] (enter same response from T1 O O No O Baseline [362] O No O Yes (report on supplemental TS form)	corrections only.	
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: O Unknown 2. Date of MRI 20	1. Protocol Time Point [4]	Complete For Study Breast Only
1a. Was MRI performed? 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: O Unknown 2. Date of MRI 20 (mm-dd-yyyy) [3] 3. Date of Interpretation 20 (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 on this MRI Exam [16] O No O Yes (report on supplemental TS form) 13. Index Lesion Identified on this MRI Exam [16] O No O Yes O Yes O Yes O Yes O No O Yes		
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: o Unknown 2. Date of MRI 20	·	9. Study Breast (same as identified in (T1) baseline)) 1401
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: O Unknown 2. Date of MRI 20 (mm-dd-yyyy) [3] O Date of Interpretation		o Right
1b. *If No, provide reason: 408	 No* (complete Q1b, then sign and date 	- ()
1b. *If No, provide reason: [408]	O Yes (proceed to Q2 and continue with	form)
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: O Unknown 2. Date of MRI 20(mm-dd-yyyy) O Unknown 2. Date of Interpretation 20(mm-dd-yyyy) A 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) 5. Scattered fibroglandular tissue O Heterogeneously dense O Extremely dense O Heterogeneously dense O Extremely dense O Heterogeneously dense O Extremely dense O Heterogeneously dense O Extremely dense O Extremely dense Ital. Were Clinically Relevant Mass(es) Identified on the Baseline [71 Form) [12] O No O Yes (report in Section A) Total Number 1 (enter same response from T1 O No O Yes (report in Section B) Total Number 1 (enter same response from T1 O No O Yes (report in Section B) Total Number 1 (enter same response from T1 O No O Yes (report in Section B) Total Number 1 (enter same response from T1 O No O Yes (report in Section B) Total Number 1 (enter same response from T1 O No O Yes (report in Section B) Total Number 1 (enter same response from T1 O No O Yes (report in Section B) Total Number 1 (enter same response from T1 O No O Yes (report in Section B) Total Number 1 (enter same response from T1 O No O Yes (report in Section B) Total Number 1 (enter same response from T1 O No O Yes (report in Section B) 12a Were Clinically Relevant Regional Enhancements now seen that were not seen on Baseline [13 form) 12b. Are New Regional Enhancements now seen that were not seen on Baseline [10] O No O Yes (report in Section B) 12a Were Clinically Relevant Regional E	41. *1651	
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: O Unknown 2. Date of MRI 20		
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: O Unknown 2. Date of MRI 20		
O Medical reason O Medical reason O Injection site complications O Claustrophobia O Participant withdrew consent O Progressive disease O Participant death O Other, specify: O Unknown 2. Date of Interpretation O mm-dd-yyyyy) 4. Reader Name: C Reader ID: Patient Weight (kgs) Patient Weight (kgs) No No (sign and date form) 11a. Were Clinically Relevant Mass(es) Identified on the Baseline (T1 Form) O No O Yes (report in Section A) Total Number I (13) No No O Yes (report on supplemental TS form) 12a Were Clinically Relevant Regional Enhancements Identified on the baseline (T1 Form) O No O Yes (report in Section B) Total Number I (15) Are New Regional Enhancements now seen that were not seen on Baseline [387] O No O Yes (report in Section B) Total Number I (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 O No O Yes O Yes O No O Yes O Yes		
O Injection site complications O Claustrophobia O Participant withdrew consent O Progressive disease O Participant death O Other, specify: O Unknown 2. Date of Interpretation	•	·
O Claustrophobia O Participant withdrew consent O Progressive disease O Participant death O Other, specify: ———————————————————————————————————		11a. Were Clinically Relevant Mass(es) Identified on the
O Participant withdrew consent O Progressive disease O Participant death O Other, specify: O Unknown 2. Date of MRI 20		r.—1
O Progressive disease O Participant death O Other, specify: O Unknown 2. Date of MRI 20		
O Participant death O Other, specify: O Unknown 2. Date of MRI 20	•	
O Participant death O Other, specify: O Unknown 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) O No O Yes (report in Section B) Total Number		Total Number [13] (enter same response from T1 Q11a)
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 C) 12b. Are New Regional Enhancements now seen that were not seen on Baseline [387] o No o Yes (report on supplemental TS form) 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 o No (sign and date form)	•	[10]
O Unknown O Unknown O Unknown O Unknown O Unknown O Ves (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	O Other, specify:	
Identified on the baseline (T1 Form) [14]	O Unknown	[409] o No
o No o Yes (report in Section B) Total Number		yyy) 12a Were Clinically Relevant Regional Enhancements
o Yes (report in Section B) Total Number	3. Date of Interpretation 20	1.4
4. Reader Name:	(mm-dd-yyyy)	
5. Reader ID: 12b. Are New Regional Enhancements now seen that were not seen on Baseline [387] 0 No 0 Yes (report on supplemental TS form) 13. Index Lesion Identified on this MRI Exam [16] 0 No 0 Yes (report on supplemental TS form) 13. Index Lesion Identified on this MRI Exam [16] 0 No 0 Yes (report on supplemental TS form) 14. Index Lesion Identified on this MRI Exam [16] 15. Are New Regional Enhancements now seen that were not seen on Baseline [387] 16. Very Regional Enhancements now seen that were not seen on Baseline [387] 17. Index Lesion Identified on this MRI Exam [16] 18. Were Clinically Relevant Enhancing Lesion(s) Identified [9] 0 No 0 Yes (report on supplemental TS form)	4 Books Nove	
6. Patient Weight (kgs) 7. Total Amount of Gadolinium Injected (cc) 8. Were Clinically Relevant Enhancing Lesion(s) Identified 9 No 13. Index Lesion Identified on this MRI Exam 16 were not seen on Baseline 9 No 9 Yes 13. Index Lesion Identified on this MRI Exam 16 o No 9 Yes	4. Reader Name:	[5] Total Number[15] (enter same response from T1 Q12a)
o No o Yes (report on supplemental TS form) 7. Total Amount of Gadolinium Injected (cc) 8. Were Clinically Relevant Enhancing Lesion(s) Identified [9] o No (sign and date form) 13. Index Lesion Identified on this MRI Exam [16] o No o Yes	5. Reader ID:	12b. Are New Regional Enhancements now seen that were not seen on Baseline [387]
8. Were Clinically Relevant Enhancing Lesion(s) Identified o No (sign and date form)	6. Patient Weight (kgs)	o No
8. Were Clinically Relevant Enhancing Lesion(s) Identified [9] o Yes	7. Total Amount of Gadolinium Injected (cc)	[8] 13. Index Lesion Identified on this MRI Exam
o Yes	o No (sign and date form)	atified
* Please remember to complete page 8	Were Clinically Relevant Enhancing Lesion(s) IdenNo (sign and date form)	o No o Yes

$\boxed{T2}$ If this is a revised or corrected form, please $\sqrt{\text{box}}$	ACRIN Study 6657 Case #
Section A: Masses All masses documented on the T1 Form must be reported in section. If new masses are now present, report on the supplementary of the suppl	this ental PLACE LABEL HERE Institution Institution No. Participant's Initials Participant's I.D. No.
TS Form.	TREATMENT
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 Cranio-Caudal Medio-Lateral Literal Literal Ref Riteral Ref	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
$ \begin{array}{c cccc} \Box & L4 & [22] & & \Box & R4 & [29] \\ \Box & L5 & [23] & & \Box & R5 & [30] \\ \Box & L6 & [24] & & \Box & R6 & [31] \end{array} $	1h. Series and Image Number of Representative Slices (list up to 3)
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] □ RG [46] □ LG [39] □ RG [47]	Series : [339] Image # [340]
1b. Size (record all three measurements [0 = not seen]) $x = $	o Yes COMMENTS:
z = mm (anterior-posterior) [50] 1c. Shape/Margin (select one) [51] o Smooth round o Smooth oval o Lobulated	[345
o Irregularo Spiculatedo No longer a mass	

$\boxed{12}$ If this is a revised or corrected form, p	olease $\sqrt{\text{box.}}$	RIN Study 6657	Case #
Section A: Masses All masses documented on the T1 Form must be section. If new masses are now present, report on TS Form.	e reported in this	titution ticipant's Initials	Institution No. Participant's I.D. No. ATMENT
2. Is the lesion identified as Mass #2 on the T1 still visible? [346] o No (skip 2a-2i) o Yes (complete 2a-2i) o Not Applicable Cranio-Caudal Medi Lateral R4 R1 R5 R2 R6 R3 D	Porm 2d. Co-Lateral RE RB RF RC RD RG 2f.	Internal Enhancem o Homogeneous o Heterogeneous o Rim enhanced o Centrally enhar o Dark septation(o Enhancing sep o No longer a ma T2 Appearance (secondary of the secondary	ent (select one) [93] confluent nced s) tation(s) ass lect one) [94] o surrounding breast tissue surrounding breast tissue urrounding breast tissue trounding breast tissue trounding breast tissue leate ment ongest degree seen) [95]
Medio-Lateral (select all that apply) □ LT [73] □ RT [81] □ LA [74] □ RB [82] □ LB [75] □ RC [84] □ LD [76] □ RD [85] □ LE [78] □ RF [86] □ LF [79] □ RG [87] □ LG [80] □ RG [87] 2b. Size (record all three measurements [0 = x = □ □ mm (medial-latera y = □ mm (superior-inferior) z = □ mm (anterior-posteration)	(i) [89] (ior) [90]	Series :	lumber of Representative [347] Image #
2c. Shape/Margin (select one) [92] o Smooth round o Smooth oval o Lobulated o Irregular o Spiculated			[353]

No longer a mass

T2 If	this is a revised or corrected form, please $\sqrt{\text{box}}$.	ACRIN	N Study 6657	Case #	
	lasses ocumented on the T1 Form must be reported in this wasses are now present, report on the supplemental	Institu Partic	tion ipant's Initials	Institution No. Participant's I.D. No. ATMENT	
still visible o No (s o Yes (o Not A	kip 3a-3i) complete 3a-3i complete 3a	3d. 3e. 3f.	Internal Enhancement O Homogeneous O Heterogeneous O Rim enhanced O Centrally enhance O Dark septation(O Enhancing septor O No longer a material T2 Appearance (seltor O Hyperintense to O Isointense to Solo Unable to evaluate Degree of Enhance (characterize by stroed of Marked Enhancement Patter (characterize by stroed of Sustained O Washout	ent (select one) [134] confluent aced s) tation(s) ass lect one) [135] a surrounding breast tissue surrounding breast tissue arrounding breast tissue	
LT LA LE LC LC LC LC LC LC LC	RA [122] RB [123] RC [124] RC [125] RC [125] RC [126] RE [127] RE [127] RF [128] RG [129] RG [129] mm (medial-lateral) [130] mm (superior-inferior) [131] mm (anterior-posterior) [132]	3h.	Series : Series : Series : Corresponds to Indo No No Yes	umber of Representative [355] Image #	[356] [358] [360]
o S o S	e/Margin (select one) [133] Smooth round Smooth oval obulated				[361]

o Irregular o Spiculated o No longer a mass

T2 If this is a revised or corrected form, please $\sqrt{\text{box}}$.	ACRIN Study 6657 Case #
Section B: Regional Enhancements All regional enhancements documented on the T1 Form must be eported in this section. If new regional enhancements are now present, report on the supplemental TS Form.	PLACE LABEL HERE Institution Participant's Initials Participant's I.D. No. TREATMENT
Is the lesion identified as Regional Enhancement #1 from the T1 Form still visible? O No (skip 1a-1i) O Yes (complete 1a-1i) O Not Applicable Cranio-Caudal Medio-Lateral Lateral Lateral	1d. Internal Enhancement (select one) 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) 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
Cranio-Caudal (select all that apply) □ L0 [141] □ R1 [149] □ L1 [142] □ R2 [150] □ L2 [143] □ R3 [151] □ L3 [144] □ 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] □ RC [166] □ LD [159] □ RD [167] □ LE [160] □ RE [168] □ LF [161] □ RF [169] □ LG [162] □ RG [170]	(characterize by strongest degree seen) o Minimal o Moderate o Marked 1g. Enhancement Pattern (characterize by strongest pattern seen) 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]
b. Largest Dimension	Series : [368] Image # [369] 1i. Corresponds to Index Lesion [177] o No
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	O NO O Yes COMMENTS: [370

