# American College of Radiology Imaging Network

## Forms Index

<table>
<thead>
<tr>
<th>Form Version</th>
<th>Version Date</th>
<th>Submission Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>ECW</td>
<td>06-21-04</td>
<td></td>
</tr>
<tr>
<td>I1b</td>
<td>09-07-04</td>
<td></td>
</tr>
<tr>
<td>I2</td>
<td>08-11-04</td>
<td></td>
</tr>
<tr>
<td>IAb</td>
<td>09-08-04</td>
<td></td>
</tr>
<tr>
<td>IAb</td>
<td>09-08-04</td>
<td></td>
</tr>
<tr>
<td>ISb</td>
<td>01-19-06</td>
<td></td>
</tr>
<tr>
<td>ISb</td>
<td>01-19-06</td>
<td></td>
</tr>
<tr>
<td>IDb</td>
<td>09-07-04</td>
<td></td>
</tr>
<tr>
<td>IMb</td>
<td>01-19-07</td>
<td></td>
</tr>
<tr>
<td>F6b</td>
<td>07-26-07</td>
<td></td>
</tr>
<tr>
<td>BX</td>
<td>06-19-07</td>
<td></td>
</tr>
<tr>
<td>S1</td>
<td>07-10-07</td>
<td></td>
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<tr>
<td>NL</td>
<td>06-26-07</td>
<td></td>
</tr>
<tr>
<td>F1</td>
<td>02-28-05</td>
<td></td>
</tr>
<tr>
<td>PR</td>
<td>03-17-08</td>
<td></td>
</tr>
<tr>
<td>M3</td>
<td>06-08-06</td>
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<tr>
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<td>06-28-07</td>
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</tr>
<tr>
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<tr>
<td>AE</td>
<td>01-18-05</td>
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</tbody>
</table>

### QC Core Submitted Forms

| QA | Breast Phantom | 04-14-04 |
| QC | Clinical Image Quality Form | 04-25-05 |

See next page for Cost Effectiveness Forms

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## Cost Effectiveness

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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</tr>
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<tbody>
<tr>
<td>CC</td>
<td>Cost Effectiveness Coversheet</td>
<td>10-20-03</td>
</tr>
<tr>
<td>Q1</td>
<td>Willingness to Pay Mammography</td>
<td>10-20-03</td>
</tr>
<tr>
<td>Q2</td>
<td>Willingness to Pay Mammography</td>
<td>10-20-03</td>
</tr>
<tr>
<td>Q3</td>
<td>Willingness to Pay Mammography</td>
<td>10-20-03</td>
</tr>
<tr>
<td>Q4</td>
<td>Willingness to Pay Mammography</td>
<td>10-20-03</td>
</tr>
<tr>
<td>Q5</td>
<td>Willingness to Pay Mammography</td>
<td>10-20-03</td>
</tr>
<tr>
<td>TL</td>
<td>Waiting-Time Trade Off Ultrasound Test (Telephone)</td>
<td>10-15-03</td>
</tr>
<tr>
<td>TM</td>
<td>Waiting-Time Trade Off Mammography (Telephone)</td>
<td>10-15-03</td>
</tr>
<tr>
<td>TS</td>
<td>Willingness to Pay Ultrasound and Mammography</td>
<td>10-17-03</td>
</tr>
<tr>
<td>T1</td>
<td>Waiting-Time Trade Off Diagnostic Mammography (Telephone)</td>
<td>10-15-03</td>
</tr>
<tr>
<td>T2</td>
<td>Waiting-Time Trade Off Diagnostic Ultrasound (Telephone)</td>
<td>10-15-03</td>
</tr>
<tr>
<td>T3</td>
<td>Waiting-Time Trade Off Ultrasound Guided Core Biopsy (Telephone)</td>
<td>10-15-03</td>
</tr>
<tr>
<td>T4</td>
<td>Waiting-Time Trade Off Stereotactict Core Biopsy (Telephone)</td>
<td>10-15-03</td>
</tr>
<tr>
<td>T5</td>
<td>Waiting-Time Trade Off Surgical Biopsy (Telephone)</td>
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</tr>
<tr>
<td>V1</td>
<td>Willingness to Pay Ultrasound</td>
<td>10-20-03</td>
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</tbody>
</table>

*The “person responsible for the data” refers to the individual who has collated 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, ‘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.

*Copyright 2005*
Instructions: Complete the worksheet prior to consent/registration of the participant. A response coded other than that prompted ( ) renders a participant ineligible for study enrollment. If assistance is needed regarding eligibility, please contact ACRIN Data Management at 215-574-3150.

1. Institutional person randomizing case (Name of individual randomizing case)

2. (Y) Has the eligibility checklist (worksheet) been completed?

3. (Y) Patient eligible for this study? (Participant meets at least one of the six high-risk criteria defined in section 5.3)

4. Date the study-specific consent form signed (Must be prior to study entry)

5. Participant’s initials (Last, First) (L,F)

6. Verifying physician

7. Patient ID # (Optional; this is an institution’s method of internally tracking a participant to a protocol case number; may code a series of 9’s)

8. Date of birth (must be ≥ 25 years old)

9. Ethnic Category
   1 Hispanic or Latino
   2 Not Hispanic or Latino
   9 Unknown

(10. Omitted)

11. Gender
   2 Female

12. Participant’s Country of Residence (if country of residence is other, complete Q18)
   1 United States
   2 Canada
   3 Other
   9 Unknown

13. Zip Code (US residents 5 digit zip code)

14. Participant’s Insurance Status
   0 Other
   1 Private Insurance
   2 Medicare
   3 Medicare and Private Insurance
   4 Medicaid
   5 Medicaid and Medicare
   6 Military or Veteran’s Administration
   7 Self Pay
   8 No means of payment
   9 Unknown/Decline to answer
15. Any care at VA or military hospital
   1  No
   2  Yes
   9  Unknown

16. Calendar base date (First study imaging scheduled date)
   mm  dd  yyyy

17. Randomization date
   mm  dd  yyyy

18. Other country, specify (complete Q18 if Q12 is other)

19. (N/Y) Race: American Indian or Alaskan Native

20. (N/Y) Race: Asian

21. (N/Y) Race: Black or African American

22. (N/Y) Race: Native Hawaiian or other Pacific Islander

23. (N/Y) Race: White

24. (N/Y) Race: Unknown
25. (N) Is participant enrolled in the first year of the Digital Mammography Imaging Screening Trial (DMIST) any contrast-enhanced breast MRI trials, tomosynthesis trial, any other trial of breast ultrasound or breast ultrasound agents, or any breast cancer screening trial?

26. (N) Has the participant undergone contrast-enhanced breast MRI or bilateral whole breast ultrasound within the past 12 months?

27. (N) Has the participant had any breast procedures (FNAB other than cyst aspiration, core biopsy, or other breast surgical procedure) within the past 12 months?

28. (N) Is the participant aware of any palpable abnormality in the breast(s), abnormal skin changes of the breast(s) and or nipple(s), bloody discharge, or spontaneous nipple discharge?

29. (Y) Does the participant meet at least one of the high-risk criteria as defined in Section 5.3 of the protocol?

30. (N) Has the participant had breast cancer diagnosed within the prior 12 months or have known distant metastases from breast cancer or have known residual cancer?

31. (N) Excluding breast cancer, basal cell or squamous cell skin cancer, and in situ cervical cancer, has the participant been diagnosed with cancer in the last five years or has the participant had a recurrence of cancer in the last five years or has residual disease been detected in the last five years?

32. (N) Does the participant have breast implant(s) in the study breast(s)?

33. (N) Is the participant pregnant, nursing, or does she have any reason to believe she may be pregnant or does she plan to become pregnant within the next 2 years?

34. (Y) Does the participant understand and agree to the follow-up requirements as outlined in Section 4.10 of the protocol?

35. Date* study mammogram scheduled (mammogram and sonogram must be within 2 weeks of each other and performed at the same site)

36. Date* of study sonogram scheduled (sonogram and mammogram must be within 2 weeks of each other and performed at the same site)

37. (N/Y) Is this the participant's first mammogram? (If yes, answer Q38 and skip Q39, if no, answer Q38 and Q39)

38. (Y) Is this a routine annual mammogram visit?

