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*The "person responsible for entry date" refers to the individual who has collected the data on this specific data form.

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

*The "date form completed" is the date the worksheet, "audit OFF, 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 in individual cases. It is recommended that the form maintain a hard copy within such 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

<table>
<thead>
<tr>
<th>Case #</th>
<th>(page 1 of 3)</th>
</tr>
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**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?
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 gonadotropin inhibitors for preventative measures, not therapeutic measures, are eligible.)

15. Does the patient have a remote history of breast cancer as defined by biopsy-proven breast cancer diagnosed greater than 60 days prior to the study?

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

1. Has the Eligibility Checklist (above) been completed?

2. Is the patient eligible for this study?

3. Date the study-specific Consent Form was signed (must be prior to study entry)

4. Birthday ( _______ / _______ / yyyy)

5. Ethnic category

6. Race (check all that apply):

7. Gender (N/A)

8. Patient’s country of residence (if country of residence is other, complete Q#)

9. Zip Code (5 digit code)

8 / 8 / yyyy

Date: 10/4/03
14. Patient's insurance status
1. Private insurance
2. Medicare
3. Medicaid and Private insurance
4. Medicaid
5. Military and Medicare
6. Military or Veterans Administration
7. Self-pay
8. No source of payment
9. Unknown/decline to answer
6. Other

15. Will any component of the patient's care be given at a military or VA facility?
1. No
2. Yes
9. Unknown

16. Calendar base date (date of registration)

17. Date of Registration (must be within two business days after completion of MRI scan)

18. Other country, specify (completed only if 012 is coded other)

Date form completed: 10/09/05
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.

Signature of person responsible for the data:

Date form completed: __________ mm-dd-yyyy

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**MRI Contralateral Breast Initial Evaluation Form**

**ACRN Study 6667**

**PLACE LABEL HERE**

If a revised or corrected form, indicate by checking box:

**Case No.**

**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. In case of questions referring to biopsy are reported for the study breast.

1. **[**] ______ DATE OF BIRTH (MM-DD-YYYY)
2. **[**] ______ MENOPAUSAL STATUS
   1. Pre-menopausal
   2. Surgical menopause
   3. Post menopausal (last menses >1 year ago)
   4. Post-menopausal (last menses <1 year ago)
   5. Unknown

2A. If date of last menstrual period is unknown, please fill in date

   **[**] ______ DATE OF LAST MENSTRUAL PERIOD (MM-DD-YYYY)

3. **[**] ______ NUMBER OF FULL TERM PREGNANCIES
   (0 = N/A or one; 1 or more full term pregnancies, complete Q7A)

3A. **[**] ______ Age at First Full Term Pregnancy (years)

4. **[**] ______ AGE AT MENARCHE (years)
   (age unknown, code "99")

5. **[**] ______ AGE AT MENopause (years)
   (if pre- or peri-menopausal, code "99", if age unknown, code "99")

6. **[**] ______ BREAST IMPLANT (study breast)
   1. No
   2. Yes

7. **[**] ______ 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)
   (1) [ ] Current use Birth Control Pills
   (12) [ ] Current use Estrogen Replacement Therapy
   (13) [ ] Current use Tamoxifen/Gemtrude Therapy
   (14) [ ] Selective Estrogens Receptor Modulator
   (15) [ ] Prior use Birth Control Pills
   (16) [ ] Prior use Estrogen Replacement Therapy
   (17) [ ] Prior use Tamoxifen/Gemtrude Therapy
   (18) [ ] Prior use Antineoplastics/Inhibitor Therapy
   (19) [ ] Prior use other, specify ()

7A. DUPLICATE NUMBER OF PRIOR BREAST BIOPSIES
    (biopsy results - check all that apply)
   (21) [ ] Benign NOS
   (22) [ ] Benign Atypical
   (23) [ ] Fibrocystic
   (24) [ ] Radical/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

8. PRIOR BIOPSY OF STUDY BREAST
   1. No (skip to Q9)
   2. Yes (complete Q9A and continue)

8A. DUPLICATE NUMBER OF PRIOR BREAST BIOPSIES
    (biopsy results - check all that apply)
   (31) [ ] Benign NOS
   (32) [ ] Benign Atypical
   (33) [ ] Invasive ductal carcinoma
   (34) [ ] Invasive lobular carcinoma
   (35) [ ] Other finding / prior biopsy

