American College of Radiology Imaging Network
Forms Index

ACRIN Study 6667
MRI Contralateral Breast
Case #: _____

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[1]The "person responsible for the data" refers to the individual who has collated the data on this specific data form

[2]The "person entering data" is the individual who enters the data from the specific form into the web data form.

[3]"The "date form completed" is the date the worksheet, 'paper' CRF, etc. is completed, not the date it is entered into the web form. However, in most instances, the date form completed will be the same as the date of web data entry.

*"Submission date" - This column is intended as a tracking tool for forms submission on individual cases. It is recommended that the RA maintain a printed copy within each case file as a tool to document form submission.

APPENDIX II

ACRIN 6667 MRI Evaluation of the Contralateral Breast in Women with a Recent Diagnosis of Breast Cancer

Eligibility Checklist

Case # _____ (page 1 of 3)

Eligibility Requirements **(a response coded other than that prompted renders a patient ineligible for enrollment).**

{24} (Y)	1.	Has the patient had a diagnosis of DCIS or invasive cancer in the non-study breast?
{25} (Y)	2.	Will the study MRI be performed within 60 days of the initial biopsy proven (including FNA) cancer diagnosis?
/{26}/	3.	Date of initial biopsy demonstrating DCIS or invasive cancer in the non-study breast. (mm/dd/yyyy)
{27} (Y)	4.	Has the patient had a negative or benign mammogram and a negative or benign clinical breast exam of the study breast within 90 days of the MRI?
/{28}/	5.	Date of negative or benign mammogram (mm/dd/yyyy)
/{29}/	6.	Date of negative or benign clinical breast exam (mm/dd/yyyy)
/{30}/	7.	Scheduled Date of MRI (mm/dd/yyyy) [MRI must be within 90 days of CBE and mammogram, and within 60 days of biopsy of initial diagnosis.]

Eligibility Requirements: Exclusion Criteria **(a response coded other than that prompted renders a patient ineligible for enrollment).**

{31} (N)	8.	Are there any contraindications to the MR imaging outlined in Section 5.2.1 of the protocol?
{32} (N)	9.	Is the patient pregnant? (Gadolinium has not been approved for this population.)
{33} (N)	10.	Is the patient less than 18 years of age?
{34} (N)	11.	Are there psychiatric or psychological or other conditions which prevent a fully informed consent?
{35} (N)	12.	Has there been a previous breast biopsy in the study breast within the past 6 months, including FNA?
{36} (N)	13.	Has the patient had an MR exam of the study breast within 12 months prior to the study MRI?

{37} (N) 14. Does the patient have current or recent history (within 6 months prior to the MRI) of adjuvant chemotherapy for cancer? (Patients receiving adjuvant hormonal therapy, tamoxifen, and/or aromatase inhibitors for **preventative** measures, not **therapeutic** measures, are eligible.)

{38} (N) 15. Does the patient have a remote history of breast cancer as defined by biopsy-proven breast cancer diagnosis greater than 60 days prior to the study?

The following questions will be asked at Study Registration for enrollment onto 6667:

{2} (Y) 2. Has the Eligibility Checklist (above) been completed?

{3} (Y) 3. Is the patient eligible for this study?

/ {4} / 4. Date the study-specific Consent Form was signed (must be prior to study entry)
(mm / dd / yyyy)

/ {8} / 8. Birthdate (/yyyy)

{9} 9. Ethnic category

1 Hispanic or Latino
2 Not Hispanic or Latino
9 unknown

10. Race (check all that apply):

{42} ☐ American Indian or Alaskan Native
{43} ☐ Asian
{44} ☐ Black or African American
{45} ☐ Native Hawaiian or other Pacific Islander
{46} ☐ White
{47} ☐ Unknown

11. Gender (N/A)

{12} 12. Patient's country of residence (if country of residence is **other, complete Q18)**

1 United States
2 Canada
3 Other
9 Unknown

{13} 13. Zip Code (5 digit code)

{14} 14. Patient's insurance status

1 Private insurance
2 Medicare
3 Medicare and Private insurance
4 Medicaid
5 Medicaid and Medicare
6 Military or Veterans Administration
7 Self-pay
8 No means of payment
9 Unknown/decline to answer
0 Other

{15} 15. Will any component of the patient's care be given at a military or VA facility?

1 No
2 Yes
9 Unknown

/{16}/ 16. Calendar base date (date of registration)
(mm / dd / yyyy)

/{17}/ 17. Date of Registration (must be within <u>two</u> business days after completion of MRI scan)
(mm / dd / yyyy)

{23} 18. Other country, specify (completed only if Q12 is coded *other*)

Date form completed: {40}/ /

B2 MRI Contralateral Breast

MRI Finding Diagram

ACRIN Study 6667

PLACE LABEL HERE

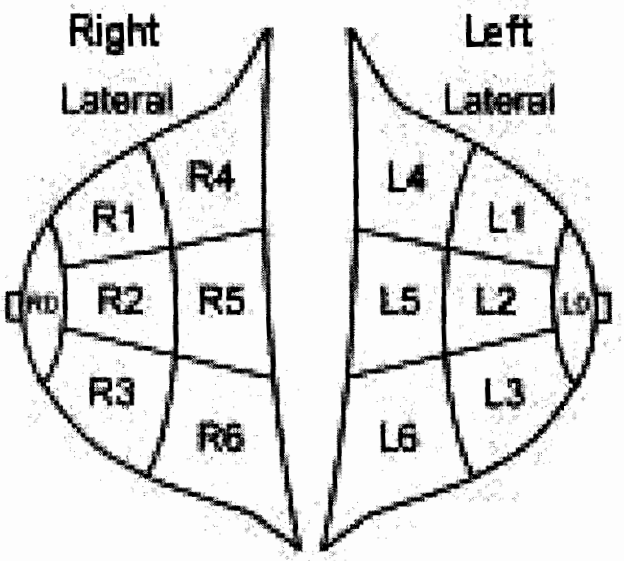
Case No. _____

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

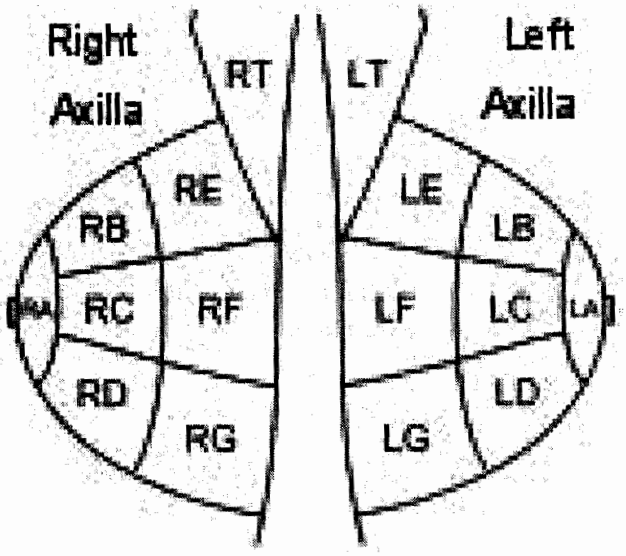
INSTRUCTIONS:

1. This form is to be completed for all findings on the initial MRI (Form M3, Question 3).
2. If follow-up imaging is done which results in additional findings, this form must be updated to include the new findings. New findings will be numbered sequentially, starting with the next available number.
3. This diagram will be used as the reference for correlating findings across imaging modalities and tracking findings throughout the entire study. Therefore, it is essential that all findings are clearly drawn on the diagrams and carefully numbered.
4. Retain this form in the Case Study File.