$\boxed{\text{1}}$ If this is a revised or corrected form, please $\sqrt{\text{box}}$.	ACRIN Study 6657 Case #
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.	Institution Institution No. Participant's Initials Participant's I.D. No. TREATMENT
2. Is the lesion identified as Regional Enhancement #2 on the T1 Form still visible? O No (skip 2a-2i) O Yes (complete 2a-2i) O Not Appliable Cranio-Caudal Medio-Lateral Lateral R4 R1 R5 R2 RB RF RC RB RF RC RB	2d. Internal Enhancement (select one) 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) o Hyperintense to surrounding breast tissue
LO LG RG RD	 Hypointense to surrounding breast tissue Isointense to surrounding breast tissue Unable to evaluate
2a. Location: Cranio-Caudal (select all that apply)	2f. Degree of Enhancement (characterize by strongest degree seen) o Minimal o Moderate o Marked
□ L4 [183] □ R4 [190] □ L5 [185] □ R5 [192] □ L6 [186] □ R6 [193] Medio-Lateral (select all that apply)	2g. Enhancement Pattern (characterize by strongest pattern seen) o Gradual o Sustained o Washout
□ LT [194] □ RT [202] □ LA [195] □ RA [203] □ LB [196] □ RC [204] □ LC [197] □ RC [205] □ LD [198] □ RD [206] □ LE [199] □ RE [207] □ LF [200] □ RF [208] □ LG [201] □ RG [209]	2h. Series and Image Number of Representative Slices (list up to 3) Series : [372] Image # [373] Series : [374] Image # [375]
2b. Largest Dimension	2i. Corresponds to Index Lesion [216]
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 Yes COMMENTS:
o Regional o Diffuse patchy	

[378]

$\boxed{1}$ If this is a revised or corrected form, please $\sqrt{\text{box}}$.	ACRIN Study 6657 Case #
	PLACE LABEL HERE
Section B: Regional Enhancements	Institution Institution No.
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.	TREATMENT
3. Is the lesion identified as Regional Enhancement #3 on the T1 Form still visible? O No (skip 3a-3i) O Yes (complete 3a-3i) O Not Applicable Cranio-Caudal Medio-Lateral Lateral Lateral REF RE REF R	3d. Internal Enhancement (select one) 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) o Hyperintense to surrounding breast tissue o Hypointense to surrounding breast tissue o Isointense to surrounding breast tissue o Unable to evaluate
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]	3f. Degree of Enhancement (characterize by strongest degree seen) o Minimal o Moderate o Marked 3g. Enhancement Pattern (characterize by strongest pattern seen) o Gradual
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]	o Sustained o Washout 3h. Series and Image Number of Representative Slices (list up to 3) Series : [380] Image # [381] Series : [382] Image # [383]
Bb. Largest Dimension	Series : [384] Image # [385] 3i. Corresponds to Index Lesion [255]
o Distribution Subtype (select one) [250] o Diffuse non-specific o Linear non-specific o Linear ductal: Smooth o Linear ductal: Irregular	o No o Yes
o Linear ductal: Clumped o Segmental o Regional	COMMENTS:

[386]

ACRIN Study 6657	Case #
PLACE LA	ABEL HERE
Institution	Institution No.
Participant's Initials	Participant's I.D. No.
TRE	ATMENT
	ified, report description data on the en determining the full extent of Medio-Lateral
Lateral L1 L4 R4 R1 L3 L5 R5 R2 R3 R6	Axilla LT RT Axilla RE RB RF RC LD LG RG RD
(indicate which diagratermine measurement or cranial - caudal or medio-lateral) b a Orientation of Long (indicate the orientate measurement direction of a or condition of a condition	est Diameter Measurement ion used to determine on) [276] Full Extent of Disease panning all disease present, we and DCIS foci, even if there
	PLACE LA Institution Participant's Initials TRE 16. Full Extent of Disease If any new lesions were ident TS form but include these which disease below. Cranio-Caudal Direction for Longer (indicate which diagrate determine measurem o cranial - caudal o medio-lateral b a Orientation of Long (indicate the orientate measurement direction o a o b o c o d Longest Diameter of (Longest diameter spincluding both invasii is normal tissue interior

$\boxed{1}$ If this is a revised or corrected form, please $\sqrt{\text{box.}}$	ACRIN Study 6657	Case #
	PLACE	LABEL HERE
17. TFQ Staging Classification	Institution	Institution No.
17. II & Staging Glassification	Participant's Initials	Participant's I.D. No.
T (select one – size of dominant lesion only) [278]	TR	REATMENT
O T0 No primary O Tis In Situ	••	
O Tis In Situ O T1a <5mm		
O T1b 5-9 mm O T1c 10-20 mm	18. Total number of mas	ses seen on this exam
O T2 21-50 mm		[405]
O T3 >50 mm O T4a chest wall	19. Total number of regi	onal enhancements seen on
O T4b skin	1 1	1
O T4c chest wall and skin O T4d inflammatory	this exam	^J [406]
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 F7 61-70111111 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		
COMMENTS:		[282]
Radiologist Signature (radiologist must sign either the completed paper form or the completed	eted/printed web form)	
	. ,	
	283]	
Signature of person responsible for data		
		20
Signature of person entering data onto web	Date for	rm completed (mm-dd-yyyy)
* Please remember t	to complete page 8	
i iodoo ioiiiotiiboi t	compicto page o	

"Copyright 2007" ACRIN 6657 T2 11-29-07 9 of 9

Visit 2 – Treatment MRI 2

(within 20-28 or 48-96 hours post Baseline)

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.

Visit 2 –Treatment MRI 2

(within 20-28 or 48-96 hours post Baseline)

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.

Visit 2 - Treatment MRI 2

(within 20-28 or 48-96 hours post Baseline)

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

Visit 2 – Treatment MRI 2

(within 20-28 or 48-96 hours post Baseline)

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.

ACRIN 6657 Extension

MRS Form: Treatment MRS - 2

If this is a revised or corrected form, please $\sqrt{\text{box}}$.

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

•	ard copy or online) with voxel positioning are required at time of saging visit.	study. Same magnet field strength and coll should be used at every
1.	Timepoint [1] O MRS 2 Treatment	7. Person responsible for voxel placement: [20] (select one)
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]	O 1 MR Technologist O 2 Research Associate O 3 Nurse O 4 PI Radiologist O 5 Physician O 88 Other personnel (specify):
3	Was MRS performed? $_{[4]}$	Phantom QC Measurement
	O 1 No (if no, complete Q3a, sign and date form) O 2 Yes (If yes, continue with form)	 8. Phantom scan performed within past 7 days? [22] O 1 No (If no, complete Q8a) O 2 Yes
	3a. If no, specify reason: [5]	8a. If no, specify reason:
	O 1 No time O 2 Technical Problem	Specify,
	O 88 Other, specify	8b. Date of last phantom scan
4.	Were baseline studies with voxel positioning used to determine MRS asquisition? $_{[7]}$	(mm-dd-yyyy) [24]
	O 1 No (Complete Q4a) O 2 Yes (If yes, complete Q4b)	9. MRS Acquisition
		Cranio-Caudal Medio-Lateral
	4a. If no, specify reason: Specify,	Lateral Axilla LT RT Aziilla
	4b. Which previous images were used for voxel placement?	LI LS RS R2 em LB LE RE RB
	MRI-1: □ hardcopy _[9] □ online _[10]	L3 L6 R6 R3 LD LG RF RC RD
	MRI - 1.1: □ hardcopy [11] □ online [12]	
Ge	eneral	Cranio-Caudal Medio-Lateral (select all that apply) (select all that apply)
5.	Date of MRI (mm-dd-yyyy) [17]	$\begin{array}{cccccccccccccccccccccccccccccccccccc$
6.	Magnet field strength [18]	\square L2 $_{[27]}$ \square R2 $_{[34]}$ \square LB $_{[41]}$ \square RB $_{[49]}$
	O 1 1.5	\square L3 $_{[28]}$ \square R3 $_{[35]}$ \square LC $_{[42]}$ \square RC $_{[50]}$
	O 2 3 O 88 Other, specify	\square L4 _[29] \square R4 _[36] \square LD _[43] \square RD _[51]
	[19]	\square L5 _[30] \square R5 _[37] \square LE _[44] \square RE _[52]
		\square L6 $_{[31]}$ \square R6 $_{[38]}$ \square LF $_{[45]}$ \square RF $_{[53]}$

☐ LG [46]

ACRIN 6657 Extension MRS Form: Treatment MRS - 2

ACRIN Study	6657
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PLACE LABEL HERE

If this is	s a revised or corrected form, please $\sqrt{\text{box.}}$		Institution No
11 11115 15	a revised of corrected form, please y box.	Participant Initials	Case No
10. Pre	-scan calibration	TRI	EATMENT
Shii	mming: [55] O manual O automatic		
Wat	ter Suppression: [56] O manual O automatic		
11. Cor	nfidence in accurate reproduction of voxel placement (che	ock one): _[57]	
Ver	y Confident01 02 03 04 05	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]		
0	ne scanner and breast coil the same as was used for the book No (Complete Q12a) Yes	paseline MRS exam? [67]	
12a	. If no, specify system used		
	Specify,	[68]	
СОММЕ	NTS:		
			[64]
Signatur	Date of person responsible for the data	e form completed	(mm-dd-yyyy) _{[66}

Visit 2 –Treatment Visit (within 20-28 or 48-96 hours post Baseline)

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).

Visit 2 – Treatment Visit (within 20-28 or 48-96 hours post Baseline)

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 2 –Treatment Visit (within 20-28 or 48-96 hours post Baseline)

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.