9. DATES OF INITIAL MALIGNANT CYTOLOGY OR HISTOLOGY DIAGNOSIS OF NON-STUDY BREAST
    (diagnosed by FNA or histology)
   (33) ______ mm. yyyy

9A. [ ] SITE OF BREAST CANCER
    1. Right Breast
    2. Left Breast

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

- [31] □ 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, [55]

COMMENTS: [58]

Date: [60], ________ (mm-dd-yyyy)

Signature of person responsible for the date: [59]

10. [46] FAMILY HISTORY OF BREAST CANCER

1. No (sign and date form)
2. Yes (complete G19A and G19B)
99 Unknown

10A. [47] NUMBER OF BLOOD RELATIVES

DIAGNOSED WITH BREAST CANCER
(Only those in table below apply)

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<tr>
<th>CODE TABLE FOR RELATIVES</th>
<th>PATERNAL GRANDMOTHER</th>
<th>MATERNAL AUNT</th>
<th>SISTER</th>
<th>DAUGHTER</th>
<th>MOTHER</th>
<th>PATERNAL GRANDMOTHER</th>
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</table>

*AGE AT DIAGNOSIS

- If age unknown, code 99

10B. RELATIVE

- Relative #1 with breast cancer
- Relative #2 with breast cancer
- Relative #3 with breast cancer
- Relative #4 with breast cancer
- Relative #5 with breast cancer

Signature of person entering data onto the web: [61]

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

Date: ____________

mm-dd-yyyy

"Copyright 2003"
1. Date of most recent mammogram
   (mm-dd-yyyy)
   (must be within 30 days prior to MRI)

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.
   99. Unknown

4. Date of mammogram prior to most recent.
   (mm-dd-yyyy)

5. 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
   5. Highly suggestive
   6. Malignant

6. 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.)
   [ ] Upper outer
   [ ] Upper inner
   [ ] Lower outer
   [ ] Lower inner
   [ ] Retroareolar

COMMENTS:

Signature of person responsible for the data:

Date form completed: (mm-dd-yyyy)
1. Date of post MRI Mammogram
   ____________ (mm-dd-yyyy)

2. Date of post MRI Mammogram interpretation
   ____________ (mm-dd-yyyy)

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

4. Data recorded represents finding #.
   (Finding # reported must be correlated with MR finding # (MD-G4) recommended for post MRI mammography.)

5. Location of finding
   1. Nipple
   2. Central region
   3. UQ
   4. LQ
   5. ULOQ
   6. LLOQ
   7. Axillary Tail
   8. Breast NOS
   9. Subareolar
   10. Other, specify ____________

COMMENTS: [ ]

Signature of person responsible for the data ____________ Date form completed ____________ (mm-dd-yyyy)

Signature of person entering data onto the web ____________

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MR Contralateral Breast
Ultrasound Assessment Form

INSTRUCTIONS: An Ultrasound form is completed on cases in which an ultrasound was done for further evaluation of an MRI 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.

SECTION I. INITIAL EVALUATION

1. [ ] Date of Ultrasound
2. [ ] Date Ultrasound Read
3. [ ] Case No.

SECTION II. CLASSIFICATION OF FINDING

4. [ ] Was the finding(s) seen on MR visualized by Ultrasound?
   1. No (skip to Q16)
   2. Yes
   3. Not applicable (skip to Q18)
5. [ ] Site of Finding(s)
   1. Right Breast
   2. Left Breast
6. [ ] Total # of findings visible on MRI
7. [ ] Total # of MR findings visible on Ultrasound
8. [ ] Total # of findings visible on ultrasound
9. [ ] Data recorded represents finding # (finding # must correlate with image finding # (MRI - Q14). A separate form is completed for each finding.)