39. (Y) Are the breast(s) heterogeneously dense or dense mammographically as defined in Section 5.3 of the protocol? (leave blank if no prior mammogram)

Participant Signature ________________________________

Signature or person responsible for the data ________________________________
(Research Associate or Principal Investigator)

Date of form completed (mm-dd-yyyy) _____ “_____” _____

Signature of person entering data on the web ________________________________

* If the study mammogram and or sonogram have been scheduled please provide the dates. If the imaging appointments have not been scheduled, please leave the question blank.
1. Date of birth ____-____-______ (mm/dd/yyyy) (age must be ≥ 25 years)

2. Have you had a prior mammogram?
   o No
   o Yes (If yes, complete Q2a and Q2b)

2a. Date of last mammogram ____-____ (record the last annual standard view exam date; if date unknown, code 12-2100)

2b. Facility where mammogram was performed __________________________
    (Internal use only) City, State (if not known, record "unknown" for Q2b)

3. Have you had a prior breast ultrasound?
   o No (Proceed to Q4)
   o Yes (If yes, complete Q3a, 3b, and 3c)

3a. Type of breast ultrasound (check all that apply) (leave blank if unknown)
    □ Targeted Right
    □ Targeted Left
    □ Whole breast Right
    □ Whole breast Left

3b. Date of most recent breast ultrasound ____-____ (if date unknown, code 12-2100)

3c. Facility where breast ultrasound was performed __________________________
    (Internal use only) City, State (if not known, record "unknown" for Q3c)

4. Have you had a prior MRI of the breast(s) with contrast?
   o No
   o Yes (If yes, complete Q4a, 4b, and 4c)

4a. Check which breast imaged with MR
    □ Right
    □ Left

4b. Date of breast MRI ____-____ (if date unknown, code 12-2100)

4c. Facility where breast MRI performed __________________________
    (Internal use only) City, State (if not known, record "unknown" for Q4c)

5. Age at first menstrual period [____] (If unknown, code "99")

6. How long ago was your last menstrual period?
   o Within the last month
   o Less than 1 year ago
   o More than one year ago
   o Surgical menopause: year [____] (If year is unknown code "2100")
   o Unknown/I cannot remember
7. Number of live births [ ]

7a. __________ Age at first live birth (If unknown, code “99”)

8. Bra Cup size (If breasts are different sizes, code larger size)
   - A
   - B
   - C
   - D
   - DD
   - Other, specify ______________________

9. History of Hormone use:
   - No (proceed to Q10)
   - Yes (complete Q9a)

**Hormone Use Code Table (Q9a)**

1. Current
2. Not currently using, but previous use
3. Never used

9a. __________ Estrogen Replacement Therapy
    - Number of years ___ and months___ used
9b. __________ Tamoxifen
    - Number of years ___ and months___ used
9c. __________ Raloxifene (EVISTA)
    - Number of years ___ and months___ used
9d. __________ Aromatase Inhibitor (e.g. Arimidex)
    - Number of years ___ and months___ used
9e. __________ Birth Control Pills
    - Number of years ___ and months___ used
9f. __________ Soy/over the counter daily hormonal preparation
    - Number of years ___ and months___ used

10. Have you had cosmetic breast surgery?
    - No (proceed to Q11)
    - Yes (Complete Q10a)

10a. Record year of most recent cosmetic surgery (If the year unknown, code “2100”)

<table>
<thead>
<tr>
<th>Right Breast</th>
<th>Left Breast</th>
</tr>
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<tbody>
<tr>
<td>Reduction</td>
<td>__________ (yyy)</td>
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<tr>
<td>Lift</td>
<td>__________ (yyy)</td>
</tr>
<tr>
<td>Implant placed</td>
<td>__________ (yyy)</td>
</tr>
<tr>
<td>Implant removed</td>
<td>__________ (yyy)</td>
</tr>
</tbody>
</table>

CONTINUED ON NEXT PAGE...
11. Prior Diagnosis of Breast Cancer
   - No (proceed to Q12)
   - Yes
     - Pathology report is available
     - Pathology report is not available
   - Unknown (proceed to Q12)

11a. Pathology (If year of Pathological diagnosis unknown, code "2100")

<table>
<thead>
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<th>Breast</th>
<th>Pathology</th>
<th>Lymph nodes involved?</th>
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<td>o R</td>
<td>o L</td>
<td>o N o Y o Unknown</td>
</tr>
<tr>
<td></td>
<td>o R</td>
<td>o L</td>
<td>o N o Y o Unknown</td>
</tr>
<tr>
<td></td>
<td>o R</td>
<td>o L</td>
<td>o N o Y o Unknown</td>
</tr>
<tr>
<td></td>
<td>o R</td>
<td>o L</td>
<td>o N o Y o Unknown</td>
</tr>
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</table>

11b. Treatment (If year of breast cancer treatment unknown, code "2100")

<table>
<thead>
<tr>
<th>Year</th>
<th>Breast</th>
<th>Treatment</th>
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</thead>
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<tr>
<td></td>
<td>o R</td>
<td>Lumpectomy and radiation</td>
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<tr>
<td></td>
<td>o L</td>
<td>Mastectomy and radiation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Mastectomy alone</td>
</tr>
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</table>

11c. Was chemotherapy given?
   - No
   - Yes (If yes, code time point)
     - Prior to surgery
     - After surgery
     - Both before and after surgery

12. Prior cyst excision and/or cyst aspiration

12a. Number of prior benign biopsies other than cyst(s)

12b. List 4 most significant occurrences

<table>
<thead>
<tr>
<th>Year</th>
<th>Breast</th>
<th>Biopsy result</th>
<th>Type of Biopsy</th>
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<td>o R</td>
<td>o L</td>
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</table>

Pathology Code Table (Q11a)
1. Malignant, NOS
2. Invasive ductal carcinoma*
3. DCIS
4. Invasive ductal carcinoma and DCIS
5. Invasive lobular carcinoma
6. Invasive ductal and lobular carcinoma
7. Lymphoma
8. Metastatic from outside breast
9. Other
99. Unknown
* Invasive ductal carcinoma includes: medullary, colloid, mucinous, tubular

NOTE: LCIS (lobular carcinoma in situ) is not cancer, but a high-risk lesion to be listed in Q12.

Benign Biopsy result Code table A (Q12b)
1. LCIS (lobular carcinoma in situ)
2. Atypical lobular hyperplasia (ALH)
3. Lobular neoplasia, NOS
4. LCIS and ADH
5. Atypical ductal hyperplasia (ADH)
6. Atypical Papilloma
7. Radial scar/complex sclerosing lesion
8. Atypical cytology (FNA)
9. Atypical, unsure of type
10. Columnar alteration with atypia
11. Papilloma
12. Sclerosing Adenosis
13. Fibroadenoma
14. Fibrocytic changes
15. Stromal fibrosis
16. PASH
17. Benign, unsure of details
99. Unknown

Type of Biopsy code table B (Q12b)
1. Fine needle aspiration (FNA) only
2. Core biopsy +/- initial FNA
3. Excision
4. Any needle biopsy and excision
99. Unknown
13. Family History of Breast Cancer
   - No (proceed to Q14)
   - Yes (complete Q13a and Q13b)
   - Unknown (proceed to Q14)

13a. Number of relatives with breast cancer

13b. List 4 (closest) relatives:

<table>
<thead>
<tr>
<th>Code table for Relatives</th>
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</thead>
<tbody>
<tr>
<td>1 Mother</td>
</tr>
<tr>
<td>2 Sister</td>
</tr>
<tr>
<td>3 Daughter</td>
</tr>
<tr>
<td>4 Maternal Grandmother</td>
</tr>
<tr>
<td>5 Paternal Grandmother</td>
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<th>Breast code table C (Q13b)</th>
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<td>1 Unilateral</td>
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<td>2 Bilateral</td>
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<tr>
<td>99 Unknown</td>
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   Age at Diagnosis*  ("99" if unknown)

   | Relative 1 w/breast cancer |
   | Relative 2 w/breast cancer |
   | Relative 3 w/breast cancer |
   | Relative 4 w/breast cancer |

   * (If only the age decade is known, record midpoint of decade, e.g. 25, 35…)

14. Family History of Ovarian Cancer
   - No (proceed to Q15)
   - Yes (complete Q14a and Q14b)
   - Unknown (proceed to Q15)

14a. Number of relatives with ovarian cancer

14b. List 4 (closest) relatives:

<table>
<thead>
<tr>
<th>Code table for Relatives</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Mother</td>
</tr>
<tr>
<td>2 Sister</td>
</tr>
<tr>
<td>3 Daughter</td>
</tr>
<tr>
<td>4 Maternal Grandmother</td>
</tr>
<tr>
<td>5 Paternal Grandmother</td>
</tr>
</tbody>
</table>

   Age at Diagnosis*  ("99" if unknown)

   | Relative 1 w/ovarian cancer |
   | Relative 2 w/ovarian cancer |
   | Relative 3 w/ovarian cancer |
   | Relative 4 w/ovarian cancer |

   * (If only the age decade is known, record midpoint of decade, e.g. 25, 35…)

"Copyright 2004"
15. Are you willing to answer questions about familial genetic tests?
   o No (proceed to Q18)
   o Yes (complete Q15a)

15a. Genetic testing has been performed to evaluate possible familial risk of breast cancer?
   o No (proceed to Q18)
   o Yes
     o Self only (proceed to Q16)
     o Family member(s) only (proceed to Q17)
     o Both self and family member(s) (proceed to Q16)

16. Genetic changes for self found by test?
   o No (proceed to Q17)
   o Yes (complete Q16a-Q16c)
   o Unknown (proceed to Q17)

16a. Changes in BRCA-1 gene
   o No
   o Yes
   o Unknown

16b. Changes in BRCA-2 gene
   o No
   o Yes
   o Unknown

16c. Changes in other gene
   o No (proceed to Q17)
   o Yes
   o Unknown (proceed to Q17)

Yes, check all gene changes that apply:
   □ HNPPC
   □ PTEN
   □ p5
   □ Other

17. Family member (blood relative) with change in BRCA-1 or BRCA-2?
   o No family members tested (proceed to Q18)
   o No family members had changes (proceed to Q18)
   o Yes (complete table 17a & 17b)
   o Unknown (proceed to Q18)

17a. Number of relatives with change in BRCA-1 or BRCA-2

18. Prior radiation treatment to the chest, axilla, and/or mediastinum not for breast cancer.
   o No (proceed to Q19)
   o Yes (complete Q18a, 18b and 18c)
   o Unknown (proceed to Q19)

18a. Age at radiation treatment
   (If age is unknown, code “99”)

18b. Year of radiation treatment
   (yyyy: record year of last radiation treatment, if unknown code “2100”)

18c. Hodgkin’s disease
   o No
   o Yes
   o Other, specify

19. Lifetime risk for breast cancer by Gail Model:
   [ ] % (attach printout)
   Code 98 if not applicable (e.g. participant is younger than 35 and/or has personal history of cancer or LCIS)

20. Lifetime risk for breast cancer by Claus Model:
   [ ] % (attach printout)
   Code 98 if not applicable (e.g. no family history of breast cancer and/or participant has personal history of cancer or LCIS)

Comments:

Signature of person responsible for data

Signature of person entering data onto the web

If the information reported directly on the form has been obtained through participant interview or participant self-completion, signature of the participant must appear below.
Instructions: The I2 is completed through participant interview in addition to the I1. Both the RA and participant’s signatures must appear on the completed form. If the participant is eligible based on 5-year Gail model risk (Q22 or Q23), then a printout of the Gail model risk must be included in the participant file.