Visit 2 – Treatment Visit (within 20-28 or 48-96 hours post Baseline)

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

/	
f this is a revised or corrected form, please $\sqrt{\sf box}$.	

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]	Complete For Study Breast Only
••	o Optional MRI Inter-regimen Treatment	
	o optionarivite regimen reatherit	9. Study Breast (48)
	1a. Was MRI performed? [407]	9. Study Breast [10] o Right
	O No* (complete Q1b, then sign and date form)	o Left
	O Yes (proceed to Q2 and continue with form)	
	,	10. Density of Breast Parenchyma
	1b. *If No, provide reason: [408]	(same as identified in (T1) baseline)) [11]
	O Scheduling problem	o Mostly fat o Scattered fibroglandular tissue
	O Equipment failure	o Heterogeneously dense
	O Participant refusal	o Extremely dense
	O Medical reason	·
	O Injection site complications	11a. Were Clinically Relevant Mass(es) Identified on the
	O Claustrophobia	Baseline (T1 Form) [12]
	O Participant withdrew consent	o No o Yes (report in Section A)
	O Progressive disease	
	O Participant death	Total Number [13] (enter same response from T1 Q11a
	•	11b. Are New Masses now seen that were not seen
	O Other, specify:	on Baseline [362]
	[409]	o No [362]
	O Unknown	o Yes (report on supplemental TS form)
	20	
2.	Date of MRI 20(mm-dd-yyyy) [3]	40. W - 01. 1. II. B. I 4 B 1 1. E. I 1 1.
_	Date of Interpretation 20 _[4]	12a. Were Clinically Relevant Regional Enhancements
3.	(mm-dd-yyyy)	Identified on the baseline (T1 Form) [14]
	(IIIII-aa-yyyy)	o Yes (report in Section B)
4.	Reader Name:[5]	Total Number
		[15] (enter same response nom 11 Q12a)
5.	Reader ID: [6]	12b.Are New Regional Enhancements now seen that were
	[6]	not seen on Baseline [387]
6.	Patient Weight (kgs)	o No
	[/]	o Yes (report on supplemental TS form)
7.	Total Amount of Gadolinium Injected (cc)	
	[8]	13. Index Lesion Identified on this MRI Exam [16]
8.	Were Clinically Relevant Enhancing Lesion(s) Identified [9]	o No
	o No (sign and date form)	o Yes
	o Yes	
		* Diago romambar to complete name 9
		* Please remember to complete page 8

	$\overline{\Gamma 3}$ If this is a revised or corrected form, please $\sqrt{\text{box}}$.	ACR	RIN Study 6657	Case #
	in this is a revised of corrected form, prease V box.		PLACE LA	BEL HERE
	ction A: Masses	Insti	tution	Institution No.
	masses documented on the T1 Form must be reported in this ction. If new masses are now present, report on the supplemental	Part	icipant's Initials	Participant's I.D. No.
	Form.	OP ⁻	TIONAL MRI INTER	R-REGIMEN TREATMENT
:	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 Cranio-Caudal Medio-Lateral Lateral Lat	1d. 1e. 1f.	o Hypointense to so Isointense to sur o Unable to evalua Degree of Enhancem	ed) tion(s) s ct one) [53] surrounding breast tissue surrounding breast tissue rounding breast tissue te
1a.	Location: Cranio-Caudal (select all that apply) □ L0 □ R0 □ R1 □ [25] □ L1 □ R1 □ R1 □ [26] □ L2 □ □ R2 □ [27] □ L3 □ R3 □ R4 □ [28] □ L4 □ R5 □ R5 □ R6 □ R6 □ R6 □ R6 □ R6	1g. 1h.	o Gradual o Sustained o Washout	n gest pattern seen) _[55] mber of Representative
	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]	1i .	Series : [3 Series : [3 Series : [3 Corresponds to Inde o No	Image #
1b.	Size (record all three measurements [0 = not seen])		o Yes	
	x = mm (medial-lateral) [48]			
	y = mm (superior-inferior) [49]	COMI	MENTS:	
	z = mm (anterior-posterior) _[50]			
1c.	Shape/Margin (select one) [51]			
	o Smooth round o Smooth oval			
	o Lobulated			[345
	o Irregular o Spiculated o No longer a mass			

T.	If this is a revised or corrected form, please $\sqrt{\text{box}}$.	ACRIN Study		Case #
All ma	on A: Masses sses documented on the T1 Form must be reported in this n. If new masses are now present, report on the supplemental rm.	Institution Participant's		Institution No. Participant's I.D. No. REGIMEN TREATMENT
2. Is sti	the lesion identified as Mass #2 on the T1 Form ill visible? [346] No (skip 2a-2i) Yes (complete 2a-2i) Not Applicable Cranio-Caudal Medio-Lateral Literal Ref RB RF RC RITERA	2d. Interno	nal Enhancement (Iomogeneous confleterogeneous kim enhanced centrally enhanced centrally enhanced confleterogeneous kim enhanced centrally enhanced confleterogeneous kim enhanced confleterogeneous kim enhancing septation to longer a mass copearance (select of the select of the sel	(select one) [93] fluent n(s) one) [94] rrounding breast tissue rounding breast tissue unding breast tissue
2b. 2c.	□ LT [73] □ RA [81] □ LA [74] □ RB [82] □ LB [75] □ RC [84] □ LD [77] □ RE [86] □ LF [78] □ RF [87] □ LG [80] □ RG [88] Size (record all three measurements [0 = not seen]) x = □ □ mm (medial-lateral) [89] y = □ □ mm (superior-inferior) [90] z = □ □ mm (anterior-posterior) [91] Shape/Margin (select one) o Smooth round	Series Series Series Series Onre	s (list up to 3) s	Image # [348] Image # [350] Image # [352]
	o Smooth oval o Lobulated o Irregular			[353]

o Spiculatedo No longer a mass

	If this is a revised or corrected form, please $\sqrt{\text{box}}$.	ACR	IN Study 6657	Case #
	etion A: Masses	Instit	PLACE LA	Institution No.
	masses documented on the T1 Form must be reported in this tion. If new masses are now present, report on the supplemental	Parti	cipant's Initials	Participant's I.D. No.
	Form. Is the lesion identified as Mass #3 on the T1 Form	OPT		R-REGIMEN TREATMENT
	Still visible? [354] O No (skip 3a-3i) O Yes (complete 3a-3i) O Not Applicable Cranio-Caudal Medio-Lateral Lateral Lateral	3d. 3e.	o Homogeneous o Heterogeneous o Rim enhanced o Centrally enhan o Dark septation o Enhancing sep o No longer a ma T2 Appearance (see o Hyperintense to o Isointense to s o Unable to evalue	nced (s) ptation(s) ass plect one) [135] o surrounding breast tissue surrounding breast tissue urrounding breast tissue urrounding breast tissue
3a.	Location: Cranio-Caudal (select all that apply) \[\begin{array}{c ccccccccccccccccccccccccccccccccccc	3f. 3g.	o Minimal o Moderate o Marked Enhancement Patt	ongest degree seen) _[136]
	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] □ RF [127] □ LG [121] □ RG [128]	3h.	Series and Image No Slices (list up to 3) Series : Series : Series :	Image # [356] Image # [358] [359] Image # [360] [360]
3b.	Size (record all three measurements [0 = not seen]) x = mm (medial-lateral) [130] y = mm (superior-inferior) [131] z = mm (anterior-posterior) [132]	3i.	Corresponds to Inc o No o Yes //ENTS:	lex Lesion _[138]
3c.	Shape/Margin (select one) [133] o Smooth round o Smooth oval			

0

0

"Copyright 2007"

Lobulated
Irregular
Spiculated
No longer a mass

[361]

$\boxed{13} \hspace{0.2in} \text{If this is a revised or corrected form, please } \sqrt{\text{box.}} \hspace{0.2in} \boxed{}$	ACRIN Study 6657 Case # PLACE LABEL HERE
Section B: Regional Enhancements All regional enhancements documented on the T1 Form must be eported in this section. If new regional enhancements are now present, report on the supplemental TS Form.	Institution Institution No. Participant's Initials Participant's I.D. No. OPTIONAL MRI INTER-REGIMEN TREATMENT
Is the lesion identified as Regional Enhancement #1 from the T1 Form still visible? [363]	1d. Internal Enhancement (select one) O Homogeneous confluent O Heterogeneous non-specific O Heterogeneous stippled, punctate O Heterogeneous clumped O Septal, dendritic O Asymmetric O Not applicable 1e. T2 Appearance (select one) O Hyperintense to surrounding breast tissue O Hypointense to surrounding breast tissue O Unable to evaluate 1f. Degree of Enhancement (characterize by strongest degree seen) O Minimal O Moderate O Marked 1g. Enhancement Pattern (characterize by strongest pattern seen) O Gradual O Sustained O Washout 1h. Series and Image Number of Representative Slices (list up to 3) Series : [364] Image # [367] Series : [368] Image # [367] Series : [368] Image # [367] Corresponds to Index Lesion O Yes COMMENTS:
	[370]

$\boxed{T3} \hspace{0.2in} \text{If this is a revised or corrected form, please } \sqrt{\text{box.}} \hspace{0.2in} \phantom{AAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAA$	ACRIN Study 6657 Case #
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? O No (skip 2a-2i)	Institution Institution No. Participant's Initials Participant's I.D. No. OPTIONAL MRI INTER-REGIMEN TREATMENT 2d. Internal Enhancement (select one) O Homogeneous confluent O Heterogeneous non-specific
O Yes (complete 2a-2i) O Not Appliable Cranio-Caudal Medio-Lateral Axilla LT RE RE RE RE RE RE RE RE RE R	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
2a. Location: Cranio-Caudal (select all that apply)	2f. Degree of Enhancement (characterize by strongest degree seen) o Minimal o Moderate o Marked
□ L5 [184] □ 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]	2g. Enhancement Pattern (characterize by strongest pattern seen) o Gradual o Sustained o Washout 2h. Series and Image Number of Representative Slices (list up to 3)
☐ LD [198] ☐ RD [206] ☐ LE [199] ☐ RE [207] ☐ LF [200] ☐ RF [208] ☐ LG [201] ☐ RG [209]	Series : [372] Image # [373] Series : [374] Image # [375]
2b. Largest Dimension	Series : [376] Image # [377] 2i. Corresponds to Index Lesion [216]
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	o No o Yes COMMENTS:

T3	If this is a revise	d or corrected form, please $\sqrt{\text{box.}}$	ACI	RINS
All region reported		locumented on the T1 Form must be new regional enhancements are now	Par	itutio ticipa
on tl 0 0 0	he T1 Form still vis No (skip 3a-3i) Yes (complete 3a-3i Not Applicable Cranio-Caudal	Medio-Lateral	3d.	Inte
	L1	LB LE RB RF RC LD LG RG RD	3e.	T2 0 0 0 0
	Location: Cranio-Caudal <i>(</i> se	elect all that apply)	3f.	Do
]]]]	L0 [219] L1 [220] L2 [221] L3 [222] L4 [223]	□ R0 _[226] □ R1 _[227] □ R2 _[228] □ R3 _[229] □ R4 _[230]	31.	(ch 0 0 0
] [☐ L5 [224]	☐ R5 [231]	3g.	Enl
	⊐ີເ _[225] Medio-Lateral <i>(</i> se≀	[232]		(ch o
]	☐ LT _[233] ☐ LA _[234]	☐ RT [241] ☐ RA recor		0 0
	☐ LC [236] ☐ LD [237] ☐ LE [238]	□ RB [242] □ RC [244] □ RD [245] □ RE [246] □ RF [247]	3h.	Ser Slic
[☐ LF _[239]	☐ RF [247] ☐ RG [248]		Sei
26	[240]			Sei
3b.	Largest Dimension			Ser

		[249]
3c.	Dis	stribution Subtype (select one) [250]
	0	Diffuse non-specific
	0	Linear non-specific
1		

Linear ductal: Smooth
 Linear ductal: Irregular
 Linear ductal: Clumped
 Segmental
 Regional

o Diffuse patchy

ACRIN Study 6657

Case #

PLACE LABEL HERE

nstitution Institution No.