SECTION III. MORPHOLOGIC FEATURES

10. [ ] Mass
    1. No (skip to Q11)
    2. Yes (complete Q10A - Q10C)
10A. [ ] Mass Shape
    1. Ovoid
    2. Round
    3. Irregular
10B. [ ] Mass Orientation (to skin)
    1. Not seen
    2. Parallel
10C. [ ] Mass Margin
    1. Circumscribed, thin rim or no perceptible rim (skip to Q11B)
    2. Circumscribed, thick rim (skip to Q11C)
    3. Irregular (corrode Q10D)

10D. [ ] Irregular margin features (check all that apply)
   14. [ ] Irregular
   15. [ ] Angular
   16. [ ] Microlobulated
   17. [ ] Spiculated / Retractile

11. [ ] Mass Posterior Acoustic Features
    1. None
    2. Enhance on contrast
    3. Shadowing
    4. Combination

12. [ ] Mass Surrounding Tissue
    1. No effect (skip to Q11)
    2. Identifiable effect (corrode Q15G and continue)

13. [ ] Identify effect (check all that apply)
   1. Duct changes
   2. Cooper's ligament changes
   3. Edema
   4. Arteriolar abnormality
   5. Venous abnormality
   6. Rectangular muscle bands and planes with intervening tissues unclear

14. [ ] Calcifications
    1. No (skip to Q12)
    2. Yes (corrode Q11A and continue)

15. [ ] Calcification Features (check all that apply)
   28. [ ] Macrocalcifications
   29. [ ] Microcalcifications out of mass
   30. [ ] Microlacifications in mass

16. [ ] Special Case(s)
    1. No (skip to Q13)
    2. Yes (corrode Q12A and continue)

17. [ ] Special Case Features (check all that apply)
   32. [ ] Mass in or on skin
   33. [ ] Forearm bulk
   34. [ ] Lymph nodes - noninflammatory
   35. [ ] Lymph nodes - axilla

18. Vascularity
    1. None
    2. Serve as normal tissue
    3. Decreased
    4. Increased
    5. Cannot assess

"Copyright 2003"
14. Referencing the diagram, check each region in which the finding is visible.

Cranio-Caudal  Medio-Lateral  Oblique

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

Cranio-Caudal

16. Size of Finding

17. Depth of finding from the skin:
### MRI Contralateral Breast
Initial MRI Assessment Form

**ACRN Study 9667**

**PLACc LABEL HERE**

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

**Case No.**

---

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

---

### I. GENERAL INFORMATION

1. **1.13** Was an MRI done?
   - 1 No
   - 2 Yes (complete form)

2. **2. Date of MRI Scan**
   - 21
   - (mm-dd-yyyy)

2A. **2.A. Date of MRI Interpretation**
   - (mm-dd-yyyy)

2B. **2B. Reader ID**
   - (Redacted)

3. **3. Total number of findings on study breast MRI.**
   - (If zero (0), skip to Q11). If 1 or more, complete B1.

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

---

### II. FINDING

5. **5.78 Finding type (study breast)**
   - 1 Focal (lesion < 5 mm (skip to Q5))
   - 2 Mass (answer Q3 then skip to Q9)
   - 3 Non mass enhancement (skip to Q7)

   - (Redacted)

6A. **6.A. Mass Shape**
   - 1 Round
   - 2 oval
   - 3 Lobulated
   - 4 Irregular

6B. **6.B. Mass Margin**
   - 1 Smooth
   - 2 Irregular
   - 3 Spiculated

---

### 6C. **6.13 Mass Internal Enhancement**

- 1 Homogenous
- 2 Heterogeneous
- 3 Rim enhancement
- 4 Dark internal separation(s)
- 5 Enhanced internal septation(s)
- 6 Central internal enhancement

### 6D. **6.D Mass Degree of Enhancement**

- 1 Minimal
- 2 Moderate
- 3 Marked

- **Provide to question 8**

### 7. **7.13 Type of non-mass enhancement**

- 1 Focal area
- 2 Linear
- 3 Ductal
- 4 Segmental
- 5 Regional
- 6 Multiple regions
- 7 Diffuse

### 7A. **7.A. Non-Mass enhancement symmetry**

- 1 Symmetric
- 2 Asymmetric

### 7B. **7.B. Non-Mass enhancement internal characteristics**

- 1 Homogenous
- 2 Heterogeneous
- 3 Slightly punctate
- 4 Clustered
- 5 Reticular/ductal