Cranio-Caudal



Medio-Lateral



_____

Signature of person responsible for the data [1]

Date form completed[3] ____-____-_____ (mm-dd-yyyy)

I1 MRI Contralateral Breast Initial Evaluation Form

ACRIN Study 6667

PLACE LABEL HERE

Case No. _____

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

INSTRUCTIONS: After participant enrollment onto the study this form is completed based on information obtained from the participant's history and physical, clinic or hospital chart or questionnaire completed and signed by the participant . Dates are recorded as MM-DD-YYYY unless otherwise noted. Of note, questions referring to biopsy are recorded for the study breast.

1. {1} _____-_____-_____ **DATE OF BIRTH**
-yyyy)

2. {2} **MENOPAUSAL STATUS**
1 Pre-menopausal
2 Surgical menopause
3 Post menopausal (last menses >1 year ago)
4 Peri-menopausal (last menses <1 year)
99 Unknown

2A. If date of last menstrual period is unknown, place a check in the box below. Otherwise, please fill in date

{3} ☐ Unknown

DATE OF LAST MENSTRUAL PERIOD
(if pre or peri-menopausal)

{4} _____-_____-_____
(mm-dd-yyyy)

3. {5} **NUMBER OF FULL TERM PREGNANCIES**
(0 = N/A or none; if 1 or more full term pregnancies, complete Q3A)

3A. {6} **Age at First Full Term Pregnancy** (years)

4. {7} **AGE AT MENARCHE** (years)
(If age unknown, code "99")

5. {8} **AGE AT MENOPAUSE** (years)
(If pre- or peri- menopausal, code "98" - N/A;
if age unknown, code "99")

6. {9} **BREAST IMPLANT** (study breast)
1 No
2 Yes

7. {10} **HISTORY OF HORMONE USE**
1 No (skip to Q8)
2 Yes (complete Q7A and continue to Q8)

7A. CURRENT OR PRIOR HORMONE USE
(check all that apply)

{11} ☐ Current use Birth Control Pills
{12} ☐ Current use Estrogen Replacement Therapy
{13} ☐ Current use Tamoxifen/Serm* Therapy
(*Selective Estrogen Receptor Modulator)
{14} ☐ Current use Aromatase Inhibitor Therapy
{62} ☐ Current use other, specify {63} _____
{15} ☐ Prior use Birth Control Pills
{16} ☐ Prior use Estrogen Replacement Therapy
{17} ☐ Prior use Tamoxifen/Serm* Therapy
{18} ☐ Prior use Aromatase Inhibitor Therapy
{64} ☐ Prior use other, specify {65} _____

8. {19} **PRIOR BIOPSY OF STUDY BREAST**
1 No (skip to Q9)
2 Yes (complete Q8A and continue)

8A. {20} **NUMBER OF PRIOR BREAST BIOPSIES**
(biopsy results - check all that apply)

{21} ☐ Benign, NOS
{22} ☐ Benign Atypical
{23} ☐ Fibroadenoma
{24} ☐ Radial Scar
{25} ☐ Papilloma
{26} ☐ LCIS
{27} ☐ Malignant, NOS
{28} ☐ DCIS
{29} ☐ DCIS with microinvasion
{30} ☐ Invasive ductal carcinoma
{31} ☐ Invasive lobular carcinoma
{32} ☐ Other finding / prior Biopsy

9. **DATE OF INITIAL MALIGNANT CYTOLOGY OR HISTOLOGY DIAGNOSIS OF NON-STUDY BREAST**
(diagnosis by FNA or histology)

{33} _____-_____
mm yyyy

9A. {34} **SITE OF BREAST CANCER**
1 Right Breast
2 Left Breast

9B. HISTOLOGY OF RECENT CANCER DIAGNOSIS
(check all that apply)

{35} ☐ Lobular carcinoma in situ
{36} ☐ Ductal carcinoma in situ
{37} ☐ In situ carcinoma with ductal and lobular features
{38} ☐ Infiltrating ductal carcinoma NOS
{39} ☐ Infiltrating lobular carcinoma
{40} ☐ Infiltrating carcinoma with ductal and lobular features
{41} ☐ Tubular carcinoma
{42} ☐ Mucinous carcinoma
{43} ☐ Medullary carcinoma
{44} ☐ Other, specify {45} _____

10. {46} FAMILY HISTORY OF BREAST CANCER
1 No (sign and date form)
2 Yes (complete Q10A and Q10B)
99 Unknown

10A. {47} NUMBER OF BLOOD RELATIVES DIAGNOSED WITH BREAST CANCER
(Only those in table below apply).

CODE TABLE FOR RELATIVES

1	Mother	5	Paternal Grandmother
2	Sister	6	Maternal Aunt
3	Daughter	7	Paternal Aunt
4	Maternal Grandmother	8	Male relative

10B. RELATIVE — ***AGE AT DIAGNOSIS** (*if age unknown, code '99')

{48} Relative #1 with breast cancer {49}
{50} Relative #2 with breast cancer {51}
{52} Relative #3 with breast cancer {53}
{54} Relative #4 with breast cancer {55}
{56} Relative #5 with breast cancer {57}

COMMENTS: {58} _____

Date from completed[3] {60}-____-_____ (mm-dd-yyyy)

{59} _____
Signature of person responsible for the data [1]

{61} _____
Signature of person entering data onto the web [2]

If information reported directly on the form has been obtained through participant interview only, signature of the participant must appear below.

_____

Date _____-_____-_____
mm-dd-yyyy

IA MRI Contralateral Breast
Initial Mammography Assessment Form

ACRIN Study 6667
PLACE LABEL HERE

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

Case No. _____

INSTRUCTIONS: All questions are completed based on the study breast images. The form is completed based on the mammography imaging done prior to study entry and within 90 days of the MRI. The completed form is submitted to the ACR. Dates are reported MM/DD/YYYY unless otherwise noted.

1. Date of most recent Mammogram
{1} _____-_____-_____(mm-dd-yyyy)
(must be within 90 days prior to MRI)

2. {2} In addition to standard mammography views, were other views obtained?

1 No
2 Yes
99 Unknown

3. If date of mammogram prior to most recent is unknown, place a check in box below. Otherwise, please fill in date.

{3} ☐ Unknown

3a. Date of mammogram prior to most recent.

{4} _____-_____-_____(mm-dd-yyyy)

4. {5} Density of Breast Parenchyma

1 Mostly Fat: <10% dense
2 Scattered Fibroductal Densities: 11-50% dense
3 Heterogeneously Dense: 51-90% dense
4 Extremely Dense: >90% dense

5. {6} Overall Mammographic Impressions (This is an overall diagnostic impression of the study breast.)

0 Incomplete, need additional evaluation
1 Negative (no findings)
2 Benign
3 Probably Benign
4 Suspicious Abnormality
5 Highly Suggestive of Malignancy

6. {7} Was an Ultrasound performed as part of the evaluation of the study breast?