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

OP.	TIONAL MRI INTER-REGIMEN TREATMENT
3d.	Internal Enhancement (select one) 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) o Minimal o Moderate o Marked
3g.	Enhancement Pattern (characterize by strongest pattern seen) 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
COMI	MENTS:

[386]

1 If this is a revised or corrected form, please $\sqrt{\text{box.}}$	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)	16. Full Extent of Disease
☐ Other masses [257]	If any new lesions were identified, report description data on the
Other regional enhancements [258]	TS form but include these when determining the full extent of
☐ Diffuse enhancement(s) [259]	disease below.
☐ Scattered, stippled enhancement(s) [260]	Cranio-Caudal Medio-Lateral
☐ Not applicable/None [261]	Cranio-Caudal Medio-Lateral
	Lateral LT RT Assilla
15. Other Findings [262]	R4 R1 Axilla RE
o No (proceed to question 16) o Yes (continue, characterize other findings)	Qua 1.2 L.5 RS R2 cm LB RF RC cm
c (community or an action <u>not</u> can be minimized)	LS L6 R6 R3 LC LF RF RC RD
Characterization of Other Findings	LG RG
(select all that apply)	7 7
☐ Nipple retraction [263]	Direction for Longest Diameter Measurement
☐ Nipple invasion [264]	(indicate which diagram above was used to
☐ Pectoralis muscle invasion [265]	determine measurement direction) [275]
☐ Pre-contrast high duct signal [266]	o cranial - caudal o medio-lateral
 □ Skin thickening (focal) [267] □ Skin thickening (diffuse) [267] 	
☐ Skin thickening (diffuse) [268] ☐ Skin invasion [269]	h C d
☐ Edema [270]	U d
☐ Lymph Adenopathy [271]	a— — a
☐ Hematoma/blood [272]	d b
☐ Abnormal signal void [273]	c c
☐ Cyst(s) [274]	Orientation of Longest Diameter Measurement
☐ Other [388] [389]	(indicate the orientation used to determine
[600]	measurement direction) [276]
	o a o b
	0 b 0 c
	o d
	Land Birman (F. HE 4 of CB)
	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]
	[211]

* Please remember to complete page 8				
Signature of person entering data onto web	[285] –	20		
Signature of person responsible for data	[283]			
Radiologist Signature (radiologist must sign either the completed paper form or the complete pa	oleted/printed web form	n)		
		[202]		
COMMENTS:		[282]		
O Q4 four quadrants of suspicious enhancement				
O Q2 two quadrants of suspicious enhancement O Q3 three quadrants of suspicious enhancement				
 Q (select one - number of quadrants involved) [281] O Q0 no quadrant of suspicious enhancement O Q1 one quadrant of suspicious enhancement 				
size mm. _[280]				
O F9 81-90 mm O F10 91-100 mm O FX >100 mm, please record				
O F7 61-70 mm O F8 71-80 mm				
O F4 31-40 mm O F5 41-50 mm O F6 51-60 mm				
O F1 ≤10mm O F2 11-20 mm O F3 21-30 mm				
F (select one – size of full extent of disease) [279] O F0 no other area of suspicious enhancement				
O T4c chest wall and skin O T4d inflammatory	this exam	[406]		
O T3 >50mm O T4a chest wall O T4b skin	1	of regional enhancements seen on		
O T1c 10-20 mm O T2 21-50 mm	18. Total number	of masses seen on this exam [405]		
O Tis In Situ O T1a <5 mm O T1b 5-9 mm				
 T (select one – size of dominant lesion only) [278] O TO No primary 	OPTIONAL MI	RI INTER-REGIMEN TREATMENT		
17. TFQ Staging Classification	Participant's Initi	· · · · · · · · · · · · · · · · · · ·		
	Institution	Institution No.		
If this is a revised or corrected form, please √box.	PLA	CE LABEL HERE		
If this is a revised or corrected form places . / hay	ACRIN Study 665	-		

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Visit 3 – Inter-Regimen Treatment MRI 3

(performed 12 weeks after completing treatment)

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.

Visit 3 – Inter-Regimen Treatment MRI 3

(performed 12 weeks after completing treatment)

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.

Visit 3 – Inter-Regimen Treatment MRI 3

(performed 12 weeks after completing treatment)

- 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.
- 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.

Visit 3 – Inter-Regimen Treatment MRI 3

(performed 12 weeks after completing treatment)

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.

ACRIN 6657 Extension

MRS Form: MRS Inter-regimen

If this is a revised or corrected form, please $\sqrt{\text{box}}$.

ACRIN Study 6657

PLACE LABEL HERE

Institution	Institution No.	
Participant Initia	s 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]	7. Person responsible for voxel placement: [20] (select one)
	O MRS 3 MRS Inter-regimen Treatment	O 1 MR Technologist
3.	Was MRS performed? [4]	O 2 Research Associate
٠.	• •	O 3 Nurse
	O 1 No (if no, complete Q3a, sign and date form) O 2 Yes (If yes, continue with form)	O 4 PI Radiologist
	O 2 Tes (ii yes, continue with form)	O 5 Physician
	3a. If no, specify reason: [5]	O 88 Other personnel (specify):
	O 1 No time	
	O 2 Technical Problem	
	O 88 Other, specify	Phantom QC Measurement
4.	Were baseline studies with voxel positioning used to determine MRS asquisition? [7]	8. Phantom scan performed within past 7 days? O 1 No (If no, complete Q8a) O 2 Yes
	O 1 No (Complete Q4a) O 2 Yes (If yes, complete Q4b)	
	O 2 Tes (II yes, complete Q4b)	8a. If no, specify reason:
	4a. If no, specify reason:	Specify,
	Specify,	8b. Date of last phantom scan
	4b. Which previous images were used for voxel placement?	- -
	MRI-1: \Box hardcopy $_{[9]}$ \Box online $_{[10]}$	9. MRS Acquisition
	MRI - 1.1: ☐ hardcopy [11] ☐ online [12]	Cranio-Caudal Medio-Lateral
	MRI-2: □ hardcopy _[13] □ online _[14]	
Ge	eneral	Lateral Lateral R4 R1 LB LE RE RB RB RC RA
5.	Date of MRI (mm-dd-yyyy) [17]	L5 L6 R6 R3 LD LG RG RD
6.	Magnet field strength [18]	" 7 F
	O 1 1.5	Cranio-Caudal Medio-Lateral
	O 2 3	(select all that apply) (select all that apply)
	O 88 Other, specify	
	11	\square LO $_{[25]}$ \square RO $_{[32]}$ \square LT $_{[39]}$ \square RT $_{[47]}$
		\square L1 $_{[26]}$ \square R1 $_{[33]}$ \square LA $_{[40]}$ \square RA $_{[48]}$
		\square L2 $_{[27]}$ \square R2 $_{[34]}$ \square LB $_{[41]}$ \square RB $_{[49]}$
		$\square L3_{[28]}^{[27]} \square R3_{[35]}^{[47]} \square LC_{[42]}^{[47]} \square RC_{[50]}^{[47]}$
		$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$
		$\square $
		\square L5 $_{[30]}$ \square R5 $_{[37]}$ \square LE $_{[44]}$ \square RE $_{[52]}$
		$\square $

☐ LG [46]

☐ RG _[54]

ACRIN 6657 Extension
MRS Form: MRS Inter-regimen

ACRIN Study 6657

PLACE LAREL HERE

MRS - 3	TEAGL LABLE HERE
	Institution Institution No
If this is a revised or corrected form, please √box	Participant Initials Case No.
	MRS INTER-REGIMEN
0. Pre-scan calibration	
Shimming: [55] O manual O automatic	
Water Suppression: [56] O manual O automatic	
1. Confidence in accurate reproduction of voxel placement (check one): [57]
Very Confident	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]
2. Is the scanner and breast coil the same as was used for the	e baseline MRS exam? _[67]
O No (Complete Q12a)	
O Yes	
12a. If no, specify system used	
Specify,	
Specify,	[68]
COMMENTS:	
	[64]
	Date form completed (mm-dd-yyyy) _{[66}
Signature of person responsible for the data	Date form completed (mm-dd-yyyy) [66]
O the first and the second second second	

Visit 3 – Inter-regimen Treatment Visit (12 weeks after completing treatment)

V3 MRS Form - Completion Instructions

In accordance with protocol, four to five spectroscopy exams may be reported. Visit #3 (Interregimen 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.