---

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III. ASSOCIATED FINDINGS

5. Associated findings (Study Breast)
   1. No. (skip to Q6)
   2. Yes. (complete c69A and continue)

6A. Characterization of Associated findings
   (Check all that apply)
   - Nipple retraction or inversion
   - Skin retraction
   - Pre-contrast high-duct signal
   - Skin thickening
   - Skin invasion
   - Edema
   - Lymphadenoopathy
   - Pectoralis muscle invasion
   - Chest wall invasion
   - Hormonal/blood
   - Abnormal signal void (absence of signal due to artifact)
   - Cyst(s)
   - Other, specify [33]

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

9. Location of finding
   - Nipple
   - Central Region
   - LEC
   - LOQ
   - Axillary tail
   - Breast, NOS
   - Subsural
   - Other, Specify [34]

9A. Maximum Distance of Finding From the Nipple
   [35] m

ACRN Study 5667
PLACE LABEL HERE

9B. Location of Finding
   Reference the diagram, check each region in which the finding is visible.

Craniocaudal
   - Mediolateral

(36) R0 (43) L0
   - Mediolateral

(37) R1 (44) L1
   - Mediolateral

(38) R2 (45) L2
   - Mediolateral

(39) R3 (46) L3
   - Mediolateral

(40) R4 (47) L4
   - Mediolateral

(41) R5 (48) L5
   - Mediolateral

(42) R6 (49) L6
   - Mediolateral

V. KINETIC CURVE ASSESSMENT

10. Initial enhancement phase
   - Not applicable
   - Slow
   - Rapid

10A. Delayed enhancement phase (after 2 minutes or if cure begins to change)
   - Not applicable
   - Persistent
   - Plateau
   - Washout

VI. OVERALL ASSESSMENT OF FINDING

Questions 11 and 12 record recommendations specific to the finding #1 reported in Q4.

11. Assessment
   - Incomplete, need additional evaluation
   - Negative, no abnormal enhancement
   - Benign
   - Probably benign finding, short interval follow-up
   - Suspicious abnormality, biopsy should be considered
   - Highly suggestive of malignancy

*Copyright 2002*
appropriate action should be taken

11A. Specific recommendations

1. Routine follow-up
2. Ultrasound targeted to area of finding
3. Diagnostic mammography
4. Short interval MRI, specify time point

(70) Immediate
☐ 3 months
☐ 6 months
5. Biopsy

12. Probability of Malignancy (based on MR)

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

COMMENTS: ______________________________________________________________________

Date form completed: __________ (mm-dd-yyyy)

Signature of person responsible for the data: ____________________________

Signature of person entering data onto the web: ____________________________
**MRI Contralateral Breast**

**MRI Short Interval Assessment Form**

If this is a repeat or corrected form, please box □

**INSTRUCTIONS:** This form is completed only for the follow-up MRI of the study breast. The study MRI report is done blind. This form is not to be completed by the radiologist. A separate form is completed for each finding or enhancement on study. Reports are dated MMD/YYYY. Measurements are reported in mm.

### I. GENERAL INFORMATION

1. **1.** Was an MRI done? (If MRI is not done, provide a comment)
   - 1. Yes
   - 2. No (complete form)

2. **2.** Follow-up MRI Timepoint
   - 1. Immediate
   - 2. 3 months
   - 3. 6 months
   - 4. Other: Specify (3)

3. **3A.** Date of MRI Scan
   - (mm-dd-yyyy)

3B. **3B.** Date of MRI Interpretation
   - (mm-dd-yyyy)

4. **4.** M. 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 C11.

5. **5.** Data recorded represents finding #. Finding # must correlate with MRI finding # (M3-QA) recommended for post on study MRI.

### II. FINDING

6. **6.** Finding type (study breast)
   - 1. Focal area
   - 2. Linear
   - 3. Ductal
   - 4. Segmental
   - 5. Regional
   - 6. Multiple regions
   - 7. Diffuse

7. **7.** Mass size encompassed by Osd enhancement
   - Record three dimensions (mm x mm x mm)
   - (med-lat) mm
   - (super-infr) mm
   - (anterior-posterior) mm

8. **8.** Mass Shape
   - 1. Round
   - 2. Oval
   - 3. Lobulated
   - 4. Irregular