1 No (skip Q7)
2 Yes (completed Q7)
99 Unknown (skip Q7)

7. Quadrant(s) of the study breast scanned with ultrasound. (Check all that apply.)

{8} ☐ Upper outer
{9} ☐ Lower outer
{10} ☐ Upper inner
{11} ☐ Lower inner
{12} ☐ Retroareolar

COMMENTS: {13} _____

_____ _____
Signature of person responsible for the data [1]

Date form completed[3] {15}_____-_____-_____ (mm-dd-yyyy)

_____
Signature of person entering data onto the web [2]

IM MRI Contralateral Breast Post MRI Mammography Assessment Form

ACRIN Study 6667

PLACE LABEL HERE

Case No. _____

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

INSTRUCTIONS: All questions are completed based on the study breast images. The form is completed based on the mammography imaging recommended as a result of the initial MRI. **A separate form is completed for each finding.** The completed form is submitted to the ACR. Dates are reported MM/DD/YYYY unless otherwise noted.

1. Date of post MRI Mammogram
{1} _____-_____-_____ (mm-dd-yyyy)

2. Date of post MRI Mammogram interpretation
{2} _____-_____-_____ (mm-dd-yyyy)

3. {3} In addition to standard mammography views, were other views obtained?
1 No
2 Yes
99 Unknown

4. {4} Data recorded represents finding #.
(Finding # reported must be correlated with MR finding # (M3-Q4) recommended for post MRI mammography.)

5. {5} Location of finding
1 Nipple
2 Central region
3 UIQ
4 LIQ
5 UOQ
6 LOQ
7 Axillary Tail
8 Breast, NOS
9 Subareolar
10 Other, specify {6} _____

6. {7} Overall Mammographic Impressions
(This is an overall diagnostic impression of the study breast.)
0 Incomplete, need targeted US
1 Negative (no findings)
2 Benign
3 Probably Benign
4 Suspicious Abnormality
5 Highly Suggestive of Malignancy

COMMENTS: {8} _____

_____

_____

_____
Signature of person responsible for the data [1]

Date form completed[3] {10}_____-_____-_____ (mm-dd-yyyy)

_____
Signature of person entering data onto the web [2]

IS MRI Contralateral Breast Ultrasound Assessment Form

ACRIN Study 6667

PLACE LABEL HERE

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

Case No. _____

INSTRUCTIONS: An Ultrasound form is completed on cases in which an ultrasound was done for further evaluation of an MR finding seen on the imaging of the study breast. The completed form is submitted to the ACR. A separate form is submitted for each lesion visible on US. Dates are recorded as MM/DD/YYYY.

☐ DE

SECTION I. INITIAL EVALUATION

1. {1} _____ **Date of Ultrasound**

2. {2} _____ **Date Ultrasound Read**

3. Reader I.D.# not required

4. {4} **Was the Finding(s) seen on MR visualized by Ultrasound?**
   - 1 No (skip to Q18)
   - 2 Yes
   - 98 Not applicable (skip to Q18)

5. {5} **Site of Finding(s)**
   - 1 Right Breast
   - 2 Left Breast

6. {6} **Total # of findings visible on MRI**

7. {7} **Total # of MR findings visible on Ultrasound**

8. {8} **Total # of findings visible on Ultrasound**

9. {9} **Data recorded represents finding #** (Finding # must correlate with image finding # (M3 - Q4)*. A separate form is completed for each finding.)

SECTION II. CLASSIFICATION OF FINDING

10. {10} **Mass**
    - 1 No (skip to Q11)
    - 2 Yes (complete Q10A - Q10C)

10A. {11} **Mass Shape**
- 1 Oval
- 2 Round
- 3 Irregular

10B. {12} **Mass Orientation** (to skin)
- 1 Not parallel
- 2 Parallel

10C. {13} **Mass Margins**
- 1 Circumscribed, thin rim or no perceptible rim (skip to Q10E)
- 2 Circumscribed, thick rim (skip to Q10E)
- 3 Irregular (complete Q10D)

10D. Irregular margin features (check all that apply)
- {14} ☐ Indistinct
- {15} ☐ Angular
- {16} ☐ Microlobulated
- {17} ☐ Spiculated / Stellate

10E. {18} **Mass Posterior Acoustic Features**
- 1 None
- 2 Enhancement
- 3 Shadowing
- 4 Combined pattern

10F. {19} **Mass Surrounding Tissue**
- 1 No effect (skip to Q11)
- 2 Identifiable effect (complete Q10G and continue)

10G. Identifiable effect (check all that apply)
- {20} ☐ Duct changes
- {21} ☐ Cooper's Ligament changes
- {22} ☐ Edema
- {23} ☐ Architectural distortion
- {24} ☐ Skin thickening
- {25} ☐ Skin retraction/irregularity
- {26} ☐ Pectoral muscle seen, but plane with anterior tissue is unclear

11. {27} **Calcifications**
    - 1 No (skip to Q12)
    - 2 Yes (complete Q11A and continue)

11A. Calcification Features (check all that apply)
- {28} ☐ Macrocalcifications
- {29} ☐ Microcalcifications out of mass
- {30} ☐ Microcalcifications in mass

12. {31} **Special Case(s)**
    - 1 No (skip to Q13)
    - 2 Yes (complete Q12A and continue)

12A. Special Case Features (check all that apply)
- {32} ☐ Mass in or on skin
- {33} ☐ Foreign body
- {34} ☐ Lymph nodes - intramammary
- {35} ☐ Lymph nodes - axilla

13. {36} **Vascularity**
    - 1 None
    - 2 Same as normal tissue
    - 3 Decreased
    - 4 Increased
    - 98 Cannot assess

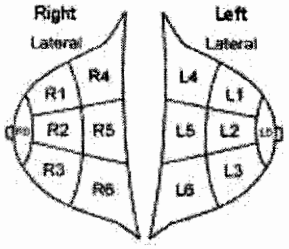
IS **Contralateral MRI Breast Study # 6667** **Case #_____** **Revision** ☐

SECTION III. LOCATION OF FINDING

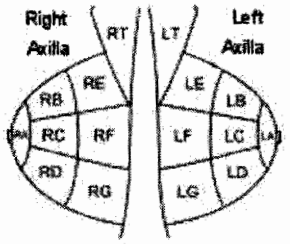
14. Referencing the diagram, check each region in which the finding is visible.

Cranio-Caudal				Medio-Lateral Oblique			
{37}☐	R0	☐ L0	{44}	{51}☐	RT	☐ LT	{59}
{38}☐	R1	☐ L1	{45}	{52}☐	RA	☐ LA	{60}
{39}☐	R2	☐ L2	{46}	{53}☐	RB	☐ LB	{61}
{40}☐	R3	☐ L3	{47}	{54}☐	RC	☐ LC	{62}
{41}☐	R4	☐ L4	{48}	{55}☐	RD	☐ LD	{63}
{42}☐	R5	☐ L5	{49}	{56}☐	RE	☐ LE	{64}
{43}☐	R6	☐ L6	{50}	{57}☐	RF	☐ LF	{65}
				{58}☐	RG	☐ LG	{66}

Cranio-Caudal



Medio-Lateral



15. Of the regions in which the finding is visible, identify the region of greatest involvement

{67} Cranio-Caudal

20	RO	10	LO
21	R1	11	L1
22	R2	12	L2
23	R3	13	L3
24	R4	14	L4
25	R5	15	L5
26	R6	16	L6

{68} Medio-Lateral

21	RT	11	LT
22	RA	12	LA
23	RB	13	LB
24	RC	14	LC
25	RD	15	LD
26	RE	16	LE
27	RF	17	LF
28	RG	18	LG

16. Size of Finding

{69}___ mm x (trans) {70}___ mm y (long) {71}___ mm z (r)

17. Depth of finding from the skin: {72}___ mm

SECTION IV. CONCLUSIONS - FOR THIS FINDING

18. {73} Final Ultrasound Assessment - Independent of MRI

1 Negative
2 Benign finding
3 Probably benign
4 Suspicious abnormality
5 Highly suggestive of malignancy

19. {74} Post-Ultrasound MR Assessment

1 Negative
2 Benign finding
3 Probably benign
4 Suspicious abnormality
5 Highly suggestive of malignancy

Additional Instructions:

[4]Q9. If a "new" finding is identified during US, the next sequential number is assigned to the "new" finding).