21. Have you had a clinical breast examination in the past year?  
   - No (proceed to Q21a)  
   - Yes, provide date: _____-_______ (mm-yyyy) (code 12/2100 if unknown)

21a. Do you perform regular self breast examination?  
   - No (proceed to Q22)  
   - Yes, monthly (proceed to Q22)  
   - Occasionally, not routinely (proceed to Q22)

22. What is the 5-year risk for breast cancer by Gail Model?  
   _____% (5-year risk per printout from Q19)  
   If not applicable (e.g. participant is younger than 35 and/or has personal history of breast cancer or LCIS, code 98.0, stop and sign form)  
   If the 5-year risk by Gail Model is < 1.7%, stop and sign form.

23. Does the participant have extremely dense breast(s) (>75% dense) on prior mammography?  
   - No (stop and sign form)  
   - Yes (proceed)  
     Please multiply the 5-year Gail Model risk (per Q22) by 1.5 and record value: _____%  
   STOP and sign form.

Comments:  
________________________________________________________________________  
________________________________________________________________________  
________________________________________________________________________

Signature of Person responsible for the data 1  
Date Form Completed (mm-dd-yyyy)  

Signature of person entering data onto web 2  
Participant signature

1The “person responsible for the data” refers to the individual who has collated the data on this specific data form  
2The “person entering data” is the individual who enters the data from the specific form into the web data form.
ACRIN Study 6666

**Mammography Interpretation**

If this is a revised or corrected form, please check (✓) box and fax to 215-717-0936.

**Instructions:** The Radiologist who interprets the patient’s routine study mammogram completes this form. Study mammogram must be within **2 weeks** of the sonogram and at the **same** site. The Radiologist completing this form must not be the same Radiologist who performs(ed) the initial survey ultrasound and must not have reviewed study US prior to completing this form. Please note that comparison to prior mammograms is encouraged. However, neither prior nor current US examinations should be reviewed at the time of annual study mammogram interpretations.

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
<th>Instructions</th>
</tr>
</thead>
<tbody>
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</tr>
<tr>
<td>2. Date of Study Interpretation</td>
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<tr>
<td>3. Time in study</td>
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<td>o Initial screening</td>
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<td>o 24 month screening</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3a. Record actual months since study entry</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3b. Was the scheduled mammogram performed?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o No (complete and stop, sign form)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3c. Image Presentation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Film-Screen</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Digital</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Prior Films</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Present with interpretation (proceed to Q4a)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Not present with interpretation (proceed to Q4a)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Participant does not have prior films (proceed to Q5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4a. Date of most Recent Prior Standard View Mammogram</td>
<td>(mm-dd-yyyy)</td>
<td>Check box if date of prior Standard View Mammogram is unknown.</td>
</tr>
<tr>
<td>5. Date of study Mammogram</td>
<td>(mm-dd-yyyy)</td>
<td></td>
</tr>
<tr>
<td>6. Which breast(s) are included on study?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Bilateral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Right breast only</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Left breast only</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Has patient had breast conservation surgery for cancer?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o No (proceed to Q8)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Yes (provide which breast(s))</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Right breast only</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Left breast only</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Density of Breast Parenchyma (current exam)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8a. Subjective rating of % of breast where tissue is dense.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Less than 25%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o 26-40%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o 41-60%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o 61-80%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Greater than 80%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Not applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8b. Where is parenchyma dense? (check all that apply)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>R</td>
<td>L</td>
<td></td>
</tr>
<tr>
<td>o Diffusely dense</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Anteriorly</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o UOQ</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Scattered focal areas</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Not dense</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Other, Specify</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. Mammographic Findings to be reported</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o No (proceed to Q13)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Yes (complete and proceed to Q9a)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Right breast only</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Left breast only</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Bilateral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9a. Total number of lesion(s) you wish to describe</td>
<td>(up to 4 separate lesions in each breast). Note: If there are multiple bilateral benign appearing findings to be described, code as one lesion and describe largest one.</td>
<td></td>
</tr>
<tr>
<td>o Right Breast</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Left Breast</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. First Lesion Description</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10a. Lesion # M (e.g. MR1, MB1, ML1 etc.)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Use # from previous exam if new use next sequential #. Describe any new or suspicious findings first.)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10b. Change in this lesion from prior mammogram?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o New</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Gone</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Decreasing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Stable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Fluctuating bilateral circumscribed masses</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Increasing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Other suspicious change</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Increasing and other suspicious change</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o Not applicable, no prior</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10c. Distance from the nipple</td>
<td>cm</td>
<td></td>
</tr>
<tr>
<td>(largest diameter)</td>
<td>(largest perpendicular dimension)</td>
<td></td>
</tr>
<tr>
<td>[NOTE: Code 100 X 100 for diffuse scattered calcifications with no discrete group.]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10d. Location (check all that apply)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10e. Distance from the nipple</td>
<td>cm</td>
<td></td>
</tr>
<tr>
<td>[Code 20 for diffuse scattered calcifications.]</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
10f. Lesion type (check all that apply)
- Mass (select worst margin feature present)
  - Circumscribed (select one)
    - Fat-containing
    - Not fat-containing
  - Microlobulated
  - Obscured
  - Indistinct
  - Spiculated
- Associated features
  - Yes (check all that apply)
  - No
- Asymmetry (code type)
  - Focal (complete)
  - Symmetry seen on
    - One view
    - Both views
  - Global
- Architectural Distortion
- Calcifications (code morphology and distribution)
  - Morphology of calcifications (check all that apply)
    - Coarse typically benign
    - Milk of calcium
    - Coarse heterogeneous
    - Punctate (<0.5 mm, uniformly round)
    - Amorphous/Indistinct
    - Pleomorphic
    - Branching/Fine linear
  - Distribution of calcifications (check all that apply)
    - Clustered
    - Multiple clusters (same morphology)
    - Regional
    - Linear
    - Segmental
    - Diffuse scattered
    - In mass or asymmetry

10g. Is this lesion at the site of prior biopsy?
- No
- Yes (if yes, select procedure)
  - Core/vacuum biopsy site with clip
  - Core/vacuum biopsy site without clip
  - Surgical biopsy site (select diagnosis)
    - Benign
    - Atypical/high-risk lesion
    - Cancer site
    - Unknown
  - Biopsy details unknown
  - FNAB
  - Not applicable, multiple bilateral circumscribed masses

11. Assessment/Recommendations for this lesion

11a. % Likelihood of malignancy for this lesion
(best guess from 0-100)

11b. Assessment for this lesion
- 1 Negative
- 2 Benign
- 3 Probably Benign
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion
- 5 Highly Suggestive of Malignancy

11c. Recommendation for this lesion
- Routine screening in 1 year
- Diagnostic follow-up in 1 year
- Short-interval follow-up in 6 months with mammography
- Intervention and/or Additional Imaging (detail intervention and/or additional imaging)
  - Aspiration w/core biopsy if solid
  - US-guided core biopsy
  - Vacuum-assisted biopsy, guidance by US
  - Vacuum-assisted biopsy, guidance by mammography
  - Excisional biopsy
- Additional Imaging (check all that apply)
  - Targeted Ultrasound (lesion seen on mammography)
  - Comparison to prior mammograms is required
  - Additional mammographic projections

11d. Is this lesion assessed as probably benign AND recommended for intervention?
- No (proceed to Q12)
- Yes (specify dominant reason)
  - Participant preference
  - Cancer present now
  - In this breast
  - In opposite breast
  - Patient risk factors
  - Vaguely palpable
  - Follow-up not reasonable
  - Interval increase (>20% in volume for masses)
  - Interval suspicious change
  - Investigator uncertainty

12. Are there additional lesions you wish to describe?
- No (proceed to Q13)
- Yes (proceed to Q15)
13. Final assessment of right breast

- Not on study (proceed to Q14)

13a. [___/___/___] \% Likelihood of malignancy for right breast (best guess from 0-100)

13b. Assessment for right breast

- 1 Negative
- 2 Benign
- 3 Probably Benign
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion
- 5 Highly Suggestive of Malignancy