Visit 3 – Inter-regimen Treatment Visit (12 weeks after completing treatment)

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



ACRIN 6657 Extension Mammography Interpretation Form

	ACRII	N Study	66	57	
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PLACE LABEL HERE				
Institution	Institution No			
Participant Initials	Case No			
PRE-SURGERY				

If this is a revised or corrected form, please $\sqrt{\text{box.}}$

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.

with	in 2 weeks of each study mammogram via the ACRIN website.	Submit paper form only for revision	is or corrections.	
1.	Protocol Time Point [1] o Pre-surgery Anticipated surgery date	SECTION A: CLINICALLY RELEVANT MASSES (Report index lesion if visualized. Report descriptive data for the three most prominent masses.)		
	(mm-dd-yyyy) _[2]	Reporting Mass # [18]		
2.	Date of Mammogram:	Cranio-Caudal	Medio-Lateral Oblique	
3.	Date of Interpretation:	Lateral Rd RI	Axilla LT RT Axilla	
4.	Reader Name:	12 L5 R5 R2 R0	LB LE RB RF RC RF	
	Reader ID: [7]	L5 R6 R5	LD LG RG RD	
6.	Clinically Relevant Lesion(s) Identified [8] o No (proceed to question 15)		7 4	
	o Yes	Mass Location:		
7	Study Breast [9]	Cranio-Caudal (selec	ct all that apply)	
	o Right	L0 [19]	R0 [26]	
	o Left	L1 roo1	☐ K1 [27]	
	o Bilateral		$ \begin{array}{ccc} & R2_{[28]}^{[27]} \\ & R3_{[28]}^{[28]} \end{array} $	
_	Daniella of Daniel Barranahama	LO root	R3 [29]	
8.	Density of Breast Parenchyma [10]	L4 [23] L5 [24]	R4 [30] R5 [24]	
	o Mostly fato Scattered fibroglandular densities		D6 [31]	
	o Scattered fibroglandular densities o Heterogeneously dense	[20]	[32]	
	o Extremely dense	Medio-Lateral (selec	τ all triat apply) □ RT	
	·	☐ LT [33] ☐ LA [34]	□ RT [41] □ RA [42]	
12.	Index Lesion Identified on Mammogram [17]	1 1341	□ RB [⁴²]	
	o No	☐ LB [35] ☐ LC [36]	□ RC [43]	
	o Yes	LD [37]	$\square \qquad RD_{[45]}^{[44]}$	
		☐ LE [38]	☐ RE [16]	
9.	Clinically Relevant Mass(es) Identified [11]	l F (**)	□ RE''''	
	o No	☐ LG [39]	☐ RG [47]	
	o Yes (report in section A)		all three measurements)	
	Total Number [12]		ial-lateral) _[49]	
10.	Remember to complete Clinically Relevant	y =mm (supe	rior-inferior) _[50]	
	Calcification Cluster on page 3 - Section B	1 1 1 1	rior-posterior) [51]	
11.	Remember to complete Clinically Relevant Architectural Distortions on page 5 - Section C	Largest Dimension o	of Mass	

ACRIN 6657 Extension Mammography Interpretation Form	PLACE LAB
If this is a revised or corrected form, please $\sqrt{\text{box}}$.	Institution Participant Initials
Maca Shana (aglast and)	PRE-SUR
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	Medio-Lateral (select all
Distance Between Ends of Spiculation (answer if margin is spiculated)	Size of Mass (record all to x =mm (medial-log prior- y =mm (superior- z =mm (anterior-
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]	Largest Dimension of M Mass Shape (select one) o Round o Oval o Lobulated o Irregular Mass Margins (select one) o Circumscribed o Microlobulated o Obscured o Indistinct o Spiculated
Mass Corresponds to Index Lesion [63] o No o Yes Additional Masses [64] o No (proceed to section B) o Yes (continue) Reporting Mass #	Distance Between Ends (answer if margin is spicu)
Mass Location: Cranio-Caudal (select all that apply)	Associated Features (see Calcifications [104] Architectural distortion Skin thickening [106] Solitary dilated duct Multiple dilated ducts None [109] Mass Corresponds to Internal Calculations (104)

y 6657 EL HERE Institution No. Case No. **GERY** hree measurements) lateral) [96] -inferior) [97] posterior) [98] Mass mm [99]) _[100] ne)_[101] of Spiculation lated) e)_[103] elect all that apply) ons _[105] 107] [108] Mass Corresponds to Index Lesion $_{[110]}$

No

Yes

0

0

ACRIN 6657 Extension **Mammography Interpretation Form** If this is a revised or corrected form, please $\sqrt{\text{box}}$. Additional Masses [111]
o No (proceed to section B) Yes (continue) Reporting Mass # _____ Mass Location: Cranio-Caudal (select all that apply) R0_[120] L0 [113] R1 L1 [114] [121] L2 [115] R2 П [122] L3 [116] R3 [123] R4 [124] [117] [124] L5 [118] R5 [125] L6 [119] R6 [126] Medio-Lateral (select all that apply) RT_[135] LT [127] RA [135] RB [136] RC [137] RC [138] RD [139] RE [140] RF [141] RG [142] LA [128] LB [129] LC [130] LD [131] LE [132] LF [132] П LF [133] LG [134] Size of Mass (record all three measurements) $\mathbf{x} =$ mm (medial-lateral) [143] y = mm (superior-inferior) $_{[144]}$ mm (anterior-posterior) [145] Largest Dimension of Mass LLL mm [146] Mass Shape (select one) [147] Round Oval 0 Lobulated Irregular Mass Margins (select one) [148] Circumscribed Microlobulated Obscured Indistinct Spiculated **Distance Between Ends of Spiculation** (answer if margin is spiculated) **」mm** _[149] Mass Density (select one) [150] High Equal

ACRIN Study 6657

PLACE LABEL HERE

Institution	Institution No.	
Participant Initials	Case No.	

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]

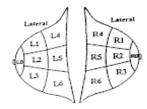
- o No
- o Yes (report in section B)

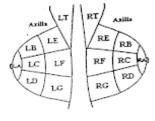
Total Number [14]

Reporting Calcification Cluster# [159]

Cranio-Caudal

Medio-Lateral Oblique





Calcification Location:

Cranio-Caudal (select all that apply)

L0 [160]		R0 _{[167}
L1 [161]		R1 [168]
L2 [161]		R2 [160]
L3 [162]		R3 [170]
L4 [164]		R4 [170]
L5 [104]	П	R5 [17]
L0 [160] L1 [161] L2 [162] L3 [163] L4 [164] L5 [165] L6 [166]		R0 [167] R1 [168] R2 [169] R3 [170] R4 [171] R5 [172] R6 [173]

Low

Fat containing

N4	ACRIN 6657 Extension Mammography Interpretation Form				Study 6657 ABEL HERE	
	,	Institut	ion			
If this is a re	evised or corrected form, please $\sqrt{\text{box.}}$		pant Initials			
Mac	dio-Lateral (select all that apply)	Particip				
	$LT_{[174]}$ \square $RT_{[182]}$ $LA_{[175]}$ \square $RA_{[183]}$	Reporting	PI g Calcification	RE-SURGE	1	
	LD 14=03 ND 140.43	1	alcification Lo		[197]	
	LD [178]		ranio-Caudal		at apply) R0 _[205]	
	$\begin{array}{cccccccccccccccccccccccccccccccccccc$		L2 [199]		R2 [206]	
Lar	gest Dimension of Calcification Cluster		[201]		R3 _[208] R4 _{rass}	
Moi	mm _[190] rphology of Calcification: <i>(select one)</i>		[203]		R5 _[210] R6 _[211]	
	ign Appearing [191]		ledio-Lateral (annlv)	
0	Skin Calcifications Vascular Calcifications		LT [212]		RT _[220] RA _[221]	
0	Coarse ("Pop-corn-like") Large Rod-like Round		LC _[215]		RC _[222]	
0 0	Lucent centered Eggshell or Rim		LE [217] LF [218]		RD [224] RE [225] RF [226] RG [227]	
0	Milk of Calcium Suture Dystrophic	L	argest Dimen		ication Cluster	
	Punctate		mm _{[228}	8]		
	rmediate Concern	B ₀	lorphology of enign Appearin	Calcification	: (select one) [229]	
	Amorphous or Indistinct ner Probability	0	Skin Calcific Vascular Ca			
0	Pleomorphic or Heterogenous (Granular) Fine, Linear, Branching (Casting)	0 0	Coarse ("Po Large Rod-li	p-corn-like")		
0	cification Distribution (select one) [192] Grouped/Clustered Linear	0 0	Round Lucent cente Eggshell or Milk of Calci	Rim		
	Segmental Regional Diffuse/Scattered	0 0	Suture Dystrophic Punctate			
	cification Cluster Associated with Mass	In	termediate Cor	ncern		
Rep o	oorted on This Form [193] No	0	Amorphous	or Indistinct		
0	Yes, associated with previously identified		igher Probabilit	•	(One and an)	
	mass # [] (#1-3) _[194]	0	•	cor Heterogen , Branching (C	ous (Granular) asting)	
0	cification Cluster Corresponds to Index Lesion [195] No	C	alcification Di	i stribution (s	elect one) [230]	
0 Add	Yes ditional Calcification Clusters _[196]	0	Linear	30.0100		
0	No (proceed to section C) Yes (continue)	0 0	Segmental Regional Diffuse/Scat	tered		

	_	ľ	N		4	
I	f	th	iis	is	а	re

ACRIN 6657 Extension

Mammography Interpretation Form		ACRIN Study 6657 PLACE LABEL HERE			ERE	
If this is a revised or corrected form, please $\sqrt{\text{box.}}$ Calcification Cluster Associated with Mass			n		on No	
		Participa	ant Initials		0	
Calcification Cluster Associated with Mass Reported on This Form [231] o No o Yes, associated with previously identified mass # [41-3] [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)			0 0 0 0 0	PRE- Icification Distri Grouped/Cluste Linear Segmental Regional Diffuse/Scattere Icification Clust ported on This No Yes, associated	ed er Associated Form _[269]	l with Mass
Reporting	Calcification Cluster#	<u> </u> [235]		mass # (#		
Cal Cra	Cification Location: Canio-Caudal (select all that L0 [236]	apply) R0 [243] R1 [244] R2 [245] R3 [246] R4 [247] R5 [248] R6 [249] [249] [258] RA [259] RB [260] RC [261] RD [262] RE [263] RF [264] RG [265]	SECTION ODISTORTIC descriptive distortions. Architecture No o Ye	Icification Cluster No Yes Iditional Calcific No Yes C: CLINICALLY F ONS (Report inde	RELEVANT AF ex lesion if visue e most promine ldentified [15]	CHITECTURAL alized. Report
Mo Ben	rphology of Calcification: nign Appearing Skin Calcifications	(select one) [267]	Cr Lateral	ranio-Caudal	, (,	Lateral Oblique
0 0 0 0 0 0 0 0 0 0 0 0 0	Vascular Calcifications Coarse ("Pop-corn-like") Large Rod-like Round Lucent centered Eggshell or Rim Milk of Calcium Suture Dystrophic Punctate		Ar Cr	chitectural Distoranio-Caudal (See	elect all that ap □ R	n: ply)
Inte	rmediate Concern			L1 [275] L2 [275]		2 [202]
0	Amorphous or Indistinct			13 ^[276]		2 [203]
Higl	her Probability			L4 _[278]		14 [285]
0 0	Pleomorphic or Heterogenou Fine, Linear, Branching (Cas			L5 [279] L6 _[280]		25 _[286] 26 _[287]

<u>-</u>		
	N4	•
11	f this is a	re
	N	/le]]

ACRIN 6657 Extension

Mammography Interpretation Form evised or corrected form, please $\sqrt{\text{box}}$. edio-Lateral (select all that apply) RT_[296] RA_[297] LT [288] LA [289] RB [298] RC [299] LB [290] LC [291] LD [292] LE [293] LF [294] RD [300] RE [301] RF [302] П [294] [302] RG [303] LG _[295] П **Largest Dimension of Architectural Distortion** | _____ **mm** _[304] **Architectural Distortion Associated with Mass** Reported on This Form [305] Yes, associated with previously identified mass # [__] (#1-3) [306] **Architectural Distortion Corresponds to Index** Lesion [307] No o Yes Additional Architectural Distortions [308] o No (proceed to question 13) o Yes (continue) **Architectural Distortion Location:** Cranio-Caudal (select all that apply) L0_[310] R0_[317] L1 [311] L2 [312] R1 [318] R2 [319] L3 [312] L4 [313] L5 [315] R3 [320] R4 [321] R5 [322] R6 [323] L6 [316] Medio-Lateral (select all that apply) RT_[332] LT_[324] RA [333] LA [325] RB [334] RC [335] LB [326] LC [327] RD [336] RE [337] RF [338] RG [339] LD [328] LE [329] LF [330] LG [331] **Largest Dimension of Architectural Distortion** |____ **mm** _[340]