9. **9A.** Non-Mass Enhancement Symmetry
   - 1. Asymmetric
   - 2. Symmetric

10. **10A.** Non-Mass Enhancement Internal Characteristics
    - 1. Heterogeneous
    - 2. Homogeneous
    - 3. Stippled/punctate
    - 4. Crumpled
    - 5. Reticular/sandwiched

---

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**ACRH Study 6667**

**PLACE LABEL HERE**

**institution no.**

**Case No.**

**6667 M4 T-8-04 1 of 3**
III. ASSOCIATED FINDINGS

9. [Q4] 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 dual signal
   [24] Skin thickening
   [25] Skin invasion
   [26] Edde
   [27] Lymphadenopathy
   [28] Posterior 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 is Q4)

10. [35] Location of finding
    1) Nipple
    2) Central Region
    3) UQ
    4) LQ
    5) UOC
    6) LOC
    7) Axillary Tail
    8) Breast, NDB
    9) Subareolar
    10) Other, Specify [36]____________________________

10A. Maximum distance of Finding From the Nipple
     [37] ____________ mm

19B. Location of Finding
    Referencing the diagram, check each region in which
    the finding is visible.

   [38] CR-UA-1O (45) 55 21 FT 21 LT [60] 1
   [40] CR-UA-1O (47) 58 21 RB 21 LE [62] 3
   [41] CR-UA-1O (48) 59 21 RC 21 LC [63] 4
   [42] CR-UA-1O (49) 60 21 RD 21 LD [64] 5
   [43] CR-UA-1O (50) 61 21 RE 21 LE [65] 6
   [45] CR-UA-1O (52) 63 21 RG 21 LG [67] 8

V. KINETIC CURVE ASSESSMENT
    (If Q4 = 0 findings, code Q11 and Q11A as "O" Not applicable)

11. [46] Initial enhancement phase
    [5] Not applicable
    1 Slow
    2 Medium
    3 Rapid

11A. [47] Delayed enhancement phase
    (after 2 minutes or after curve begins to change)
    [0] Not applicable
    1 Perilente
    2 Plateau
    3 Washout
VI. OVERALL ASSESSMENT OF FINDING
Questions 12 and 13 record recommendations specific to the finding # reported in Q5.

12. ( ] Assessment
   0 Inconclusive, need additional evaluation
   1 Negative, no abnormal enhancement
   2 Benign
   4 Suspicious Abnormality, biopsy should be considered
   5 Highly suggestive of malignancy, appropriate action should be taken

12A. [ ] Specific recommendations
   1 Routine follow-up
   2 Ultrasound targeted to area of finding
   3 Diagnostic mammography
   5 Biopsy

13. ( ] Probability of Malignancy (based on MR)
   1 Definitely not
   2 Probably not
   3 Possible
   4 Probable
   5 Definite

COMMENTS: ( ]

Date form completed ( ]

Signature of person entering data onto the form

Copyright 1994
1. Was a Biopsy Performed? 
   - Yes (complete Q1B, sign and date form) 
   - No (complete Q1A and continue) 

   Date of procedure: [______] (mm/dd/yyyy)

2. Total Number of Lesions Biopsied: [______]

3. Data recorded represents Lesion # [______] (Lesion # must correlate with image, lesion # A separate form is completed for each lesion biopsied)

4. Site of Lesion Biopsied: 
   - Right Breast 
   - Left Breast 

5. Location of Lesion Epicenter: 
   - N/A 
   - Central Portal 
   - UOQ 
   - LQO 
   - 6/7 
   - 7/8 
   - 8/9 
   - 10/11 
   - 12/13 
   - 14/15 
   - 16/17 
   - 18/19 
   - 20/21 
   - 22/23 
   - 24/25 

6. Specify which of the following procedures was performed:
   - Core Needle Biopsy 
   - Excisional Biopsy 
   - Lymphangiogram 
   - Mastectomy 
   - Other, specify: [______]

7. Specify the Type of Guidance System Used: 
   - None 
   - Ultrasound
   - Stereotactic 
   - MRI Guidance (complete Section III) 
   - Other, specify: [______]

8. Method of MR Guided Tissue Sampling: 
   - Core biopsy (complete Q11, 11A, 11B)
   - Wire localization and excision (complete Q12)