COMMENTS: {75}_____

Date form completed[3] {76}___-___-____ (mm-dd-yyyy)

Signature of person responsible for the data [1]

Signature of person entering data onto the web [2]

M3 MRI Contralateral Breast
Initial MRI Assessment Form

ACRIN Study 6667
PLACE LABEL HERE

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

Case No. _____

INSTRUCTIONS: This form is completed **only for the initial MRI of the study breast** and submitted to the ACR. Interpretation is done blind to US. Please pay particular attention when identifying findings so that consistency among forms is maintained. **A separate form is completed for each finding or enhancement on study.** Reports are dated MM/DD/YYYY. Measurements are reported in mm.

☐ DE

I. GENERAL INFORMATION

1. {1} Was an MRI done?
(If MRI is not done, proceed to comments)
1 No
2 Yes (complete form)

2. Date of MRI Scan
{2} _____-_____-_____ (mm-dd-yyyy)

2A. Date of MRI Interpretation
{3} _____-_____-_____ (mm-dd-yyyy)

2B. Reader ID# {4} | | | | | |

3. {5} Total number of findings on study breast MRI.
(If zero (0), skip to Q11). If 1 or more, complete B2.

4. {6} Data recorded represents finding #. (A separate form must be completed for each finding.)

II. FINDING

5. {7} Finding type (study breast)
1 Focus/foci < 5 mm (skip to Q8)
2 Mass (answer Q6 then skip to Q8)
3 Non mass enhancement (skip to Q7)

6. Mass size encompassed by Gd enhancement (record three dimensions)

{8} | | | $_x$ mm {9} | | | $_y$ mm {10} | | | $_z$ mm
med-lat sup-inf ant-post

6A. {11} Mass Shape
1 Round
2 Oval
3 Lobulated
4 Irregular

6B. {12} Mass Margin
1 Smooth
2 Irregular
3 Spiculated

6C. {13} Mass Internal Enhancement
1 Homogeneous
2 Heterogeneous
3 Rim enhancement
4 Dark internal septation(s)
5 Enhanced internal septation(s)
6 Central internal enhancement

6D. {14} Mass Degree of Enhancement
1 Minimal
2 Moderate
3 Marked

*** proceed to question 8 ***

7. {15} Type of non-mass enhancement
1 Focal area
2 Linear
3 Ductal
4 Segmental
5 Regional
6 Multiple regions
7 Diffuse

7A. {16} Non-Mass enhancement symmetry
1 Symmetric
2 Asymmetric

7B. {17} Non-Mass enhancement internal characteristics
1 Homogeneous
2 Heterogenous
3 Stippled/punctate
4 Clumped
5 Reticular/dendritic

M3 Revision ☐

ACRIN Study 6667

PLACE LABEL HERE

Case No. _____

III. ASSOCIATED FINDINGS

8. {18} Associated findings (Study Breast)

1 No (skip to Q9)
2 Yes (complete Q8A and continue)

8A. Characterization of Associated findings
(Check all that apply)

{19}☐ Nipple retraction or inversion
{20}☐ Skin retraction
{21}☐ Pre-contrast high duct signal
{22}☐ Skin thickening
{23}☐ Skin invasion
{24}☐ Edema
{25}☐ Lymphadenopathy
{26}☐ Pectoralis muscle invasion
{27}☐ Chest wall invasion
{28}☐ Hematoma / blood
{29}☐ Abnormal signal void (absence of signal due to artifact)
{30}☐ Cyst(s)
{31}☐ Other, specify {32} _____

IV. Finding Location (location of finding noted in Q4)

9. {33} Location of finding

1 Nipple
2 Central Region
3 UIQ
4 LIQ
5 UOQ
6 LOQ
7 Axillary Tail
8 Breast, NOS
9 Subareolar
10 Other, Specify {34} _____

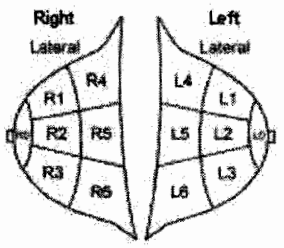
9A. Maximum Distance of Finding From the Nipple

{35} ___ mm

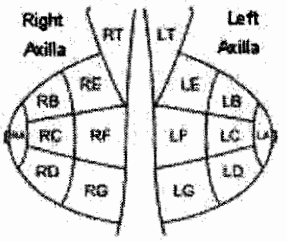
9B. Location of Finding

Referencing the diagram, check each region in which the finding is visible.

Cranio-Caudal



Medio-Lateral



Cranio-Caudal

{36}☐ R0 {43}☐ L0
{37}☐ R1 {44}☐ L1
{38}☐ R2 {45}☐ L2
{39}☐ R3 {46}☐ L3
{40}☐ R4 {47}☐ L4
{41}☐ R5 {48}☐ L5
{42}☐ R6 {49}☐ L6

Medio-Lateral

{50}☐ RT ☐ LT {58}
{51}☐ RA ☐ LA {59}
{52}☐ RB ☐ LB {60}
{53}☐ RC ☐ LC {61}
{54}☐ RD ☐ LD {62}
{55}☐ RE ☐ LE {63}
{56}☐ RF ☐ LF {64}
{57}☐ RG ☐ LG {65}

V. KINETIC CURVE ASSESSMENT

10. {66} Initial enhancement phase

0 Not applicable
1 Slow
2 Medium
3 Rapid

10A. {67} Delayed enhancement phase (after 2 minutes or after curve begins to change)

0 Not applicable
1 Persistent
2 Plateau
3 Washout

VI. OVERALL ASSESSMENT OF FINDING

Questions 11 and 12 record recommendations specific to the finding # reported in Q4.

11. {68} Assessment

0 Incomplete, need additional evaluation
1 Negative, no abnormal enhancement
2 Benign
3 Probably Benign finding, short interval follow-up
4 Suspicious Abnormality, biopsy should be considered
5 Highly Suggestive of malignacy,

M3 Revision ☐

ACRIN Study 6667

PLACE LABEL HERE

Case No. _____

appropriate action should be taken

11A. {69} **Specific recommendations**

1 Routine follow-up
2 Ultrasound targeted to area of finding
3 Diagnostic mammography
4 Short interval MRI, specify timepoint
{70} ☐ Immediate
☐ 3 months
☐ 6 months
5 Biopsy

12. {71} **Probability of Malignancy (based on MR)**

1 Definitely not
2 Probably not
3 Possible
4 Probable
5 Definite

COMMENTS: {72} _____

_____

_____

Date form completed[3] {73}-____-_____ (mm-dd-yyyy)

_____

Signature of person responsible for the data [1]

_____

Signature of person entering data onto the web [2]

M4 MRI Contralateral Breast MRI Short Interval Assessment Form

ACRIN Study 6667

PLACE LABEL HERE

Institution No. _____

Case No. _____

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

INSTRUCTIONS: This form is completed **only for the follow-up MRI of the study breast**, recommended from the initial on-study MRI. Interpretation is done blind to US. Please pay particular attention when identifying findings so that consistency among forms is maintained. **A separate form is completed for each finding or enhancement on study.** Reports are dated MM/DD/YYYY. Measurements are reported in mm.