ACRIN Study 6657

PLACE LAREL HERE

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Institution	Institution No		
Participant Initials	Case No.		
PRE-SUR	GERY		
Architectural Distortion	on Associated with Mass		

Reported on This Form $_{[341]}$

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

Architectural Distortion Corresponds to Index Lesion [343]

- No
- Yes

Additional Architectural Distortions $_{[344]}$

- o No (proceed to question 13)
- Yes (continue)

Reporting Architectural Distortion # [345]

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

L0 [346]		R0 _[353]
L0 _[346] L1 _[347] L2 _[348] L3 _[349] L4 _[350] L5 _[351] L6 _[352]		R0 [353] R1 [354] R2 [355] R3 [356] R4 [357] R5 [358] R6 [359]
L2 [348]		R2 [355]
L3 [340]		R3 [356]
L4 [349]	$\overline{\Box}$	R4 [350]
L5 [350]		R5 [357]
L6 [351]		R6 [330]
[352]		1359

Medio-Lateral (select all that apply)

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

- No
- Yes, associated with previously identified mass # [___] (#1-3) [378]

Architectural Distortion Corresponds to Index Lesion [379]

- No
- Yes

N4

ACRIN 6657 Extension Mammography Interpretation Form

If this is a revised or corrected form, please $\sqrt{\text{box.}}$

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)

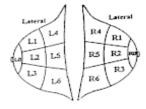
- ☐ Intramammary Lymph Node [382]
- ☐ Asymmetric Breast Tissue [383]
- ☐ Focal Asymmetric Density [384]

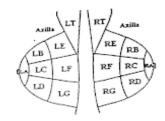
14. Full Extent of Disease

(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

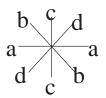
ACRIN Study 6657

PLACE LABEL HERE

Institution _____ Institution No. ____

Participant Initials _____ Case No.

PRE-SURGERY



Orientation of Longest Diameter Measurement

(refer to above diagrams - use same orientation for all mammograms) $_{\mbox{\tiny 13861}}$

- 0 8
- o b
- o C
- 0 0

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]

- 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 o	r the completed/printed	web form)
Signature of person responsible for data	[390]	2 0 0
Signature of person entering data onto web	[392]	

Visit 4 – Pre-Surgery Visit (after final chemotherapy treatment and before surgery)

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.

Visit 4 – Pre-Surgery Visit (after final chemotherapy treatment and before surgery)

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.

Visit 4 – Pre-Surgery Visit (after final chemotherapy treatment and before surgery)

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.

Visit 4 – Pre-Surgery Visit (after final chemotherapy treatment and before surgery)

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

If this is a revised or corrected form, please $\sqrt{\text{box}}$.

ACRIN Study 6657

Case #

PLACE LABEL HERE

Institution

Institution No.

Participant's Initials

Participant's I.D. No.

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	Complete For Study Breast Only		
o Pre-Surgery			
 1a. Was MRI performed? [407] O No* (complete Q1b, then sign and date form) 	9. Study Breast [10] o Right o Left		
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 Yes (report on supplemental TS form)		
 Date of MRI 20(mm-dd-yyyy) [3] Date of Interpretation 20[4] 	12a.Were Clinically Relevant Regional Enhancements Identified on the baseline (T1 Form) o No o Yes (report in Section B)		
4. Reader Name:			
 5. Reader ID: [6] 6. Patient Weight (kgs) [7] 	12b.Are New Regional Enhancements now seen that were not seen on Baseline [387] o No		
6. Fatient Weight (kgs) [7]	o Yes (report on supplemental TS form)		
7. Total Amount of Gadolinium Injected (cc) [8]	13. Index Lesion Identified on this MRI Exam [16]		
 Were Clinically Relevant Enhancing Lesion(s) Identified No (sign and date form) Yes 	NI NI		
	* Please remember to complete page 8		

$\boxed{14}$ If this is a revised or corrected form, please $\sqrt{\text{box}}$.	ACRIN Study 6657 Case #
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	Institution Institution No. Participant's Initials Participant's I.D. No.
TS Form.	PRE-SURGERY
I. 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 Cranio-Caudal Medio-Lateral	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
Lateral Lateral R4 R1 R5 R2 R0 R5 R2 R0 LD LC LF R6 R3 R6 R3 R6 R3	 T2 Appearance (select one) [53] Hyperintense to surrounding breast tissue Hypointense to surrounding breast tissue Isointense to surrounding breast tissue Unable to evaluate 1f. Degree of Enhancement (characterize by strongest degree seen) Minimal Moderate
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]	1g. Enhancement Pattern (characterize by strongest pattern seen) o Gradual o Sustained o Washout 1h. Series and Image Number of Representative Slices (list up to 3)
Medio-Lateral (select all that apply) □ LT [32] □ RT [40] □ LA [33] □ RA [41] □ LB [34] □ RB [42] □ LC [35] □ RC [43] □ LD [36] □ RE [44] □ LE [37] □ RF [45] □ LF [38] □ RG [46] □ LG [39] □ RG [47] Ib. Size (record all three measurements [0 = not seen]) x = □ □ □ mm (medial-lateral) [48] y = □ □ mm (superior-inferior) [49]	Series : : : : : : : : :
z = mm (anterior-posterior) [50] Ic. Shape/Margin (select one) [51] o Smooth round o Smooth oval o Lobulated o Irregular o Spiculated o No longer a mass	[345]

$\boxed{14}$ If this is a revised or corrected form, please	e √box.	RIN Study 6657	Case #
Section A: Masses All masses documented on the T1 Form must be reposection. If new masses are now present, report on the suTS Form.	orted in this	titution ticipant's Initials	Institution No. Participant's I.D. No.
2a. Location: Cranio-Caudal (select all that apply) L0	2d.	Internal Enhanceme o Homogeneous o Heterogeneous o Rim enhanced o Centrally enhan o Dark septation(s o Enhancing sept o No longer a ma T2 Appearance (sele o Hyperintense to o Hypointense to o Isointense to su o Unable to evalua Degree of Enhancer (characterize by stro o Minimal o Moderate o Marked Enhancement Patte	ent (select one) [93] confluent ced s) ation(s) ss ect one) [94] surrounding breast tissue surrounding breast tissue irrounding breast tissue ate enent ingest degree seen) [95]
L4 [63]	0]	o Gradual o Sustained o Washout Series and Image N Slices (list up to 3) Series : Series : Carical	umber of Representative 347] Image # [348] 349] Image # [350] [350] Image # [352]
o Irregularo Spiculatedo No longer a mass			[353]

T^2	If this is a revised or corrected form, please $\sqrt{\text{box}}$.	ACRI	N Study 6657	Case #	
All mas	on A: Masses uses documented on the T1 Form must be reported in this If new masses are now present, report on the supplemental m.	Institu	ution cipant's Initials	Institution No. Participant's I.D. No. SURGERY	
	he lesion identified as Mass #3 on the T1 Form I visible? [354] No (skip 3a-3i) Yes (complete 3a-3i) Not Applicable Cranio-Caudal Medio-Lateral Literal R5 R2 R2 R6 R5 R2 LC LF RF RC R6 RF RC R7 RF RC R7 RF RC R6 RF RC R7 RF RC R8 RF RC R8	3d. 3e. 3f.	Internal Enhancement O Homogeneous O Heterogeneous O Rim enhanced O Centrally enhan O Dark septation(O Enhancing sepi O No longer a max T2 Appearance (seli O Hyperintense to O Hypointense to O Isointense to so O Unable to evalue Degree of Enhancer (characterize by stro O Minimal O Moderate O Marked Enhancement Patter	ent (select one) [134] confluent ced s) tation(s) tass ect one) [135] surrounding breast tissue surrounding breast tissue surrounding breast tissue atterion and the surrounding breast tissue atterior and the surrounding breast tissue atter	
3b.	Medio-Lateral (select all that apply) □ LT [114] □ RT [122] □ LA [115] □ RA [123] □ LB [116] □ RB [124] □ LC [117] □ RC [125] □ LD [118] □ RE [127] □ LF [120] □ RF [128] □ LG [121] □ RG [129] Size (record all three measurements [0 = not seen]) x = □ □ mm (medial-lateral) [130] y = □ mm (superior-inferior) [131] z = □ □ mm (anterior-posterior) [132]	3h. 3i.	Series :: Series :: Series :: Corresponds to Ind No No No No No No	umber of Representative [355] Image # [357] Image # [359] Image # ex Lesion [138]	[356] [358] [360]
3c.	Shape/Margin (select one) [133] o Smooth round o Smooth oval o Lobulated				[361]

o Irregular o Spiculated o No longer a mass

$\boxed{14} \hspace{0.2in} \text{If this is a revised or corrected form, please } \sqrt{\text{box.}} \hspace{0.2in} $	ACRIN Study 6657 Case # PLACE LABEL HERE
Section B: Regional Enhancements All regional enhancements documented on the T1 Form must be eported in this section. If new regional enhancements are now	Institution Institution No. Participant's Initials Participant's I.D. No.
All regional enhancements documented on the T1 Form must be eported in this section. If new regional enhancements are now present, report on the supplemental TS Form. Is the lesion identified as Regional Enhancement #1 from the T1 Form still visible? [363]	
b. Largest Dimension	1i. Corresponds to Index Lesion [177] o No o Yes COMMENTS:

$\boxed{14} \hspace{0.2in} \text{If this is a revised or corrected form, please } \sqrt{\text{box.}} \hspace{0.2in} \boxed{}$	ACRIN Study 6657 Case # PLACE LABEL HERE
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.	Institution Institution No. Participant's Initials Participant's I.D. No. PRE-SURGERY
2. Is the lesion identified as Regional Enhancement #2 on the T1 Form still visible? O No (skip 2a-2i)	2d. Internal Enhancement (select one) O Homogeneous confluent O Heterogeneous non-specific O Heterogeneous stippled, punctate O Heterogeneous clumped O Septal, dendritic O Asymmetric O Not applicable 2e. T2 Appearance (select one) O Hyperintense to surrounding breast tissue O Hypointense to surrounding breast tissue O Hypointense to surrounding breast tissue O Unable to evaluate 2f. Degree of Enhancement (characterize by strongest degree seen) O Minimal O Moderate O Marked 2g. Enhancement Pattern (characterize by strongest pattern seen) O Gradual O Sustained O Washout 2h. Series and Image Number of Representative Slices (list up to 3) Series : [372] Image #
2b. Largest Dimension	2i. Corresponds to Index Lesion [216] o No o Yes
2c. Distribution Subtype (select one) 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	COMMENTS:

[378]

Τ	If this is a revised or corrected form, please $\sqrt{\text{box}}$.	ACR	RIN Study 6657	Case # BEL HERE
All re	ion B: Regional Enhancements gional enhancements documented on the T1 Form must be ted in this section. If new regional enhancements are now int, report on the supplemental TS Form.		itution icipant's Initials	Institution No. Participant's I.D. No.
3. Is o o o o o o o o o o o o o o o o o o	Sthe lesion identified as Regional Enhancement #3 In the T1 Form still visible? [379] No (skip 3a-3i) Yes (complete 3a-3i) Not Applicable Cranio-Caudal Medio-Lateral	3d. 3e. 3f. 3h.	Internal Enhancement O Homogeneous co O Heterogeneous no O Heterogeneous sto O Heterogeneous sto O Heterogeneous sto O Heterogeneous clo O Septal, dendritic O Asymmetric O Not applicable T2 Appearance (sele O Hyperintense to sto O Isointense to surro O Unable to evaluate Degree of Enhancer (characterize by strong O Minimal O Moderate O Marked Enhancement Patter (characterize by strong O Gradual O Sustained O Washout	int (select one) [251] Influent Influen
3c.	Distribution Subtype (select one) 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	СОМІ	o Yes	

[386]

$\boxed{1}$ If this is a revised or corrected form, please $\sqrt{\text{box}}$.	AC
	Ins
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]	16. If an TS f dise
15. Other Findings [262] o No (proceed to question 16) o Yes (continue, characterize other findings) Characterization of Other Findings (select all that apply)	ı
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]	

ACRIN Study 6657

Case #

PLACE LABEL HERE

Institution

Institution No.