9. Initial Needle Pass Location: 
   - Medial-lateral 
   - Ante-Posterior

10. Needle Gauge MRI Guidance: 
    - 14 gauge 
    - Other: Specify [______]

11. Total Number of Needle Passes: [______]

12. Record Final Wire Hook Position: 
    - Medial-lateral 
    - Ante-Posterior

Date form completed: [______] (mm/dd/yyyy)
1. **SITE SPECIMEN DATA**
   1. (11) [ ] Date of Procedure
   2. [ ] Data recorded represents Lesion # (Lesion # must correlate with image lesion # recorded on Att form #3. A separate form is completed for each lesion undergoing Core Needle Biopsy)

2. **BREAST**
   1. Right
   2. Left

3. **SITE PATHOLOGY**
   4. [ ] Biopsy, non-palpative
   10. Benign, non-palpative
   11. Benign, proliferative, NOS
   12. Fibroadenoma
   13. Radial Scar
   14. Other, specify [6]

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. [ ] 13 Benign, non-palpative

4B. [ ] 20 Atypical ductal hyperplasia
   21. Atypical lobular hyperplasia

4C. [ ] 30 Tubular carcinoma in situ
   31. Ductal carcinoma in situ
   32. In situ carcinoma with ductal and lobular features

4D. [ ] 40 Infiltrating ductal carcinoma NOS
   41. Infiltrating lobular carcinoma
   42. Infiltrating carcinoma with ductal and lobular features
   43. Tubular carcinoma
   44. Micropapillary carcinoma
   45. Medullary carcinoma
   46. Other, specify [11]

- **COMMENTS:** (11)

---

**Signature of person responsible for the data:**

**Signature of person entering data onto the web:**

*Copydate 2023*
1. **SITE SPECIMEN DATA**

   1. (____) __________________ Date of Procedure

2. **Data recorded represents lesion #:**
   - Lesion # must correlate with image lesion # recorded on A2 form G3. A separate form is completed for each lesion undergoing excisional biopsy.

3. **SIZE OF EXCISED LESION (mm)**
   - **(med-lat)**
   - **(super-infr)**
   - **(anter-post)**

4. **PATHOLOGIC TNM STAGE (see code table on page 2)**
   - T (____)
   - N (____)
   - M (____)

5. **1-) Breast**
   - 1) Right
   - 2) Left

6. **SITE PATHOLOGY**

   6.1. **HISTOLOGY OF INDEPENDENT LESION**
   - 1) Benign (Go to G6)
   - 2) Atypial (Go to G6)
   - 3) In situ carcinoma (Go to G6)
   - 4) Invasive carcinoma (Go to G6)

      0a. **10) Benign, non-proliferative**
      11) Benign, proliferative, NOS
      12) Fibroadenoma
      13) Fibroadenoma
      14) Other, specify (____)

   0b. **20) Atypical ductal hyperplasia**
   21) Atypical lobular hyperplasia

   0c. **30) Lobular carcinoma in situ**
   31) Ductal carcinoma in situ
   32) In situ carcinoma with ductal and lobular features

   0d. **40) Infiltrating ductal carcinoma NOS**
   41) Infiltrating lobular carcinoma
   42) Infiltrating carcinoma with ductal and lobular features
   43) Tubular carcinoma
   44) Medullary carcinoma
   45) Other, specify (____)

"Copyright 2003"
1. **GRADE OF INVASIVE CANCER**
   1. I
   2. II
   3. III
   4. Not applicable

2. **GRADE OF DCIS**
   1. Well differentiated
   2. Moderately differentiated
   3. Poorly differentiated
   4. Not applicable

3. **DCIS PATTERNS**
   1. No (skip to Q7)
   2. Yes. (check all that apply)
   3. Not applicable (skip to Q10)

4. **LOCATION OF NON-METASTATIC TUMOR**
   1. Lobe
   2. Quadrant
   3. Other
   4. Not applicable

5. **SITE OF FIRST RECURRENT
   1. Lobe
   2. Quadrant
   3. Other
   4. Not applicable

6. **EXTENT OF DCIS ADJACENT TO INVASIVE TUMOR**
   1. Absent
   2. Slight
   3. Moderate
   4. Marked
   5. Not applicable