13c. Recommendation for right breast

- Routine screening in 1 year
- Diagnostic follow-up in 1 year
- Short-interval follow-up in 6 months with mammography
- Intervention and/or Additional Imaging
  - Intervention (complete)
    - Aspiration w/core biopsy if solid
    - US-guided core biopsy
    - Vacuum-assisted biopsy, guidance by US
    - Vacuum-assisted biopsy, guidance by mammography
    - Excisional biopsy
  - Additional Imaging (check all that apply)
    - Additional evaluation
    - Comparison to prior mammogram is required
    - Targeted ultrasound
    - Additional mammographic projections
    - Repeat mammogram
      - Incomplete
      - Motion artifacts/other technical problem

14. Final assessment of left breast

- Not on study (form complete, sign and date below)

14a. [___/___/___] \% Likelihood of malignancy for left breast (best guess from 0-100)

14b. Assessment for left breast

- 1 Negative
- 2 Benign
- 3 Probably Benign
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion
- 5 Highly Suggestive of Malignancy

14c. Recommendation for left breast

- Routine screening in 1 year
- Diagnostic follow-up in 1 year
- Short-interval follow-up in 6 months with mammography
- Intervention and/or Additional Imaging
  - Intervention (complete)
    - Aspiration w/core biopsy if solid
    - US-guided core biopsy
    - Vacuum-assisted biopsy, guidance by US
    - Vacuum-assisted biopsy, guidance by mammography
    - Excisional biopsy
  - Additional Imaging (check all that apply)
    - Additional evaluation
    - Comparison to prior mammogram is required
    - Targeted ultrasound
    - Additional mammographic projections
    - Repeat mammogram
      - Incomplete
      - Motion artifacts/other technical problem

Form complete. Sign and date below.

Comments:

________________________________________

________________________________________

Signature of Radiologist responsible for the data  

Signature of person entering data onto web  

Date Form Completed (mm-dd-yyyy)
15. Additional Lesion Description

15a. Lesion # [M] (e.g. MR1, MB1, ML1 etc.)
(Use # from previous exam if new use next sequential #. Describe any new or suspicious findings first.)

15b. Change in this lesion from prior mammogram?
- New
- Gone
- Decreasing
- Stable
- Fluctuating bilateral circumscribed masses
- Increasing
- Other suspicious change
- Increasing and other suspicious change
- Not applicable, no prior

15c. [ ] [ ] mm X [ ] [ ] mm
(largest diameter) (largest perpendicular dimension)

15d. Location (check all that apply)
Note: for multiple bilateral findings with similar appearances, check "bilateral, multiple" and indicate specific location of the largest such finding.
- Right
- Left
- Bilateral, multiple
- Axillary tail
- Retroareolar
- Inner
- Outer
- Central

15e. Distance from the nipple [ ] cm

15f. Lesion type (check all that apply)
- Mass (select worst margin feature present)
  - Circumscribed (select one)
  - Fat-containing
  - Not fat-containing
  - Microlobulated
  - Obscured
  - Indistinct
  - Spiculated
- Associated features
  - No
  - Yes (check all that apply)
  - Calcifications (detail below)
  - Architectural distortion
  - Skin thickening
  - Dilated duct(s)
- Asymmetry (code type)
  - Focal (complete)
  - Asymmetry seen on
    - One view
    - Both views
  - Global
- Calcifications (code morphology and distribution)
  - Morphology of calcifications (check all that apply)
    - Coarse typically benign
    - Milk of calcium
    - Coarse heterogeneous
    - Punctate (<0.5 mm, uniformly round)
    - Amorphous/Indistinct
    - Pleomorphic
    - Branching/Fine linear
- Distribution of calcifications (check all that apply)
  - Clustered
  - Multiple clusters (same morphology)
  - Regional
  - Linear
  - Segmental
  - Diffuse scattered
  - In mass or asymmetry
  - Architectural Distortion

16. Assessment/Recommendations for this lesion

16a. [ ] [%] Likelihood of malignancy for this lesion
(best guess from 0-100)

16b. Assessment for this lesion
- 1 Negative
- 2 Benign
- 3 Probably Benign
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion
- 5 Highly Suggestive of Malignancy

16c. Recommendation for this lesion
- Routine screening in 1 year
- Diagnostic follow-up in 1 year
- Short-interval follow-up in 6 months with mammography
- Intervention and/or Additional Imaging (detail intervention and/or additional imaging)
  - Intervention (complete)
    - Aspiration w/core biopsy if solid
    - US-guided core biopsy
    - Vacuum-assisted biopsy, guidance by US
    - Vacuum-assisted biopsy, guidance by mammography
    - Excisional biopsy
  - Additional Imaging (check all that apply)
    - Targeted Ultrasound (lesion seen on mammography)
    - Comparison to prior mammograms is required
    - Additional mammographic projections

16d. Is this lesion assessed as probably benign AND recommended for intervention?
- No (proceed to Q17)
- Yes (specify dominant reason)
  - Participant preference
  - Cancer present now
  - In this breast
  - In opposite breast
  - Patient risk factors
  - Vaguely palpable
  - Follow-up not reasonable
  - Interval increase (>20% in volume for masses)
  - Interval suspicious change
  - Investigator uncertainty

17. Are there additional lesions you wish to describe?
- No (proceed to Q13)
- Yes (proceed to Q18)
18. Additional Lesion Description

18a. Lesion # M (e.g. MR1, MB1, ML1 etc.)
(Use # from previous exam if new use next sequential #. Describe any new or suspicious findings first.)

18b. Change in this lesion from prior mammogram?
- New
- Gone
- Decreasing
- Stable
- Decreasing bilateral circumscribed masses
- Increasing
- Other suspicious change
- Increasing and other suspicious change
- Not applicable, no prior

18c. __________ mm X __________ mm
(largest diameter) (largest perpendicular dimension)

18d. Location (check all that apply)
Note: for multiple bilateral findings with similar appearances, check "bilateral, multiple" and indicate specific location of the largest such finding.
- Right
- Left
- Bilateral, multiple
- Axillary tail
- Retroareolar
- Central

18e. Distance from the nipple ______ cm

18f. Lesion type (check all that apply)
- Mass (select worst margin feature present)
  - Circumscribed (select one)
  - Fat-containing
  - Not fat-containing
  - Microlobulated
  - Obscured
  - Indistinct
  - Spiculated
- Associated features
  - No
  - Yes (check all that apply)
    - Calcifications (detail below)
    - Architectural distortion
    - Dilation
    - Dilated duct(s)
  - Asymmetry (code type)
    - Focal (complete)
      - Asymmetry seen on
        - One view
        - Both views
    - Global
  - Calcifications (code morphology and distribution)
    - Morphology of calcifications (check all that apply)
      - Coarse typically benign
      - Milk of calcium
      - Coarse heterogenous
      - Punctate (<0.5 mm, uniformly round)
      - Amorphous/Indistinct
      - Pleomorphic
      - Branching/Fine linear
    - Distribution of calcifications (check all that apply)
      - Clustered
      - Multiple clusters (same morphology)
      - Regional
      - Linear
      - Segmental
      - Diffuse scattered
      - In mass or asymmetry
- Architectural Distortion

18g. Is this lesion at the site of prior biopsy?
- No
- Yes (if yes, select procedure)
  - Core/vacuum biopsy site with clip
  - Core/vacuum biopsy site without clip
  - Surgical biopsy site (select diagnosis)
    - Benign
    - Atypical/high-risk lesion
    - Cancer site
    - Unknown
    - Biopsy details unknown
  - FNAB
  - Not applicable, multiple bilateral circumscribed masses

19. Assessment/Recommendations for this lesion

19a. ______ % Likelihood of malignancy for this lesion
(best guess from 0-100)

19b. Assessment for this lesion
- 1 Negative
- 2 Benign
- 3 Probably Benign
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion
- 5 Highly Suggestive of Malignancy

19c. Recommendation for this lesion
- Routine screening in 1 year
- Diagnostic follow-up in 1 year
- Short-interval follow-up in 6 months with mammography
- Intervention and/or Additional Imaging
  - Intervention (complete)
    - Aspiration/w/core biopsy if solid
    - US-guided core biopsy
    - Vacuum-assisted biopsy, guidance by US
    - Vacuum-assisted biopsy, guidance by mammography
    - Excisional biopsy
  - Additional Imaging (check all that apply)
    - Targeted Ultrasound (lesion seen on mammography)
    - Comparison to prior mammograms is required
    - Additional mammographic projections

19d. Is this lesion assessed as probably benign AND recommended for intervention?
- No (proceed to Q20)
- Yes (specify dominant reason)
  - Participant preference
  - Cancer present now
  - In this breast
  - In opposite breast
  - Patient risk factors
  - Vaguely palpable
  - Follow-up not reasonable
  - Interval increase (>20% in volume for masses)
  - Interval suspicious change
  - Investigator uncertainty

20. Are there additional lesions you wish to describe?
- No (proceed to Q13)
- Yes (proceed to Q21)
21. Additional Lesion Description

21a. **Lesion #** \[ M \] (e.g. MR1, MB1, ML1 etc.)

(Use # from previous exam if new use next sequential #. Describe any new or suspicious findings first.)

21b. **Change in this lesion from prior mammogram?**

- New
- Gone
- Decreasing
- Stable
- Fluctuating bilateral circumscribed masses
- Increasing
- Other suspicious change
- Increasing and other suspicious change
- Not applicable, no prior

21c. \[ \underline{\_}\underline{\_}\underline{\_}\underline{\_} \text{mm} \times \underline{\_}\underline{\_}\underline{\_}\underline{\_} \text{mm} \]

(largest diameter) (largest perpendicular dimension)

21d. **Location** (check all that apply)

Note: for multiple bilateral findings with similar appearances, check "bilateral, multiple" and indicate specific location of the largest such finding.