Participant's Initials

Participant's I.D. No.

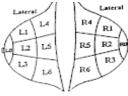
PRE-SURGERY

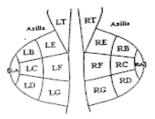
16. Full Extent of Disease

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

Cranio-Caudal

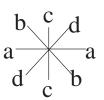
Medio-Lateral





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]

- 0
- o b

а

- 0 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]

8 of 9

$\boxed{14}$ If this is a revised or corrected form, please $\sqrt{\text{box}}$.	ACRIN Study 6657	Case #
	PLACE 1	LABEL HERE
17. TFQ Staging Classification	Institution	Institution No.
17. IT & Staying Glassification	Participant's Initials	Participant's I.D. No.
T (select one – size of dominant lesion only) $_{[278]}$	DRI	E-SURGERY
O T0 No primary O Tis In Situ	1111	E-SONGEN1
O T1a <5mm		
O T1b 5-9 mm O T1c 10-20 mm	18. Total number of mas	sses seen on this exam [405]
O T2 21-50 mm O T3 >50 mm		[400]
O T4a chest wall	19. Total number of reg	ional enhancements seen on
O T4b skin O T4c chest wall and skin	this exam	[406]
O T4d inflammatory		[400]
F (select one – size of full extent of disease) [279]		
O F0 no other area of suspicious enhancement		
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		
1 1 1		
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		
COMMENTS:		
		[282]
		[]
Radiologist Signature		
(radiologist must sign either the completed paper form or the comp	leted/printed web form)	
	[283]	
Signature of person responsible for data	- ·	
	[285]	20 _[284]
Signature of person entering data onto web	Date for	rm completed (mm-dd-yyyy)
* Please remember	to complete page 8	

"Copyright 2007" ACRIN 6657 T4 11-29-07 9 of 9

Visit 4 - Pre-Surgery MRI 4

(within 3-4 weeks after chemotherapy and prior to surgery)

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.

Visit 4 - Pre-Surgery MRI 4

(within 3-4 weeks after chemotherapy and prior to surgery)

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.

Visit 4 - Pre-Surgery MRI 4

(within 3-4 weeks after chemotherapy and prior to surgery)

- 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.
- 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.

Visit 4 - Pre-Surgery MRI 4

(within 3-4 weeks after chemotherapy and prior to surgery)

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.

_	ACRIN 6657 Extension			A CDIN C4	.d. 6657
l	Ultrasound Interpretatio	n Form	ACRIN Study 6657 PLACE LABEL HERE		
	 -		Institution		Institution No
If thi	nis is a revised or corrected form, please $\sqrt{1}$	oox.	Participant Initia	ls	Case No
	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		PRE-SURGERY		
adiol he in ultras	ructions: In accordance with protocol, two optiologist if a diagnostic ultrasound is performed. Rendex lesion only. The index lesion corresponds to sound via the ACRIN website. Submit paper for performed.	eport only ultrasound ex to the tumor used to de	kams corresponding to fine participant eligibili	the last MRI ex ty. Submit this	kam. Please report characteristics of form within two weeks of each
	Protocol Time Point [1] o Pre-surgery		INDEX LESION (The index lesi participant elig	ion correspon	nds to the tumor used to define
2. D	Date of Ultrasound	(mm-dd-yyyy) _[2]	Cranio-C	Caudal	Medio-Lateral Oblique
3. D	Date of Interpretation(mm-dd-yyy	/y) [3]	Lateral L4	Rd R1 R5 R2 R0	Azilla LT RT Azilla RE RB
	Reader Name:	[4]	13 16	R6 R3	LD LG RG RD
5. R	Reader ID: [5]		Inde	ex Lesion Lo	cation:
6 .	Study Breast [6]				select all that apply)
	o Right			L0 _[13]	☐ R0 _[20]
	o Left			L1 _[14]	\square R1 $_{[21]}$
	o Bilateral			L2 _[15]	$ \begin{array}{ccc} & R2 \\ & R2 \end{array} $
				L3 [16] L4 [17]	☐ R3 ^[22] ☐ R4 ^[24]
7.	Clinically Relevant Lesion(s) Identification	ed _[7]		L5 [17]	KO ₁₀₅₁
	o No (sign and date form)			L6 [19]	\square R6 $_{[26]}^{[25]}$
	o Yes		Med		select all that apply)
			П	LT [27]	□ RT _[35]
8.	Total Number of Clinically Relevant	Lesions 📖 📳		LA ₁₂₈₁	☐ KA ⁽³⁶⁾
		اِی		LB LOOI	☐ RB _[37]
9.	Index Legion Identified on Ultracoun	d		LC rant	
		(a _[9]		LD [31] LE [32]	□ RD _[39] □ RE _[40]
	o No (sign and date form) o Yes			LF [33]	☐ RF [41]
				LG [34]	\Box RG $_{[42]}^{[41]}$
	Doppler Characteristics [10]		0:		
	o Not applicable		1	of Index Le	
	o Hypervascular o Hypovascular		x = [mm (r	medial-lateral) [43]
	Протосомы		y = [mm (s	superior-inferior) [44]
11.	Characterize the Index Lesion [11]		z = _	mm (a	anterior-posterior) [45]
	o Cystic				
	o Solid		Larg	est Dimensi	on of Index Lesion
	o Other, specifyo Unknown	[12]		mm _[46]	
	o Unknown			[مد]	

"Copyright 2007"

ACRIN 6657 Extension ACRIN Study 6657 **Ultrasound Interpretation Form** PLACE LABEL HERE Institution No. _____ If this is a revised or corrected form, please $\sqrt{\text{box}}$. Participant Initials _____ Case No. _ **PRE-SURGERY** Homogeneity of Index Lesion (select one) [47] o Homogeneous Heterogeneous without cysts o Heterogeneous with cysts Echogenicity of Index Lesion (select one) [48] o Hypoechoic Isoechoic 0 o Hyperechoic Border of Index Lesion (select one) [49] Smooth Spiculated 0 o Lobular Irregular 0 COMMENTS:

Radiologist Signature (radiologist must sign either the completed paper form or the completed/printed web form) Signature of person responsible for data Date form completed (mm-dd-yyyy)

Signature of person entering data onto web

Visit 4 – Pre-Surgery Visit (after final chemotherapy treatment and before surgery)

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.

Visit 4 – Pre-Surgery Visit (after final chemotherapy treatment and before surgery)

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.

ACRIN 6657 Extension MRS Form: Pre-Surgery MRS - 4

If this is a revised or corrected form, please $\sqrt{\text{box}}$.

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.

	aging visit.	study. Same magnet neld strength and con should be used at eve	яy
	Timepoint [1] O MRS 4 Pre-Surgery 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	7. Person responsible for voxel placement: [20] (select one) O 1 MR Technologist O 2 Research Associate O 3 Nurse O 4 Pl Radiologist O 5 Physician O 88 Other personnel (specify): Phantom QC Measurement	_ [2·
١.	Were baseline studies with voxel positioning used to determine MRS asquisition? [7] O 1 No (Complete Q4a) O 2 Yes (If yes, complete Q4b)	 8. Phantom scan performed within past 7 days? [22] O 1 No (If no, complete Q8a) O 2 Yes 8a. If no, specify reason: 	
	4a. If no, specify reason:	Specify,	[23
	Specify,	8b. Date of last phantom scan	
	4b. Which previous images were used for voxel placement?	(mm-dd-yyyy) [24]	
	MRI-1: ☐ hardcopy _[9] ☐ online _[10]	9. MRS Acquisition	
	MRI - 1.1: □ hardcopy _[11] □ online _[12]	Cranio-Caudal Medio-Lateral	
	MRI-2: □ hardcopy _[13] □ online _[14]		
	Pate of MRI (mm-dd-yyyy)	Lateral Lateral R4 R1 R2 R4 R2 R4 R4 R4 R5 R2 R5 R2 R5 R6 R5 R6 R6 R6 R6 R6	
	Magnet field strength [18] O 1 1.5	Cranio-Caudal Medio-Lateral	
	O 2 3	(select all that apply) (select all that apply)	
	O 88 Other, specify[19]	$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$	3] 9] 9] 1

ACRIN 6657 Extension MRS Form: Pre-Surgery MRS - 4

ACRIN Study 6657

PLACE LABEL HERE

MR5 - 4	Institution	Institution No
If this is a revised or corrected form, please $\sqrt{\text{box.}}$	Participant Initials	Case No
0. Pre-scan calibration	PRE-	SURGERY
Shimming: [55] O manual O automatic		
Water Suppression: [56] O manual O automatic		
Confidence in accurate reproduction of voxel placement (c)	heck one):	
	/ [5/]	
Very Confident	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]	
2. Is the scanner and breast coil the same as was used for the	e baseline MRS exam?	
O No (Complete Q12a)	[67]	
O Yes		
42a If no openify eyetem year		
12a. If no, specify system used		
Specify,	[68]	
COMMENTS:		
		[64]
	1 1 1 1	
[65] D	Pate form completed	(mm-dd-yyyy) _[66]
Signature of person responsible for the data		[]

Visit 4 – Pre-Surgery Visit (within 3-4 weeks after chemo and prior to Surgery)

V4 MRS Form - Completion Instructions

In accordance with protocol, four to five spectroscopy exams may be reported. Visit #4 (Presurgery 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.

Visit 4 – Pre-Surgery Visit (within 3-4 weeks after chemo and prior to Surgery)

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.

ACRIN 6657 Extension Surgical Pathology Form

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f this is a revised or corrected form, please \sqrt{b}	ox.	

ACRIN Study	6657
PLACE LAB	EL HERE

Institution	Institution No.
Participant Initials	Case No.