☐ DE

I. GENERAL INFORMATION

1. {1} Was an MRI done?
(If MRI is not done, proceed to comments)
1 No
2 Yes (complete form)

2. {2} Follow up MRI timepoint
1 Immediate
2 3 months
3 6 months
4 Other, specify {3} _____

3. Date of MRI Scan
{4} ___-___-_____ (mm-dd-yyyy)

3A. Date of MRI Interpretation
{5} ___-___-_____ (mm-dd-yyyy)

3B. Reader ID# {6} | | | | | |

4. {7} Total number of findings on initial study breast MRI - see M3. Code as zero (0) if no findings are seen on the Short Interval MRI, then skip to Q11.

5. {8} Data recorded represents finding #[4]. (Finding # must correlate with MR finding # (M3 -Q4) recommended for post-on study MRI.

II. FINDING

6. {9} Finding type (study breast)
1 Focus/foci < 5 mm (skip to Q9)
2 Mass (answer Q7 then skip to Q9)
3 Non mass enhancement (skip to Q8)

7. Mass size encompassed by Gd enhancement (record three dimensions)

{10} | | | $_x$ mm {11} | | | $_y$ mm {12} | | | $_z$ mm
med-lat sup-inf ant-post

7A. {13} Mass Shape
1 Round
2 Oval
3 Lobulated
4 Irregular

7B. {14} Mass Margin
1 Smooth
2 Irregular
3 Spiculated

7C. {15} Mass Internal Enhancement
1 Homogeneous
2 Heterogeneous
3 Rim enhancement
4 Dark internal septation(s)
5 Enhanced internal septation(s)
6 Central internal enhancement

7D. {16} Mass Degree of Enhancement
1 Minimal
2 Moderate
3 Marked

*** proceed to question 9 ***

8. {17} Type of non-mass enhancement
1 Focal area
2 Linear
3 Ductal
4 Segmental
5 Regional
6 Multiple regions
7 Diffuse

8A. {18} Non-Mass enhancement symmetry
0 Not applicable
1 Symmetric
2 Asymmetric

8B. {19} Non-Mass enhancement internal characteristics
1 Homogeneous
2 Heterogenous
3 Stippled/punctate
4 Clumped
5 Reticular/dendritic

M4 Revision ☐

ACRIN Study 6667
PLACE LABEL HERE

Case No.

III. ASSOCIATED FINDINGS

9. {20} Associated findings (Study Breast)
1 No (skip to Q10)
2 Yes (complete Q9A and continue)

9A. Characterization of Associated findings
(Check all that apply)

{21} ☐ Nipple retraction or inversion
{22} ☐ Skin retraction
{23} ☐ Pre-contrast high duct signal
{24} ☐ Skin thickening
{25} ☐ Skin invasion
{26} ☐ Edema
{27} ☐ Lymphadenopathy
{28} ☐ Pectoralis muscle invasion
{29} ☐ Chest wall invasion
{30} ☐ Hematoma / blood
{31} ☐ Abnormal signal void (absence of signal due to artifact)
{32} ☐ Cyst(s)
{33} ☐ Other, specify {34} _____

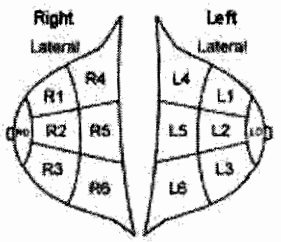
IV. Finding Location (location of finding noted in Q4)

10. {35} Location of finding
1 Nipple
2 Central Region
3 UIQ
4 LIQ
5 UOQ
6 LOQ
7 Axillary Tail
8 Breast, NOS
9 Subareolar
10 Other, Specify {36} _____

10A. Maximum distance of Finding From the Nipple
{37} ___ mm

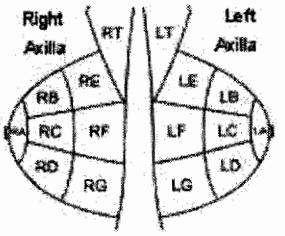
10B. Location of Finding
Referencing the diagram, check each region in which the finding is visible.

Cranio-Caudal



Cranio-Caudal

Medio-Lateral



Medio-Lateral

{38} ☐	R0	☐	L0 {45} {52}	☐	RT	☐	LT {60}
{39} ☐	R1	☐	L1 {46} {53}	☐	RA	☐	LA {61}
{40} ☐	R2	☐	L2 {47} {54}	☐	RB	☐	LB {62}
{41} ☐	R3	☐	L3 {48} {55}	☐	RC	☐	LC {63}
{42} ☐	R4	☐	L4 {49} {56}	☐	RD	☐	LD {64}
{43} ☐	R5	☐	L5 {50} {57}	☐	RE	☐	LE {65}
{44} ☐	R6	☐	L6 {51} {58}	☐	RF	☐	LF {66}
				{59} ☐	RG	☐	LG {67}

V. KINETIC CURVE ASSESSMENT

(If Q4 = 0 findings, code Q11 and Q11A as "0" Not applicable)

11. {68} Initial enhancement phase
0 Not applicable
1 Slow
2 Medium
3 Rapid

11A. {69} Delayed enhancement phase
(after 2 minutes or after curve begins to change)
0 Not applicable
1 Persistent
2 Plateau
3 Washout

M4 Revision ☐

ACRIN Study 6667
PLACE LABEL HERE

Case No. _____

VI. OVERALL ASSESSMENT OF FINDING

Questions 12 and 13 record recommendations specific to the finding # reported in Q5.

12. {70} **Assessment**
- 0 Incomplete, need additional evaluation
- 1 Negative, no abnormal enhancement
- 2 Benign
- 4 Suspicious Abnormality, biopsy should be considered
- 5 Highly Suggestive of malignacy, appropriate action should be taken

12A. {71} **Specific recommendations**
- 1 Routine follow-up
- 2 Ultrasound targeted to area of finding
- 3 Diagnostic mammography
- 5 Biopsy

13. {72} **Probability of Malignancy (based on MR)**
- 1 Definitely not
- 2 Probably not
- 3 Possible
- 4 Probable
- 5 Definite

Additional Instructions:

[4]Q5. If a "new" finding is identified at short interval MR imaging, the next sequential number is assigned to the "new" finding #.

Q12A. If coded '2', an IS-Ultrasound form is generated to the case calendar.

If coded '3', an IM-Mammography form is generated to the case calendar.

If coded '5', an AB-Biopsy form is generated to the case calendar.

COMMENTS: {73} _____

_____

_____

_____ Date form completed[3] {74}-___-___ (mm-dd-yyyy)

Signature of person responsible for the data [1]

_____

Signature of person entering data onto the web [2]

AB MRI Contralateral Breast Biopsy Procedure Form

ACRIN Study 6667 Case #

PLACE LABEL HERE

Case No.

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

INSTRUCTIONS: This form is completed and submitted upon completion of the Biopsy procedure performed on the **study breast. A separate form is completed for each lesion biopsied.** Dates are reported MM/DD/YYYY.

☐ DE

I. GENERAL INFORMATION

1. {1} **Was A Biopsy Performed?**
   1 No* (complete Q1B, sign and date form)
   2 Yes (complete Q1A and continue)

   1A. **Date of procedure** {2}-____-____ (mm-dd-yyyy)

   1B. {3} ***Specify Reason Biopsy was NOT Done**
   1 Medical contraindication
   2 Technical difficulties
   3 Patient discomfort
   4 Patient refusal
   5 Lesion absent on subsequent imaging
   6 Other, specify {4}

2. {5} **Total Number of Lesions Biopsied**

3. {6} **Data recorded represents Lesion #**
   (Lesion # must correlate with image lesion #. A separate form is completed for each lesion biopsied.)