- Right
- Left
- Bilateral, multiple
- Axillary tail
- Retroareolar
- Central

21e. **Distance from the nipple** \[ \underline{\_}\underline{\_}\underline{\_}\underline{\_} \text{cm} \]

21f. **Lesion type** (check all that apply)

- Mass (select worst margin feature present)
  - Circumscribed (select one)
  - Not fat-containing
  - Microlobulated
  - Obscured
  - Indistinct
  - Spiculated

- Associated features
  - No
  - Yes (check all that apply)
    - Calcifications (detail below)
    - Architectural distortion
    - Skin thickening
    - Dilated duct(s)

- Asymmetry (code type)
  - Focal (complete)
    - Asymmetry seen on
      - One view
      - Both views
      - Global

- Calcifications (code morphology and distribution)

- Morphology of calcifications (check all that apply)
  - Coarse typically benign
  - Milk of calcium
  - Coarse heterogeneous
  - Punctate (<0.5 mm, uniformly round)
  - Amorphous/Indistinct
  - Pleomorphic
  - Branching/Fine linear

- Distribution of calcifications (check all that apply)
  - Clustered
  - Multiple clusters (same morphology)
  - Regional
  - Linear
  - Segmental
  - Diffuse scattered
  - In mass or asymmetry
  - Architectural Distortion

21g. **Is this lesion at the site of prior biopsy?**

- No
- Yes (if yes, select procedure)
  - Core/vacuum biopsy site with clip
  - Core/vacuum biopsy site without clip
  - Surgical biopsy site (select diagnosis)
    - Benign
    - Atypical/high-risk lesion
    - Cancer site
    - Unknown
    - Biopsy details unknown
    - FNAB
    - Not applicable, multiple bilateral circumscribed masses

22. Assessment/Recommendations for this lesion

22a. \[ \underline{\_}\underline{\_}\underline{\_}\underline{\_}\underline{\_}\underline{\_} \% \text{Likelihood of malignancy for this lesion} \]

(best guess from 0-100)

22b. **Assessment for this lesion**

- 1 Negative
- 2 Benign
- 3 Probably Benign
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion
- 5 Highly Suggestive of Malignancy

22c. **Recommendation for this lesion**

- Routine screening in 1 year
- Diagnostic follow-up in 1 year
- Short-interval follow-up in 6 months with mammography
- Intervention and/or Additional Imaging
  - (detail intervention and/or additional imaging)

- Intervention (complete)
  - Aspiration w/core biopsy if solid
  - US-guided core biopsy
  - Vacuum-assisted biopsy, guidance by US
  - Vacuum-assisted biopsy, guidance by mammography
  - Excisional biopsy

- Additional Imaging (check all that apply)
  - Targeted Ultrasound (lesion seen on mammography)
  - Comparison to prior mammograms is required
  - Additional mammographic projections

22d. **Is this lesion assessed as probably benign AND recommended for intervention?**

- No (proceed to Q23)
- Yes (specify dominant reason)
  - Participant preference
  - Cancer present now
  - In this breast
  - In opposite breast
  - Patient risk factors
  - Vaguely palpable
  - Follow-up not reasonable
  - Interval increase (>20% in volume for masses)
  - Interval suspicious change
  - Investigator uncertainty

23. **Are there additional lesions you wish to describe?**

- No (proceed to Q13)
- Yes (proceed to Q24)
24. Additional Lesion Description

24a. Lesion # M (e.g. MR1, MB1, ML1 etc.)
(Use # from previous exam if new use next sequential #. Describe any new or suspicious findings first.)

24b. Change in this lesion from prior mammogram?
   o New
   o Gone
   o Decreasing
   o Stable
   o Fluctuating bilateral circumscribed masses
   o Increasing
   o Other suspicious change
   o Increasing and other suspicious change
   o Not applicable, no prior

24c. mm X mm
(largest diameter) (largest perpendicular dimension)

24d. Location (check all that apply)
Note: for multiple bilateral findings with similar appearances, check "bilateral, multiple" and indicate specific location of the largest such finding.
   o Right
   o Left
   o Bilateral, multiple
   o Axillary tail
   o Retroareolar
   o Inner
   o Outer
   o Central
   o Upper
   o Lower

24e. Distance from the nipple cm

24f. Lesion type (check all that apply)
   □ Mass (select worst margin feature present)
     o Circumscribed (select one)
     □ Fat-containing
     □ Not fat-containing
     □ Microlobulated
     □ Obscured
     □ Indistinct
     □ Spiculated
     Associated features
       □ No
       □ Yes (check all that apply)
       □ Calcifications (detail below)
       □ Architectural distortion
       □ Skin thickening
       □ Dilated duct(s)
   □ Asymmetry (code type)
     o Focal (complete)
     Asymmetry seen on
       □ One view
       □ Both views
     □ Global
   □ Calculations (code morphology and distribution)
     Morphology of calculations (check all that apply)
       □ Coarse typically benign
       □ Milk of calcium
       □ Coarse heterogeneous
       □ Punctate (<0.5 mm, uniformly round)
       □ Amorphous/Indistinct
       □ Pleomorphic
       □ Branching/Fine linear
     Distribution of calculations (check all that apply)
       □ Clustered
       □ Multiple clusters (same morphology)
       □ Regional
       □ Linear
       □ Segmental
       □ Diffuse scattered
       □ In mass or asymmetry
       □ Architectural Distortion

24g. Is this lesion at the site of prior biopsy?
   o No
   o Yes (if yes, select procedure)
     □ Core/vacuum biopsy site with clip
     □ Core/vacuum biopsy site without clip
     □ Surgical biopsy site (select diagnosis)
       □ Benign
       □ Atypical/high-risk lesion
       □ Cancer site
       □ Unknown
       □ Biopsy details unknown
       □ FNAB
   o Not applicable, multiple bilateral circumscribed masses

25. Assessment/Recommendations for this lesion

25a. % Likelihood of malignancy for this lesion
(best guess from 0-100)

25b. Assessment for this lesion
   o 1 Negative
   o 2 Benign
   o 3 Probably Benign
   o 4A Low Suspicion of Malignancy
   o 4B Intermediate Suspicion
   o 4C Moderately High Suspicion
   o 5 Highly Suggestive of Malignancy

25c. Recommendation for this lesion
   o Routine screening in 1 year
   o Diagnostic follow-up in 1 year
   o Short-interval follow-up in 6 months with mammography
   o Intervention and/or Additional Imaging (detail intervention and/or additional imaging)
     □ Intervention (complete)
       □ Aspiration w/core biopsy if solid
       □ US-guided core biopsy
       □ Vacuum-assisted biopsy, guidance by US
       □ Vacuum-assisted biopsy, guidance by mammography
       □ Excisional biopsy
     □ Additional Imaging (check all that apply)
       □ Targeted Ultrasound (lesion seen on mammography)
       □ Comparison to prior mammograms is required
       □ Additional mammographic projections

25d. Is this lesion assessed as probably benign AND recommended for intervention?
   o No (proceed to Q26)
   o Yes (specify dominant reason)
     □ Participant preference
     □ Cancer present now
     □ In this breast
     □ In opposite breast
     □ Patient risk factors
     □ Vaguely palpable
     □ Follow-up not reasonable
     □ Interval increase (>20% in volume for masses)
     □ Interval suspicious change
     □ Investigator uncertainty

26. Are there additional lesions you wish to describe?
   o No (proceed to Q13)
   o Yes (proceed to Q27)
27. Additional Lesion Description

27a. Lesion # M (e.g. MR1, MB1, ML1 etc.)
(Use # from previous exam if new use next sequential #. Describe any new or suspicious findings first.)

27b. Change in this lesion from prior mammogram?
- New
- Gone
- Decreasing
- Stable
- Fluctuating bilateral circumscribed masses
- Increasing
- Other suspicious change
- Increasing and other suspicious change
- Not applicable, no prior

27c. ______ mm X ______ mm
(largest diameter) (largest perpendicular dimension)

27d. Location (check all that apply)
Note: for multiple bilateral findings with similar appearances, check "bilateral, multiple" and indicate specific location of the largest such finding.
- Right
- Left
- Bilateral, multiple
- Axillary tail
- Retroareolar

27e. Distance from the nipple ______ cm

27f. Lesion type (check all that apply)
- Mass (select worst margin feature present)
  - Circumscribed (select one)
    - Fat-containing
    - Not fat-containing
    - Microlobulated
    - Obscured
    - Indistinct
    - Spiculated
  - Associated features
    - No
    - Yes (check all that apply)
      - Calcifications (detail below)
      - Architectural distortion
      - Skin thickening
      - Dilated duct(s)
  - Asymmetry (code type)
    - Focal (complete)
      - Asymmetry seen on
        - One view
        - Both views
      - Global
  - Califications (code morphology and distribution)
    - Morphology of califications (check all that apply)
      - Coarse typically benign
      - Milk of calcium
      - Coarse heterogenous
      - Punctate (<0.5 mm, uniformly round)
      - Amorphous/Indistinct
      - Pleomorphic
      - Branching/Fine linear
    - Distribution of califications (check all that apply)
      - Clustered
      - Multiple clusters (same morphology)
      - Regional
      - Linear
      - Segmental
      - Diffuse scattered
      - In mass or asymmetry
      - Architectural Distortion