7. **LYMPHATIC VESSEL INVASION**
   1. Absent
   2. Present
   3. Not applicable

8. **PATHOLOGIC TNM STAGE**

<p>| AJCC TNM STAGES |</p>
<table>
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<tr>
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<th>N</th>
<th>M</th>
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9. **MOST DOMINANT DCIS PATTERN**

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<tr>
<td>3</td>
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<td>4</td>
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</table>

10. **EXTENT DCIS WITHIN INVASIVE TUMOR**

<table>
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<td>3</td>
</tr>
<tr>
<td>4</td>
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<tr>
<td>5</td>
</tr>
</tbody>
</table>

11. **COMMENTS**

   [Blank]

12. **Signature of person responsible for data**

   [Signature]

13. **Date of completion**

   [Date] (mm-dd-yyyy)

14. **Signature of person entering data onto the web**

   [Signature]
7. (16) HISTOLOGY OF SPECIMEN
1. Benign (Go to Q7A)
2. Atypical (Go to Q9A)
3. In situ carcinoma (Go to Q7C)
4. Invasive carcinoma (Go to Q7D)

10. Atypical, non-proliferative
11. Benign, proliferative, NOS
12. Fibroadenoma
13.Radial Scar
14. Other, specify [15]

20. Atypical ductal hyperplasia
21. Atypical lobular hyperplasia

30. Lobular carcinoma in situ
31. Ductal carcinoma in situ
32. In situ carcinoma with ductal and lobular features

40. Infiltrating ductal carcinoma, NOS
41. Infiltrating lobular carcinoma
42. Infiltrating carcinoma with ductal and lobular features
43. Tubular carcinoma
44. Medullary carcinoma
45. Medullary carcinoma
46. Other, specify [19]

8. (19) GRADE OF INVASIVE CANCER
1
2
3
98. Not applicable

9. (1) GRADE OF DCIS
1. Well differentiated
2. Moderately differentiated
3. poorly differentiated
98. Not applicable
DCIS PATTERNS:
1. No skip to Q11
2. Yes (check all that apply)
   a. Not applicable (also to Q11)
   b. Large areas of necrosis (comedo)
   c. Small areas of necrosis
   d. Cribriform
   e. Solid
   f. Micropapillary
   g. Papillary
   h. Most Dominant DCIS Pattern (refer to #11 code table)
   i. Extent of DCIS within invasive tumor
      1. Absent
      2. Slight
      3. Moderate
      4. Masked
      5. Not Applicable

EXTENT OF DCIS ADJACENT TO INVASIVE TUMOR
1. Absent
2. Slight
3. Moderate
4. Marked
5. Not Applicable

IMMUNOHISTOCHEMICAL MARKERS
1. AE1/AE3
2. EPCAM
3. MUC4
4. MUC1
5. MUC5

IMMUNOHISTOCHEMICAL MARKERS
1. TTF-1
2. p53
3. p16
4. ER
5. PR

PATHOLOGIC TNM STAGE (code table for question 4)

AJCC TNM STAGES

T N M
0 T0 N0 M0
1 T1a N0 M0
2 T1b N0 M0
3 T1c N0 M0
4 T2 N0 M0
5 T3 a N0 M0
6 T3 b N0 M0
7 T3 c N0 M0
8 T3 d N0 M0
9 T4 N0 M0
10 T4 a N0 M0
11 T4 b N0 M0
12 T4 c N0 M0
13 T4 d N0 M0
14 T4 e N0 M0

COMMENTS:

Signature of person responsible for the data:

Date form completed: (mm-dd-yyyy)

Signature of person entering data onto the web:

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F1 MRI Contralateral Breast Follow-Up Assessment Form

1. **(1)** Time point of this follow-up
   1 72 Months
   2 24 Months
   3 Other, specify... [3]

2. **(1)** Date of follow-up contact or attempt

3. **(4)** Patient Status
   (If question 3 is coded "sped") provide date of death in QSA. If Q3 is coded "Lost to Follow-up", code last date of contact in QSP.
   1 Alive
   2 Dead
   3 Lost to follow-up; unable to contact

3A. Date of Death... [31]

3B. Date of Last Contact... [41]

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
   3 Unknown (skip to Q5)

4A. **(2)** 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... [100]