4. {7} **Site of Lesion Biopsied**
   1 Right Breast
   2 Left Breast

5. {8} **Location of Lesion Epicenter**
   1 Nipple
   2 Central Portion
   3 UIQ
   4 LIQ
   5 UOQ
   6 LOQ
   7 Axillary Tail
   8 Breast, NOS
   9 Subareolar
   10 Other, Specify {9}

6. {10} **Specify which of the following procedures was performed.**
   (If both a core and excisional biopsy were done, report excisional findings only)
   1 Core Needle Biopsy
   2 Excisional Biopsy
   3 Lumpectomy
   4 Mastectomy
   5 Other, specify {11}

7. {12} **Specify the Type of Guidance System Used**
   1 None / clinical
   2 Ultrasound
   3 Stereotactic
   4 MR Guidance (complete Section II)
   5 Other, specify {13}

II. MR GUIDED

[Questions 8 - 12 are completed only if Q7 is coded 4 (MR guidance)].

8. **ID # of person performing MR guided biopsy**
   {31}

9. **Location of Lesion Epicenter during time of tissue sampling**
   {14} $_x$ mm {15} $_y$ mm {16} $_z$ mm
   med-lat S-I ant-post

10. {17} **Method of MR Guided Tissue Sampling**
    1 Core biopsy (complete Q11, 11A, 11B)
    2 Wire localization and excision (complete Q12)

11. **Initial Needle Pass Location at Center of Sampling Chamber**
    {18} $_x$ mm {19} $_y$ mm {20} $_z$ mm
    med-lat S-I ant-post

    11A. {21} **Needle Gauge MR Guidance**
    1 14 gauge
    2 Other, Specify {22}

    11B. {23} **Total Number of Needle Passes**

12. **Record Final Wire Hook Position**
    {24} $_x$ mm {25} $_y$ mm {26} $_z$ mm
    med-lat S-I ant-post

COMMENTS: {27}

Signature of person responsible for the data [1]

Date form completed[3] {29}-____-____ (mm-dd-yyyy)

Signature of person entering data onto the web [2]

PE MRI Contralateral Breast Pathology Evaluation Form Core Needle Biopsy

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

ACRIN Study 6667 Case #
PLACE LABEL HERE

Case No. _____

INSTRUCTIONS: The form is completed by the site RA through abstraction of the information from the pathology, biopsy and or surgical pathology report(s). The supporting report(s) must be faxed to ACR Data Management Center.
Dates are reported MM/DD/YYYY. A separate form is completed for **EACH** lesion specimen submittted.

I. SITE SPECIMEN DATA

1. {1}____-____-____ **Date of Procedure**

2. {2} **Data recorded represents Lesion #**
(Lesion # must correlate with image lesion #. recorded on AB form Q3. A separate form is completed for each lesion undergoing Core Needle Biopsy)

3. {3} **BREAST**
1 Right
2 Left

II. SITE PATHOLOGY

4. {4} **HISTOLOGY OF LESION**
1 Benign (Go to Q4A)
2 Atypical (Go to Q4B)
3 In situ carcinoma (Go to Q4C)
4 Invasive carcinoma (Go to Q4D)

4A. {5}
10 Benign, non-proliferative
11 Benign, proliferative, NOS
12 Fibroadenoma
13 Radial Scar
14 Other, specify {6}

4B. {7}
20 Atypical ductal hyperplasia
21 Atypical lobular hyperplasia

4C. {8}
30 Lobular carcinoma in situ
31 Ductal carcinoma in situ
32 In situ carcinoma with ductal and lobular features

4D. {9}
40 Infiltrating ductal carcinoma NOS
41 Infiltrating lobular carcinoma
42 Infiltrating carcinoma with ductal and lobular features
43 Tubular carcinoma
44 Mucinous carcinoma
45 Medullary carcinoma
46 Other, specify {10}

COMMENTS: {11}

_____
Signature of person responsible for the data [1]

Date form completed[3] {13}____-____-____ (mm-dd-yyyy)

_____
Signature of person entering data onto the web [2]

PA MRI Contralateral Breast Pathology Evaluation Form Excisional Biopsy

ACRIN Study 6667

PLACE LABEL HERE

_____ ! _____

_____ Case No. _____

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

INSTRUCTIONS: This form is completed by the site RA through abstraction of the information from pathology or surgical-pathology report(s). The supporting reports must be faxed to the ACR Data Management center. Measurements are reported in mm. Dates are reported MM/DD/YYYY. A separate form is submitted for EACH lesion.

I. SITE SPECIMEN DATA

1. {1} -_____-_____ **Date of Procedure**

2. {2} **Data recorded represents lesion #**
(Lesion # must correlate with image lesion # recorded on AB form Q3. A separate form is completed for each lesion undergoing excision biopsy.)

3. **SIZE OF EXCISED LESION (mm)**

{3}___ x (med-lat) {4}___ y (sup-inf) {5}___ z (ant-post)

4. **PATHOLOGIC TNM STAGE** (see code table on page 2)
T {6} N {7} M {8}

5. {9} **Breast**
1 Right
2 Left

II. SITE PATHOLOGY

6. {10} **HISTOLOGY OF INDEX LESION**
1 Benign (Go to Q6a)
2 Atypical (Go to Q6b)
3 In situ carcinoma (Go to Q6c)
4 Invasive carcinoma (Go to Q6d)

6a. {11}
10 Benign, non-proliferative
11 Benign, proliferative, NOS
12 Fibroadenoma
13 Radial Scar
14 Other, specify {12}_____

6b. {13}
20 Atypical ductal hyperplasia
21 Atypical lobular hyperplasia

6c. {14}
30 Lobular carcinoma in situ
31 Ductal carcinoma in situ
32 In situ carcinoma with ductal and lobular features

6d. {15}
40 Infiltrating ductal carcinoma NOS
41 Infiltrating lobular carcinoma
42 Infiltrating carcinoma with ductal and lobular features
43 Tubular carcinoma
44 Mucinous carcinoma
45 Medullary carcinoma
46 Other, specify {16}_____

PA **Contralateral MRI Breast** **Study # 6667** **Case #** _____ **Revision** ☐

7. {17} **GRADE OF INVASIVE CANCER**
1 I
2 II
3 III
98 Not applicable

8. {18} **GRADE OF DCIS**
1 Well differentiated
2 Intermediately differentiated
3 Poorly differentiated
98 Not applicable

9. {19} **DCIS PATTERNS**
1 No (skip to Q10)
2 Yes, (check all that apply)
98 Not applicable (skip to Q10)

{20}☐ 10 Large areas of necrosis (comedo)
{21}☐ 11 Small areas of necrosis
{22}☐ 12 Cribriform
{23}☐ 13 Solid
{24}☐ 14 Micropapillary
{25}☐ 15 Papillary

9a. {26} **MOST DOMINANT DCIS PATTERN**
(refer to Q#9 code table)

10. {27} **EXTENT DCIS WITHIN INVASIVE TUMOR**
1 Absent
2 Slight
3 Moderate
4 Marked
98 Not Applicable

11. {28} **EXTENT OF DCIS ADJACENT TO INVASIVE TUMOR**
1 Absent
2 Slight
3 Moderate
4 Marked
98 Not Applicable