28. Assessment/Recommendations for this lesion

28a. ______ % Likelihood of malignancy for this lesion
(best guess from 0-100)

28b. Assessment for this lesion
- 1 Negative
- 2 Benign
- 3 Probably Benign
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion
- 5 Highly Suggestive of Malignancy

28c. Recommendation for this lesion
- Routine screening in 1 year
- Diagnostic follow-up in 1 year
- Short-interval follow-up in 6 months with mammography
- Intervention and/or Additional Imaging
  (detail intervention and/or additional imaging)
  - Intervention (complete)
    - Aspiration w/core biopsy if solid
    - US-guided core biopsy
    - Vacuum-assisted biopsy, guidance by US
    - Vacuum-assisted biopsy, guidance by mammography
    - Excisional biopsy
  - Additional Imaging (check all that apply)
    - Targeted Ultrasound (lesion seen on mammography)
    - Comparison to prior mammograms is required
    - Additional mammographic projections

28d. Is this lesion assessed as probably benign AND recommended for intervention?
- No (proceed to Q29)
- Yes (specify dominant reason)
  - Participant preference
  - Cancer present now
  - In this breast
  - In opposite breast
  - Patient risk factors
  - Vaguely palpable
  - Follow-up not reasonable
  - Interval increase (>20% in volume for masses)
  - Interval suspicious change
  - Investigator uncertainty

29. Are there additional lesions you wish to describe?
- No (proceed to Q13)
- Yes (proceed to Q30)
30. Additional Lesion Description

30a. Lesion # M (e.g. MR1, MB1, ML1 etc.)
   (Use # from previous exam if new use next sequential #.
   Describe any new or suspicious findings first.)

30b. Change in this lesion from prior mammogram?
   o New
   o Gone
   o Decreasing
   o Stable
   o Fluctuating bilateral circumscribed masses
   o Increasing
   o Other suspicious change
   o Increasing and other suspicious change
   o Not applicable, no prior

30c. ______ mm X ______ mm
   (largest diameter) (largest perpendicular dimension)

30d. Location (check all that apply)
   Note: for multiple bilateral findings with similar
   appearances, check "bilateral, multiple" and indicate
   specific location of the largest such finding.
   o Right
   o Left
   o Bilateral, multiple
   o Axillary tail
   o Retroareolar
   o Upper
   o Lower
   o Inner
   o Outer
   o Central

30e. Distance from the nipple ______ cm

30f. Lesion type (check all that apply)
   □ Mass (select worst margin feature present)
      o Circumscribed (select one)
         o Fat-containing
         o Not fat-containing
         o Microlobulated
         o Obscured
         o Indistinct
         o Spiculated
      o Associated features
         o No
         o Yes (check all that apply)
            □ Calcifications (detail below)
            □ Architectural distortion
            □ Skin thickening
            □ Dilated duct(s)
   □ Asymmetry (code type)
      o Focal (complete)
         o Asymmetry seen on
            o One view
            o Both views
            o Global
   □ Calcifications (code morphology and distribution)
      Morphology of calcifications (check all that apply)
         □ Coarse typically benign
         □ Milk of calcium
         □ Coarse heterogenous
         □ Punctate (<0.5 mm, uniformly round)
         □ Amorphous/Indistinct
         □ Pleomorphic
         □ Branching/Fine linear
      Distribution of calcifications (check all that apply)
         □ Clustered
         □ Multiple clusters (same morphology)
         □ Regional
         □ Linear
         □ Segmental
         □ Diffuse scattered
         □ In mass or asymmetry
         □ Architectural Distortion

30g. Is this lesion at the site of prior biopsy?
   o No
   o Yes (if yes, select procedure)
      o Core/vacuum biopsy site with clip
      o Core/vacuum biopsy site without clip
      o Surgical biopsy site (select diagnosis)
         o Benign
         o Atypical/high-risk lesion
         o Cancer site
         o Unknown
         o Biopsy details unknown
         o FNAB
         o Not applicable, multiple bilateral circumscribed masses

31. Assessment/Recommendations for this lesion

31a. ______ % Likelihood of malignancy for this lesion
   (best guess from 0-100)

31b. Assessment for this lesion
   o 1 Negative
   o 2 Benign
   o 3 Probably Benign
   o 4A Low Suspicion of Malignancy
   o 4B Intermediate Suspicion
   o 4C Moderately High Suspicion
   o 5 Highly Suggestive of Malignancy

31c. Recommendation for this lesion
   o Routine screening in 1 year
   o Diagnostic follow-up in 1 year
   o Short-interval follow-up in 6 months with mammography
   o Intervention and/or Additional Imaging
      (detail intervention and/or additional imaging)
      □ Intervention (complete)
         o Aspiration w/core biopsy if solid
         o US-guided core biopsy
         o Vacuum-assisted biopsy, guidance by US
         o Vacuum-assisted biopsy, guidance by mammography
         o Excisional biopsy
      □ Additional Imaging (check all that apply)
         □ Targeted Ultrasound (lesion seen on mammography)
         □ Comparison to prior mammograms is required
         □ Additional mammographic projections

31d. Is this lesion assessed as probably benign AND
     recommended for intervention?
     o No (proceed to Q32)
     o Yes (specify dominant reason)
        o Participant preference
        o Cancer present now
        o In this breast
        o In opposite breast
        o Patient risk factors
        o Vaguely palpable
        o Follow-up not reasonable
        o Interval increase (>20% in volume for masses)
        o Interval suspicious change
        o Investigator uncertainty

32. Are there additional lesions you wish to describe?
   o No (proceed to Q13)
   o Yes (proceed to Q33)
33. Additional Lesion Description

33a. Lesion #\( M \) (e.g. MR1, MB1, ML1 etc.)
(Use # from previous exam if new use next sequential #.
Describe any new or suspicious findings first.)

33b. Change in this lesion from prior mammogram?
- New
- Decreasing
- Stable
- Increasing
- Other suspicious change
- Increasing and other suspicious change
- Not applicable, no prior

33c. \( \underline{\text{__cm}} \) mm X \( \underline{\text{__cm}} \) mm
(largest diameter) (largest perpendicular dimension)

33d. Location (check all that apply)
Note: for multiple bilateral findings with similar appearances, check "bilateral, multiple" and indicate specific location of the largest such finding.
- Right
- Left
- Bilateral, multiple
- Axillary tail
- Retroareolar
- Central

33e. Distance from the nipple \( \underline{\text{__cm}} \) cm

33f. Lesion type (check all that apply)
- Mass (select worst margin feature present)
  - Circumscribed (select one)
  - Fat-containing
  - Not fat-containing
  - Microlobulated
  - Obscured
  - Indistinct
  - Spiculated
  - Associated features
    - No
    - Yes (check all that apply)
      - Calcifications (detail below)
      - Architectural distortion
      - Skin thickening
      - Dilated duct(s)
- Asymmetry (code type)
  - Focal (complete)
  - Asymmetry seen on
    - One view
    - Both views
  - Global
- Calcifications (code morphology and distribution)
  - Morphology of calcifications (check all that apply)
    - Coarse typically benign
    - Milk of calcium
    - Coarse heterogenous
    - Punctate (<0.5 mm, uniformly round)
    - Amorphous/Indistinct
    - Pleomorphic
    - Branching/Fine linear
  - Distribution of calcifications (check all that apply)
    - Clustered
    - Multiple clusters (same morphology)
    - Regional
    - Linear
    - Segmental
    - Diffuse scattered
    - In mass or asymmetry
    - Architectural Distortion

33g. Is this lesion at the site of prior biopsy?
- No
- Yes (if yes, select procedure)
  - Core/vacuum biopsy site with clip
  - Core/vacuum biopsy site without clip
  - Surgical biopsy site (select diagnosis)
    - Benign
    - Atypical/high-risk lesion
    - Cancer site
    - Unknown
    - Biopsy details unknown
    - FNAB
  - Not applicable, multiple bilateral circumscribed masses

34. Assessment/Recommendations for this lesion

34a. % Likelihood of malignancy for this lesion
(best guess from 0-100)

34b. Assessment for this lesion
- 1 Negative
- 2 Benign
- 3 Probably Benign
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion
- 5 Highly Suggestive of Malignancy

34c. Recommendation for this lesion
- Routine screening in 1 year
- Diagnostic follow-up in 1 year
- Short-interval follow-up in 6 months with mammography
- Intervention and/or Additional Imaging
  (detail intervention and/or additional imaging)
  - Intervention (complete)
    - Aspiration w/core biopsy if solid
    - US-guided core biopsy
    - Vacuum-assisted biopsy, guidance by US
    - Vacuum-assisted biopsy, guidance by mammography
    - Excisional biopsy
  - Additional Imaging (check all that apply)
    - Targeted Ultrasound (lesion seen on mammography)
    - Comparison to prior mammograms is required
    - Additional mammographic projections

34d. Is this lesion assessed as probably benign AND recommended for intervention?
- No (proceed to Final Assessment(s) Q13, Q14 etc.)
- Yes (specify dominant reason)
  - Participant preference
  - Cancer present now
  - In this breast
  - In opposite breast
  - Patient risk factors
  - Vaguely palpable
  - Follow-up not reasonable
  - Interval increase (>20% in volume for masses)
  - Interval suspicious change
  - Investigator uncertainty

Proceed to Final Assessment(s), Q13, Q14
**ACRIN Study 6666**

**PLACE LABEL HERE**

**Institution** ___________  **Institution No.** ___________

**Participant Initials** ___________  **Case No.** ___________

---

**Instructions:** To be completed by the Radiologist who performs and interprets the survey breast ultrasound. Radiologist must not have seen or interpreted the participant’s current routine mammogram, report, or IA form. Please note that comparison to prior breast ultrasound examinations is encouraged; however, neither prior nor current mammograms should be reviewed at the time of annual survey ultrasound performance or interpretation. For targeted US, stop do not use this form; use IM form. For diffuse scattered calcifications with no discrete group use code "100mm X 100mm X 10mm" (largest horizontal measurement X vertical A-P measurement X horizontal perpendicular measurement) and code "20 cm" for distance from the nipple.