SURGERY

	OUNGENT
	based on the CALGB Post-Surgery Summary Form (C-911) and/or gery via the ACRIN website. Submit paper form only for revisions or
OST-CHEMOTHERAPY SURGERY Most extensive primary surgery [1] Partial mastectomy/lumpectomy/excisional biopsy Mastectomy, NOS Date of most extensive primary surgery [2] mm/dd/yyyy Specimen laterality [3] Left Right Unknown	D. Nuclear grade (mark highest grade) 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? O No (proceed to question 7) O Yes (complete A-H)
If breast-conserving surgery was not performed, indicate principal reason: 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: ATHOLOGY: ASSESSMENT OF DUCTAL CARCINOMA ISITU (DCIS)	A. Pathologic primary tumor size, Gross
 Is DCIS present? [6] No (proceed to question 6) Yes (complete A-D) A. Is DCIS present with invasive cancer? [7] 	Lesion # 2 Pathologic tumor size (mm), Microscopic [25] Pathologic tumor size (mm), Microscopic [27] D. Histologic type [28]
o No o Yes B. Pathologic primary tumor size, if pure DCIS	o Ductal carcinoma o Lobular carcinoma o Mixed ductal/lobular carcinoma o Other, specify: [29]
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]	 E. Nuclear grade (highest grade) Grade I (low, 1 pt) Grade II (intermediate, 2 pts) Grade III (high, 3 pts) F. Mitotic count 1 2 3 Indeterminate
Other, [17] Specify: [18]	

	S	4	
If th	nis is	a re	vise
	G.	Ar	chi
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		0	2
		0	3
		0	In
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		0	G
		0	G
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PA	THC	DLO	GΥ
7.	Wa	IS S	ent
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ACRIN 6657 Extension ACRIN Study 6657 PLACE LABEL HERE Surgical Pathology Form Institution No. Institution ed or corrected form, please $\sqrt{\text{box}}$. Participant Initials _ _____ Case No. SURGERY tecture (tubule formation) [32] PATHOLOGY: DISEASE STAGING determinate 9. T stage, pathologic [42] T0 pined histologic grade (according to SBR/ Tis T4 n classification)_[33] 0 T1mic T4a chest wall rade I (low) T4b skin T1a rade II (intermediate) T1b T4c chest wall and skin rade III (high) T1c T4d inflammatory nknown T2 : ASSESSMENT OF LYMPH NODES 10. N stage, pathologic $_{[43]}$ inel node sampling performed? $_{[34]}$ N1biii N0 N1 N1biv 0 complete A-C) N1a N2 wn N3 N₁b N₁bi NX. A. Number of sentinel nodes examined: N1bii B. Total number of positive sentinel nodes: 11. M stage, pathologic [44] C. Diameter of largest positive sentinel lymph M0 node, if applicable 0 M1 ____ mm _[37] MX 8. Was axillary dissection performed? [38] 12. Stage grouping $_{[45]}$ 0 0 0 Yes (complete A-C) Unknown IΙΑ IIB A. Number of lymph nodes examined: [39] IIIA B. Total number of positive lymph nodes: IIIB IV C. Diameter of largest positive axillary lymph node, if applicable _____ mm _[41] COMMENTS: [47] Signature of person responsible for data [49]

Signature of person entering data onto web

Date form completed (mm-dd-yyyy)

ACRIN - 6657 COMPLETION INSTRUCTIONS

Visit 4 -Surgical Pathology Form

(Surgery)

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.

ACRIN - 6657 COMPLETION INSTRUCTIONS

Visit 4 -Surgical Pathology Form

(Surgery)

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

ACRIN 6657 Extension Supplemental MRI Form

If this is a revised or corrected form, please $\sqrt{\text{box}}$.

ACRIN Study 6657

Case #

PLACE LABEL HERE

Institution

Institution No.

Participant's Initials

Participant's I.D. No.

SUPPLEMENTAL MRI FORM

		OOT I ELIMENTAL MINT I O	TXIVI
seen on MRI-1). Continue to follow and report on this lesion((s) on subsequent	MRI exams. Please enter the data via the	
1. Date of MRI 20 (mm-dd-yyyy	y) _[1]		
2 Total number of new masses not previous	ly seen / reporte	ed [2]	
3 Total number of regional enhancements no Reader ID:	ot previously se	en / reported [3]	
COMMENTS:			
			[5]
Total number of regional enhancements not previously seen / reported [3] Reader ID: [4]			
Signature of paragraphic for data	[6]		[7]
Signature of person responsible for data		Date form completed (mm-c	іа-уууу)
	[8]		

Signature of person entering data onto web

ACRIN - 6657 COMPLETION INSTRUCTIONS

Supplemental MRI Form

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:

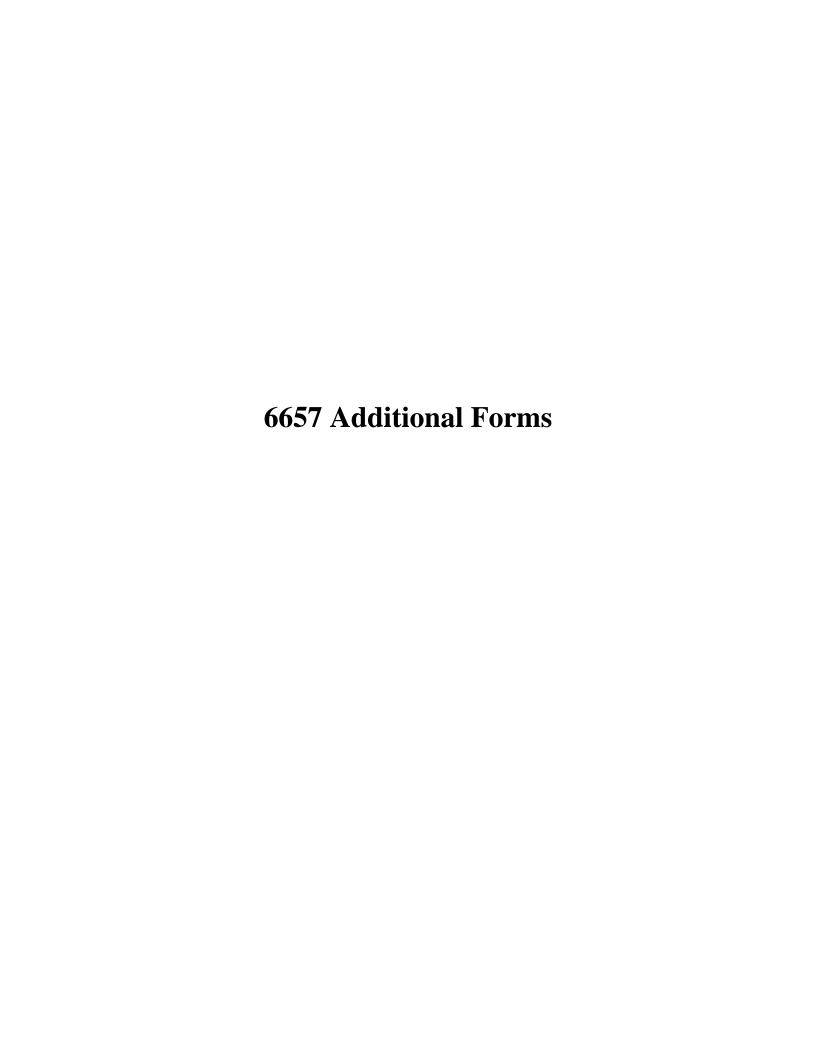
Indicate the total number of regional enhancements that were seen on this exam.

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.



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 coordinator for any	questions.						
AE Short Name (online look-up)							
Grade	Attribution [5]	Expectedness	Serious AE?	Expedited Report Submitted	Action Taken (mark 🗵 all that apply)	Outcome	Date of AE Onset and Resolution (mm-dd-yyyy); mark X 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					ed (mm-dd-yyyy)		
Investigator's signature (for external use only)							

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ACRIN FORM COMPLETION INSTRUCTIONS ADVERSE EVENT

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. <u>Category</u>: (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 <u>electronic PDF of the CTCAE version 4.0</u> or contact ACRIN's AE Coordinator.
 - b. <u>Code Description</u>: (Optional to search will narrow down the choices) you can filter further by entering partial term and or the entire term;

OR

- c. <u>MedDRA Term</u>: (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

ACRIN FORM COMPLETION INSTRUCTIONS ADVERSE EVENT

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.



ACRIN Study 6657 PLACE LAREL HERE

I LACE LA	ADEL HEKE
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.

Data Manag	gement 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:
Signature of	Person Responsible for Data Date form completed (mm-dd-yyyy)

ACRIN - 6657 COMPLETION GUIDELINES

Protocol Variation Form

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.

ACRIN - 6657 COMPLETION GUIDELINES

Protocol Variation Form

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:

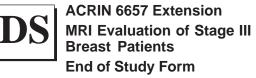
Legible signature/name of the staff member responsible for collating / reviewing the data and ensuring completion of the CRF (paper or web). If completing a web CRF only, without completing a paper CRF, the electronic summary must be printed and signed by the staff member responsible for the data. The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

ACRIN - 6657 COMPLETION GUIDELINES

Protocol Variation Form

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.



ACRIN Study 6657
PLACE LABEL HERE

	Institution	Institution No
If this is a revised or corrected form, please $\sqrt{\text{box}}$.	Participant Initials	Case No
The state of the s	END O	F STUDY FORM
Instructions: For each registered participant, please submit this fo discontinuation, including death.	rm within two (2) weeks of	study completion or premature
1. End of Study status: [1]		
O 1 Protocol specific criteria and follow-up complete (signO 2 Premature discontinuation (complete Q2 and Q2a)	and date form)	
O 3 Participant death (skip to Q3 and Q3a)		
2. Date of premature discontinuation:	(<i>mm/dd/yyyy</i>) _[2]	
2a. Primary reason for premature discontinuation: (check	conly one) _{rol}	
O Adverse events/side effect/complications (also speci	[-]	orm)
O Participant explicitly withdraws study consent/autho	rizations	
O Protocol violation		
O Did not meet baseline criteriaO Lost to follow-up (unable to obtain contact with the	narticinant during the press	eribed protocol intervals)
O Unsatisfactory therapeutic effect	participant during the prest	insed protocol intervals)
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	7]
COMMENTS:		
302.11.0.		
		[8]
Cimpature of paragraph reappropriate for the data	Data form con	npleted (mm-dd-yyyy) [10]
Signature of person responsible for the data	Date 101111 CON	ірівіви (піпт-ий-уууу)
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.

- **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 <u>protocol</u> 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 completed¹.
 - (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.

¹Imaging 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	Participant Initials/ID		
Data Item	Data Collection Calendar Due Date	Assessment/Imaging Date Recorded on Form by Institution	Comment/Explanation		
Initial evaluation for	m				
Imaging Form (speci	fy)				
Biopsy Form					
Follow-up Form					
Image Reports					
Image(s)					
Other (specify)					
	Resea	arch Associate	Date	04/04	