12. {29} **LYMPHATIC VESSEL INVASION**
1 Absent
2 Present
98 Not Applicable

PATHOLOGIC TNM STAGE (code table for question 4)

AJCC TNM STAGES

T		N		M	
0	Tx	0	NX	0	MX
1	T0	1	N0	1	M0
2	Tis	2	N1	2	M1
3	T1	3	N2		
4	T1mic	4	N2a		
5	T1a	5	N2b		
6	T1b	6	N3		
7	T1c	7	N3a		
8	T2	8	N3b		
9	T3	9	N3c		
10	T4				
11	T4a				
12	T4b				
13	T4c				
14	T4d				

COMMENTS: {30} _____

_____

_____

_____

_____ _____
Signature of person responsible for the data [1]

Date from completed[3] {31}__-__-____ (mm-dd-yyyy)

_____
Signature of person entering data onto the web [2]

PD MRI Contralateral Breast Mastectomy Pathology

ACRIN Study 6667 Case #
PLACE LABEL HERE

Case _____

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

INSTRUCTIONS: The form is completed by the site RA through abstraction of the information from the pathology or surgical-pathology reports. The supporting report(s) must be faxed to the ACR Data Management Center. Measurements are reported in mm. Dates are reported MM/DD/YYYY. A separate form is submitted for **EACH** lesion.

I. SITE SPECIMEN DATA

1. {1} _____ Date of Procedure

2. {2} **Data recorded represents Lesion #**
(Lesion # must correlate with image lesion # recorded on AB- Q3. A separate form is completed for each lesion.)

3. **SIZE OF LESION** (mm)

{3} ___ x (mid-lat) {4} ___ y (sup-inf) {5} ___ z (ant-post)

3A. **MAXIMUM DISTANCE OF LESION FROM THE NIPPLE** {6} ___ (mm)

4. **PATHOLOGIC TNM STAGE** (see code table on page 2)

T {7} N {8} M {9}

5. {10} **LOCATION OF LESION EPICENTER**
1 Nipple
2 Central Region
3 UIQ
4 LIQ
5 UOQ
6 LOQ
7 Axillary Tail
8 Breast NOS
9 Subareolar
10 Other, specify {11} _____

6. {12} **BREAST**
1 Right
2 Left

II. SITE PATHOLOGY

7. {13} **HISTOLOGY OF SPECIMEN**
1 Benign (Go to Q7A)
2 Atypical (Go to Q7B)
3 In situ carcinoma (Go to Q7C)
4 Invasive carcinoma (Go to Q7D)

7A. {14}
10 Benign, non-proliferative
11 Benign, proliferative, NOS
12 Fibroadenoma
13 Radial Scar
14 Other, specify {15} _____

7B. {16}
20 Atypical ductal hyperplasia
21 Atypical lobular hyperplasia

7C. {17}
30 Lobular carcinoma in situ
31 Ductal carcinoma in situ
32 In situ carcinoma with ductal and lobular features

7D. {18}
40 Infiltrating ductal carcinoma, NOS
41 Infiltrating lobular carcinoma
42 Infiltrating carcinoma with ductal and lobular features
43 Tubular carcinoma
44 Mucinous carcinoma
45 Medullary carcinoma
46 Other, specify {19} _____

8. {20} **GRADE OF INVASIVE CANCER**
1 I
2 II
3 III
98 Not Applicable

9. {21} **GRADE OF DCIS**
1 Well differentiated
2 Intermediately differentiated
3 Poorly differentiated
98 Not applicable

10. {22} **DCIS PATTERNS:**
1 No (skip to Q11)
2 Yes (check all that apply)
98 Not applicable (skip to Q11)

{23} ☐ 10 Large areas of necrosis (comedo)
{24} ☐ 11 Small areas of necrosis
{25} ☐ 12 Cribriform
{26} ☐ 13 Solid
{27} ☐ 14 Micropapillary
{28} ☐ 15 Papillary

10A. {29} **Most Dominant DCIS Pattern**
(refer to #10 code table)

11. {30} **EXTENT DCIS WITHIN INVASIVE TUMOR**
1 Absent
2 Slight
3 Moderate
4 Marked
98 Not Applicable

12. {31} **EXTENT OF DCIS ADJACENT TO INVASIVE TUMOR**
1 Absent
2 Slight
3 Moderate
4 Marked
98 Not Applicable

13. {32} **LYMPHATIC VESSEL INVASION**
1 Absent
2 Present
98 Not Applicable

PATHOLOGIC TNM STAGE (code table for question 4)

AJCC TNM STAGES

T		N		M	
0	Tx	0	NX	0	MX
1	T0	1	N0	1	M0
2	Tis	2	N1	2	M1
3	T1	3	N2		
4	T1mic	4	N2a		
5	T1a	5	N2b		
6	T1b	6	N3		
7	T1c	7	N3a		
8	T2	8	N3b		
9	T3	9	N3c		
10	T4				
11	T4a				
12	T4b				
13	T4c				
14	T4d				

COMMENTS: {33} _____

_____

_____

_____ _____
Signature of person responsible for the data [1]

Date form completed[3] {34}__-__-____ (mm-dd-yyyy)

_____ _____
Signature of person entering data onto the web [2]

F1 MRI Contralateral Breast Follow-Up Assessment Form

ACRIN Study 6667

PLACE LABEL HERE

Case No. _____

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

1. {1} **Time point of this follow-up**
   1 12 Months
   2 24 Months
   3 Other, specify {2} _____

2. {3} _____-_____-_____ **Date of follow-up contact or attempt**

3. {4} **Patient Status**
   (If question 3 is coded "dead" provide date of death in Q3A; if Q3 is coded "Lost to Follow-up", code last date of contact in Q3B.)
   1 Alive
   2 Dead
   3 Lost to follow-up; unable to contact

   3A. Date of Death {5} _____-_____-_____

   3B. Date of Last Contact {6} _____-_____-_____

4. {7} **Was a Clinical Breast Exam of the study breast performed in the past 12 months?**
   (If no, provide reason in Q4A; if yes, answer Q4B and Q4C).
   1 No
   2 Yes
   99 Unknown (skip to Q5)

   4A. {8} **Provide reason CBE not done:**
   1 Patient missed appointment
   2 Patient unable to be located
   3 Patient pregnant or lactating
   4 Patient refused
   5 Referring physician's choice
   6 Expired
   7 Other, specify: {9} _____

   4B. Date of follow-up CBE

   {10} _____-_____-_____
   (mm-dd-yyyy)

   4C. {11} **Specify findings of CBE[4]**
   1 Negative; benign
   2 Abnormal CBE requiring further evaluation

5. {12} **Was a mammogram of the study breast performed in the past 12 months?[5]**
   1 No (Answer Q5A)
   2 Yes, not previously reported (Answer Q5B + Q5C)
   3 Yes, previously reported (skip to Q6)

5A. {13} **Provide reason mammogram not done:**
1 Patient missed appointment
2 Patient unable to be located
3 Patient pregnant or lactating
4 Patient refused
5 Referring physician's choice
6 Expired
7 Other, specify: {14} _____

5B. Date of most recent mammogram

{15} _____-_____-_____
(mm-dd-yyyy)

5C. {16} **Mammogram Findings** (BIRADS)
[Specify findings of mammogram **and** submit copy of mammogram report.]