**Part A. All Screenings (pages 1-3)**

**I. Ultrasound Equipment**

1. **Manufacturer**
   (check manufacturer and provide model in space provided)
   - [ ] Philips/ATL Model ________________________________
   - [ ] Siemens/Acuson Model ________________________________
   - [ ] GE Model ________________________________
   - [ ] Toshiba ________________________________
   - [ ] Other, specify ________________________________

2. **Transducers utilized**
   - **2a. Center Frequency** _______ _______ MHz and Range:
     _______ _______ (high end) MHz to _______ _______ (low end) MHz linear array
   - **2b. Transducer Width** (at least 38mm)
     - [ ] 38 mm
     - [ ] 50 mm
     - [ ] Other, specify: _______ mm
   - **2c. Was a second transducer used?**
     - [ ] No (proceed to Q3)
     - [ ] Yes (proceed to Q2d and Q2e)
   - **2d. Center frequency** _______ _______ MHz and range
     _______ _______ (high end) MHz to _______ _______ (low end) MHz
   - **2e. Transducer width of second transducer**
     - [ ] 38 mm
     - [ ] 50 mm
     - [ ] Other, specify: _______ mm

3. **Reader ID #** _______ _______ _______ _______ _______
   - **3a. Radiologist performing exam**
     _______ _______ (Last, First)

4. **Time point in study**
   - [ ] Initial screening
   - [ ] 12 month screening
   - [ ] 24 month screening

---

**4a. Was the scheduled exam performed?**
   - [ ] No (complete and stop, sign form)
   - [ ] Yes

**5. Date of scan _______ _______ _______ _______ mm-dd-yyyy**

**5a. Date of Interpretation _______ _______ _______ mm-dd-yyyy**

**Note:** Time recorded in Q6 is the (hr:min) format, e.g. 01:45.

6. **6. _______ : _______ Time Radiologist entered room.**
   - **7. _______ : _______ Time scan initiated**
   - **8. _______ : _______ Time scan completed**
   - **9. _______ : _______ Time Radiologist exited room**

7. **Survey scanning was performed** (check all that apply)
   - [ ] Conventional mode
   - [ ] With spatial compounding
   - [ ] With tissue harmonic imaging

8. **Which breast(s) evaluated?**
   - [ ] Bilateral
   - [ ] Right breast only
   - [ ] Left breast only
   - **8a. Did you scan the axilla?**
     - [ ] No
     - [ ] Yes (if yes, code side scanned)
       - [ ] Bilateral
       - [ ] Right axilla only
       - [ ] Left axilla only

9. **Comparison is made to prior US?**
   - [ ] None (never had US)
   - [ ] Not available
   - [ ] Yes (check all that apply)
     - [ ] Targeted Right
     - [ ] Targeted Left
     - [ ] Whole breast Right
       - **Date of prior study:** _______ _______ _______ _______ (if different from right)
     - [ ] Whole breast Left
       - **Date of prior study:** _______ _______ _______ _______ (if different from right)

---

"Copyright 2005"
10. Greatest depth (thickness) of Breast by ultrasound

<table>
<thead>
<tr>
<th>Right</th>
<th>Left</th>
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<tbody>
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<td>&lt; 2 cm</td>
<td>&lt; 2 cm</td>
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<tr>
<td>2.0-2.9 cm</td>
<td>2.0-2.9 cm</td>
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<td>3.0-3.9 cm</td>
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<td>4.0-4.9 cm</td>
<td>4.0-4.9 cm</td>
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<td>5.0-5.9 cm</td>
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<tr>
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<tr>
<td>&gt;7 cm</td>
<td>&gt;7 cm</td>
</tr>
<tr>
<td>not applicable</td>
<td>not applicable</td>
</tr>
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</table>

11. Background Echotexture

- Homogeneous
- Diffusely Heterogeneous
- Focally Heterogeneous (If focally heterogenous, code all applicable quadrants)

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<tr>
<td>LOQ</td>
<td>LOQ</td>
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<tr>
<td>LIQ</td>
<td>LIQ</td>
</tr>
</tbody>
</table>

12. Were any simple cysts identified?
- No (proceed to Q12c)
- Yes (If yes, proceed to Q12a)

12a. Detail Largest Cyst

12b. Detail Largest Cyst

12c. Are any previously enumerated lesions from any prior sonograms now gone?
- No (proceed to Q13)
- Yes (If yes, detail below)

   Number of previously enumerated lesions now gone since last annual screening.

   Note: Do not reuse Lesion # once it has been reported as gone.

13. Were any discrete lesions other than simple cysts identified?
- No (proceed to Q14)
- Yes (complete and proceed to Q20)
  - Bilateral
  - Right breast only
  - Left breast only
14. **Final Assessment of Right Breast**
   14a. □ Not on study (proceed to Q17)

   14b. ___ ___ % Likelihood of malignancy for the right breast (best guess from 0-100)

15. **Final assessment for the entire right breast**
   - 1 Negative
   - 2 Benign
   - 3 Probably Benign
   - 4A Low Suspicion of Malignancy
   - 4B Intermediate Suspicion
   - 4C Moderately High Suspicion
   - 5 Highly Suggestive of Malignancy

16. **Recommendation for right breast**
   - Routine screening in one year
   - Diagnostic follow-up in one year
   - Short-interval follow-up in 6 months with US
   - Intervention and/or Additional Imaging
     - Intervention
       - Aspiration w/core biopsy if solid
       - US-guided core biopsy
       - Vacuum-assisted biopsy, guidance by US
       - Vacuum-assisted biopsy, guidance by Mammo
       - Excisional biopsy
   - Additional Imaging (check all that apply)
     - Comparison to current mammograms is required (lesion seen on US)
     - Comparison to prior mammograms is required
     - Additional mammographic projections

17. **Final Assessment of Left Breast**
   17a. □ Not on study (sign and date form)

   17b. ___ ___ % Likelihood of malignancy for the left breast (best guess from 0-100)

18. **Final assessment for the entire left breast**
   - 1 Negative
   - 2 Benign
   - 3 Probably Benign
   - 4A Low Suspicion of Malignancy
   - 4B Intermediate Suspicion
   - 4C Moderately High Suspicion
   - 5 Highly Suggestive of Malignancy

19. **Recommendation for left breast**
   - Routine screening in one year
   - Diagnostic follow-up in one year
   - Short-interval follow-up in 6 months with US
   - Intervention and/or Additional Imaging
     - Intervention
       - Aspiration w/core biopsy if solid
       - US-guided core biopsy
       - Vacuum-assisted biopsy, guidance by US
       - Vacuum-assisted biopsy, guidance by Mammo
       - Excisional biopsy
     - Additional Imaging (check all that apply)
       - Comparison to current mammograms is required (lesion seen on US)
       - Comparison to prior mammograms is required
       - Additional mammographic projections

Stop, sign and date form.

Comments: ____________________________________________________________

--------------------------------------------------------------------------------

Signature of Radiologist responsible for the data 1

Date Form Completed (mm-dd-yyyy)

Signature of person entering data onto web 2
Part B. Positive Findings (pages 4-27) as needed

20. List lesions other than simple cysts (maximum of 4 per breast)

20a. Number of solid findings/lesions other than simple cysts: Right Breast [ ] Left Breast [ ]

(Note: If there are multiple bilateral similar-appearing circumscribed masses, code this as one bilateral lesion).

20b. Lesion # [U] (e.g. UR1, UB1, UL1 etc.)

(Retain lesion numbering from initial study survey sonogram. If this is the first examination, begin with R1 for the first lesion in the right breast, R2 for the second lesion in the right breast etc. If the finding is new since a prior study sonogram, use next sequential #. Describe any new or suspicious findings first. Location, distance from nipple, depth to lesion center and measurements are completed for all reportable findings).

Was this "lesion" seen on a previous sonogram including any sonograms performed prior to study enrollment?

- Not applicable, no prior breast sonograms
- No
- Yes
  - Gone
  - Decreased in size since previous exam
  - Stable in size since previous exam
  - Multiple bilateral circumscribed masses fluctuating in size since previous exam
  - Increased in size since previous exam
  - Other suspicious change
  - Increasing and other suspicious change

Is this "lesion" multiple bilateral circumscribed masses?

- No
- Yes

Breast

<table>
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<th>Clockface (report on the hour)</th>
<th>Distance from the nipple</th>
<th>Depth from skin to center of lesion (to nearest 0.5 cm)</th>
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<tbody>
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20c. Lesion Size

<table>
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<tr>
<th>Largest Horizontal Meas (mm) D1</th>
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<td>o Rad</td>
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<tr>
<td>o Arad</td>
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<tr>
<td>o Oblique</td>
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<table>
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<th>Second Measured Plane</th>
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<td>o Sag</td>
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<tr>
<td>o Rad</td>
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<tr>
<td>o Arad</td>
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<tr>
<td>o Perpendicular Oblique</td>
</tr>
</tbody>
</table>

20d. Is this lesion at the site of prior biopsy?