4C. **(1)** Specify findings of CBE:
   1 Negative; benign
   2 Abnormal CBE requiring further evaluation

5. **(2)** Was a mammogram of the study breast performed in the past 12 months? [2]
   1 No (Answer Q5A)
   2 Yes, not previously reported (Answer Q5B + Q5C)
   3 Yes, previously reported (skip to 06)

5A. **(3)** 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]

6. **(7)** Was an ultrasound of the study breast performed in the past 12 months? [7]
   1 No (Answer Q6A)
   2 Yes, not previously reported (Answer Q6B + Q6C)
   3 Yes, previously reported (skip to Q7)

6A. **(1)** 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]

8667 F1 (v.6) 5-11-03 1 of 3
7. **7.2** Was an MRI of the study breast performed in the past 12 months?  
1. No, Answer Q7A  
2. Yes, not previously reported (Answer Q7B = Q7C)  
3. Yes, previously reported (skip to Q8)  

7A. **7.21** 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:  

7B. **7.25** Date of most recent MRI:  

7C. **7.25** 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, low yield  
Category 3: Probable 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. **8.7** Was other imaging of the study breast performed in the past 12 months?  
1. No (skip to Q9)  
2. Yes  
9. Unknown (skip to Q9)  

8A. **8.21** Specify type:  

8B. **8.23** Date of other imaging:  

8C. **8.25** Specify findings of other imaging:  
1. Negative, benign  
2. Abnormal, requiring further evaluation  

9. **9.1** Were there any biopsies or surgeries on the study breast in the past 12 months?  
1. No (skip to Q11)  
2. Yes, not previously reported (Answer Q9A)  
3. Yes, previously reported (skip to Q11)  
9a. Unknown (skip to Q11)  

9A. **9.25** Specify intervention by entering the date of the procedure and the accompanying Pathology Form (PA, PD, or PB).  

Data of Biopsy or Surgery:  

9B. **9.32** FNA:  
9C. **9.33** Core needle bx:  
9D. **9.34** Excisional bx (submit 81 + 85):  
9E. **9.35** Lumpectomy (submit 82 + 85):  
9F. **9.36** Mastectomy (submit 80 + 85):
**Contra lateral MRI Breast**

**Study # 6667**

**Case #**

**Revision**

---

### 10. [II] 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. [II] 10** Benign, non-proliferative
11. Benign, proliferative, NOS
12. Fibroadenoma
13. Radial scar
14. Other, specify [II]

**10B. [II] 20** Atypical ductal hyperplasia
21. Atypical lobular hyperplasia

**10C. [II] 30** Lobular carcinoma in situ
31. Ductal carcinoma in situ
32. In situ carcinoma with ductal and lobular features

**10D. [II] 40** Infiltrating ductal carcinoma, NOS
41. Infiltrating lobular carcinoma
42. Infiltrating carcinoma with ductal and lobular features
43. Tubular carcinoma
44. Micropapillary carcinoma
45. Medullary carcinoma
46. Other, specify [II]

---

### 11. [II] Method of Contact

1. At appointment
2. By mail
3. By telephone
4. Other, specify [II]

---

**COMMENTS**

---

**Date form completed:** [49] ______ (mm-dd-yyyy)

[47]

Signature of person responsible for the data

[48]

Signature of person entering data onto the web

---

**Additional Instructions:**

+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.
+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.
MR Contralateral Breast Protocol Variation Form

INSTRUCTIONS: If 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) 777-0036. If the protocol variation is found upon data or image review by headquarters staff, a copy of the headquarter generated PR form will be faxed to the site RA. Return the form in the case study file.

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

☐ Duplicate case registration
☐ Participant withdraw study consent, provide documentation
☐ MRI not performed per protocol specified time point
☐ MRI interpretation done by radiologist other than specified on site PSA
☐ Recommended MRI not done - enter date of imaging as study that recommended MRI
☐ Recommended mammography not done - enter date of imaging study that recommended mammography
☐ 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

2. Describe The Protocol Event Reported Above


Person responsible for data

Date form completed [mm-dd-yyyy]

6667 PR (v2) 8-22-03 1 of 2
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 [10]

HQ Research Associate ___________________________

Date form completed [11] __________ (mm-dd-yyyy)