Category 0	Needs additional imaging
Category 1	Negative
Category 2	Benign finding
Category 3	Probably benign finding, short interval follow-up suggested
Category 4	Suspicious abnormality - biopsy should be considered
Category 5	Highly suggestive of malignancy - appropriate action should be taken

6. {17} **Was an ultrasound of the study breast performed in the past 12 months?[5]**
   1 No (Answer Q6A)
   2 Yes, not previously reported (Answer Q6B + Q6C)
   3 Yes, previously reported (skip to Q7)

6A. {18} **Provide reason ultrasound not done:**
1 Patient missed appointment
2 Patient unable to be located
3 Patient pregnant or lactating
4 Patient refused
5 Referring physician's choice
6 Expired
7 Other, specify: {19} _____

6B. Date of most recent ultrasound:

{20} _____-_____-_____
(mm-dd-yyyy)

6C. {21} **Ultrasound Findings**
[Specify US findings **and** submit copy of ultrasound report.]

Category 0	Needs additional imaging
Category 1	Negative
Category 2	Benign finding
Category 3	Probably benign finding, short interval follow-up suggested
Category 4	Suspicious abnormality - biopsy should be considered
Category 5	Highly suggestive of malignancy - appropriate action should be taken

7. {22} **Was an MRI of the study breast performed in the past 12 months?**[5]
1 No (Answer Q7A)
2 Yes, not previously reported (Answer Q7B + Q7C)
3 Yes, previously reported (skip to Q8)

7A. {23} **Provide reason MRI not done:**
1 Patient missed appointment
2 Patient unable to be located
3 Patient pregnant or lactating
4 Patient refused
5 Referring physician's choice
6 Expired
7 Other, specify: {24} _____

7B. Date of most recent MRI:

{25} _____-_____-_____
(mm-dd-yyyy)

7C. {26} **MRI Findings**
(Specify MRI findings **and** submit copy of MRI report).

Category 0	Incomplete, needs additional imaging
Category 1	Negative, no abnormal enhancement
Category 2	Benign finding
Category 3	Probably benign finding, short interval follow-up suggested
Category 4	Suspicious abnormality - biopsy should be considered
Category 5	Highly suggestive of malignancy - appropriate action should be taken

8. {27} **Was other imaging of the study breast performed in the past 12 months?**[5]
(If yes, answer Q8A, Q8B and Q8C).
1 No (skip to Q9)
2 Yes
99 Unknown (skip to Q9)

8A. Specify type {28} _____

8B. Date of other imaging

{29} _____-_____-_____
(mm-dd-yyyy)

8C. {30} **Specify findings of other imaging**
1 Negative; benign
2 Abnormal; requiring further evaluation

9. {31} **Were there any biopsies or surgeries on the study breast in the past 12 months?**[5]
1 No (Skip to Q11)
2 Yes, not previously reported (Answer Q9A)
3 Yes, previously reported (skip to Q11)
99 Unknown (skip to Q11)

9A. Specify intervention by entering the date of the procedure most representative of the final diagnosis (i.e. encompassing the largest amount of tumor).

Submit the Pathology Report (**P1**) from that biopsy or surgery and the accompanying Pathology Form (**PA, PD,** or **PE**).

Date of Biopsy or Surgery

{32} _____-_____-_____	FNA
{33} _____-_____-_____	Core needle bx
{34} _____-_____-_____	Excisional bx (submit S2 + S5)
{35} _____-_____-_____	Lumpectomy (submit S2 + S5)
{36} _____-_____-_____	Mastectomy (submit S2 + S5)

F1 **Contralateral MRI Breast** **Study # 6667** **Case #** _____ **Revision** ☐

Diagnosis (from most representative tissue; i.e. tissue encompassing the largest amount of tumor)

10. {37} **Histology of lesion**

1 Benign (Go to Q10A)
2 Atypical (Go to Q10B)
3 In situ carcinoma (Go to Q10C)
4 Invasive carcinoma (Go to Q10D)

10A. {38}
10 Benign, non-proliferative
11 Benign, proliferative, NOS
12 Fibroadenoma
13 Radial Scar
14 Other, specify {39}

10B. {40}
20 Atypical ductal hyperplasia
21 Atypical lobular hyperplasia

10C. {41}
30 Lobular carcinoma in situ
31 Ductal carcinoma in situ
32 In situ carcinoma with ductal and lobular features

10D {42}
40 Infiltrating ductal carcinoma NOS
41 Infiltrating lobular carcinoma
42 Infiltrating carcinoma with ductal and lobular features
43 Tubular carcinoma
44 Mucinous carcinoma
45 Medullary carcinoma
46 Other, specify {43}

11. {44} **Method of Contact**
1 At appointment
2 By mail
3 By telephone
4 Other, specify {45}

COMMENTS: {46}

Date form completed[3] {48}-___-_____ (mm-dd-yyyy)

{47}
Signature of person responsible for the data [1]

{49}
Signature of person entering data onto the web [2]

Additional Instructions:

[4]Q4 code = 1
If the patient reports CBE is negative, source documentation includes hospital chart, clinic chart, or patient interview documented on this form, signed and dated by the RA.

Q4 Code = 2
If the CBE is positive this must be documented by the hospital or clinic chart.

[5]Q5, Q6, Q7, Q8, Q9 code = 1
If the patient reports no additional imaging or interventions, source documentation includes hospital or clinic chart or patient interview documented on this form, signed and dated by the RA

Q5, Q6, Q7, Q8, Q9 code = 2
All imaging and interventions must be documented by associated reports. Submit reports and forms to the ACR.

PR MRI Contralateral Breast Protocol Variation Form

ACRIN Study 6667 Case #
PLACE LABEL HERE

Case No.

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

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 event. Fax a copy to ACRIN Headquarters @ (215) 717-0936. If the protocol variation is found upon data or image review by headquarters staff, a copy of the headquarters generated PR form will be faxed to the site RA. Retain the form in the case study file.

1. Check The Protocol Event Being Reported: (report only one per form)

{1}
- ☐ Duplicate case registration
- ☐ Participant withdrew study consent, provide documentation
- ☐ MRI not performed per protocol specified time point
- ☐ MRI interpretation done by radiologist other than specified on site PSA
- ☐ Recommended US not done - enter date of imaging study that recommended US {2} -___-___
- ☐ Recommended MRI not done - enter date of imaging study that recommended MRI {3} -___-___
- ☐ Recommended mammography not done - enter date of imaging study that recommended mammography {4} -___-___
- ☐ Initial MR images lost, unable to archive
- ☐ MR technical parameters outside protocol specifications (6667 QC)
- ☐ MR guided biopsy performed by personnel other than radiologist specified on site PSA
- ☐ Other, specify {5} _____

_____

2. Describe The Protocol Event Reported Above

{6} _____

_____

_____

_____ _____
Person responsible for data

Date form completed {11} -___-___ (mm-dd-yyyy)

Imaging: (Internal Reporting, findings found upon data review).

3. Deviations

{7} ☐ Incorrect scanning parameters utilized
- {8} ○ Only one post-contrast enhanced scan acquired
- ○ No post-contrast scans submitted

☐ Incorrect slice thickness utilized
☐ Incorrect matrix utilized
☐ Incorrect FOV utilized
☐ Incorrect utilization of TR
☐ Incorrect utilization of TE
☐ Incorrect timing of study breast
☐ Scan quality insufficient
☐ No contrast agent visible

4. Comments {9} _____

_____

☐ HQ Use Only {13}

_____
HQ Research Associate

Date form completed {11}__-__-____ (mm-dd-yyyy)