- No
- Yes (if yes, select prior procedure)
  - Core/vacuum biopsy with clip (if procedure performed, select diagnosis)
  - Core/vacuum biopsy without marker (if procedure performed, select diagnosis)
  - Surgical biopsy site (if procedure was performed, select diagnosis)
    - Benign
    - Atypical/high-risk lesion
    - Cancer site
    - Unknown
    - Biopsy details unknown
    - FNAB
  - Not applicable, multiple bilateral circumscribed masses

20e. Special Case (see choices below)

- No
- Yes (if yes, detail below then proceed to Q20n)

<table>
<thead>
<tr>
<th>Special Case Features</th>
</tr>
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<tbody>
<tr>
<td>o Complicated Cyst</td>
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</table>

(Special Case Features)

- Homogeneous low-level echoes
- Fluid-Debris Level
- Mobile internal echoes
- Multiple bilateral complicated cysts in company of simple cysts
- Multiple bilateral solid oval, circumscribed masses
- Mass in or on skin
- Clustered microcysts
- Intraductal mass
- Lymph node
- Calcifications without a mass
- Foreign body
- Post-Surgical scar
- Other, specify:  

Note: Volume is programmed to be calculated on line; however, as verification, please calculate volume based on horizontal, vertical and perpendicular measurements as a validation.
### 20f. Shape
- Oval
- Two or three gentle lobulations
- Round
- Irregular

### 20g. Orientation
- Parallel to skin
- Not parallel (includes round)

### 20h. Margin
- Circumscribed
- Not circumscribed (If not circumscribed, choose dominant feature)
  - Indistinct
  - Angular
  - Microlobulated
  - Spiculated

### 20i. Boundary Zone
- Abrupt Interface
- Echogenic Halo

### 20j. Echo Pattern
- Anechoic
- Hyperechoic
- Complex cystic
- Hypoechoic with few tiny cystic areas
- Isoechoic to fat
- Mixed hyperechoic and hypoechoic
- Hypoechoic to fat

### 20k. Posterior Features
- None
- Enhancement
- Combined shadowing/enhancement
- Shadowing

### 20l. Surrounding Tissue
- No effect
- Effect (check all that apply)
  - Duct changes
  - Edema
  - Cooper's ligament distortion
  - Architectural distortion
  - Skin thickening
  - Skin retraction

### 20m. Vascularity (flow)
- None
- Yes (check all that apply)
  - Present in lesion
  - Present immediately adjacent to lesion
  - Increased in surrounding tissue
- Not performed

### 20n. Calcifications
- None
- Present (check all that apply)
  - Macrolcalifications (> 0.5 mm)
  - Microcalcifications in mass
  - Microcalcifications outside mass

### 20o. Lesion palpable in retrospect during sonography?
- No
- Yes

### 21. % Likelihood of malignancy for this lesion (best guess from 0-100)

#### 21a. Assessment for this lesion
- 1 Negative
- 2 Benign (complete Q21b)
- 3 Probably Benign
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion
- 5 Highly Suggestive of Malignancy

#### 21b. Known benign by prior biopsy? (only complete if Q21a = Benign)
- No (proceed to Q22)
- Yes (complete)
  - < 1 year ago
  - 1-2 years ago
  - > 2 years ago

### 22. Recommendation for this lesion
- Routine screening in one year
- Diagnostic follow-up in one year
- Short-interval follow-up in 6 months with US
- Intervention and/or Additional Imaging
  - Intervention
    - Aspiration w/core biopsy if solid
    - US-guided core biopsy
    - Vacuum-assisted biopsy, guidance by US
    - Vacuum-assisted biopsy, guidance by Mammo
    - Excisional biopsy
  - Additional Imaging (check all that apply)
    - Comparison to current mammogram is required (lesion seen on US)
    - Comparison to prior mammograms is required
    - Additional mammographic projections

### 23. Is this lesion assessed as probably benign AND recommended for intervention?
- No (proceed to Q24)
- Yes (specify dominant reason)
  - Participant preference
  - Cancer present now
  - In this breast
  - In opposite breast
  - Patient risk factors
  - Vaguely palpable
  - Follow-up not reasonable
  - Increased (> 20% in volume for masses)
  - Interval suspicious change
  - Investigator uncertainty
24. **For lesion evaluation, techniques used** (check all that apply)
- Conventional imaging
- Spatial compounding
- Power Doppler
- Tissue Harmonic Imaging
- Panoramic display

24a. **If spatial compounding was used, what was its influence?** (please answer the following questions)
   - No influence (proceed to Q25)
   - Influenced (please answer the following questions in bold)
     - **Margin depiction**
       - Better
       - Same
       - Worse

     - **Internal structure depiction**
       - Better
       - Same
       - Worse

     - **Posterior feature depiction**
       - Better
       - Same
       - Worse

     - **Confidence in lesion characterization**
       - Better
       - Same
       - Worse

24b. **Change in likelihood of malignancy with spatial compounding?**
   - None
   - Looks more benign with spatial compounding
   - Looks more malignant with spatial compounding

25. **Are there additional lesions you wish to describe?**
   - No (proceed to Q14)
   - Yes (proceed to Q26)
26. Additional lesions other than simple cysts (maximum of 4 per breast)

26a. Lesion # [U] (e.g. UR1, UB1, UL1 etc.)
   (Retain lesion numbering from initial study survey sonogram. If this is the first examination, begin with R1 for the first lesion in the right breast, R2 for the second lesion in the right breast etc. If the finding is new since a prior study sonogram, use next sequential #. Describe any new or suspicious findings first. Location, distance from nipple, depth to lesion center and measurements are completed for all reportable findings).

26b. Was this "lesion" seen on a previous sonogram including any sonograms performed prior to study enrollment?
   - Not applicable, no prior breast sonograms
   - No
   - Yes
     - Decreased in size since previous exam
     - Stable in size since previous exam
     - Multiple bilateral circumscribed masses fluctuating in size since previous exam
     - Increased in size since previous exam
     - Other suspicious change
     - Increasing and other suspicious change

Is this "lesion" multiple bilateral circumscribed masses? If yes, describe location and measurement of largest mass.
   - No
   - Yes

<table>
<thead>
<tr>
<th>Breast</th>
<th>Clockface</th>
<th>Distance from</th>
<th>Depth from skin to</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(report on the hour)</td>
<td>the nipple</td>
<td>center of lesion</td>
</tr>
<tr>
<td></td>
<td>(report on hour and 1/2 hour)</td>
<td>(to nearest 0.5 cm)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>e.g. 7:00 = 0700, 12:30 = 1230</td>
<td>cm</td>
<td>cm</td>
</tr>
<tr>
<td>O R L</td>
<td>o'clock</td>
<td>cm</td>
<td>cm</td>
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</tbody>
</table>

26c. Lesion Size

<table>
<thead>
<tr>
<th>Largest</th>
<th>Measured Plane</th>
<th>Vertical A-P meas (mm) D2</th>
<th>Horizontal Perpendicular meas (mm) D3</th>
<th>Second Measured Plane</th>
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</thead>
<tbody>
<tr>
<td>Horizontal Meas (mm) D1</td>
<td>o Trv</td>
<td>o Sag</td>
<td>X</td>
<td>o Trv</td>
</tr>
<tr>
<td></td>
<td>o Rad</td>
<td>X</td>
<td>mm</td>
<td>o Sag</td>
</tr>
<tr>
<td></td>
<td>o Arad</td>
<td>mm</td>
<td>mm</td>
<td>o Arad</td>
</tr>
<tr>
<td></td>
<td>o Oblique</td>
<td>X</td>
<td>mm</td>
<td></td>
</tr>
</tbody>
</table>

26d. Is this lesion at the site of prior biopsy?
   - No
   - Yes (if yes, select prior procedure)
     - Core/vacuum biopsy with clip (if procedure performed, select diagnosis)
     - Core/vacuum biopsy without marker (if procedure performed, select diagnosis)
     - Surgical biopsy site (if procedure was performed, select diagnosis)
       - Benign
       - Atypical/high-risk lesion
       - Cancer site
       - Unknown
       - Biopsy details unknown
       - FNAB
     - Not applicable, multiple bilateral circumscribed masses

26e. Special Case (see choices below)
   - No
   - Yes (if yes, detail below then proceed to Q26n)
     (Special Case Features)
       - Complicated Cyst (Note: Do not use this term for "complex cystic masses". For complex cystic masses code "No" for Q26e, proceed to Q26f and indicate "complex cystic" at Q26j.)
         - Homogeneous low-level echoes
         - Fluid-Debris Level
         - Mobile internal echoes
         - Multiple bilateral complicated cysts in company of simple cysts
         - Multiple bilateral solid oval, circumscribed masses
         - Mass in or on skin
         - Clustered microcysts
         - Intraductal mass
         - Lymph node
         - Calcifications without a mass
         - Foreign body
         - Post-Surgical scar
         - Other, specify ________________________________

Note: Volume is programmed to be calculated on line; however, as verification, please calculate volume based on horizontal, vertical and perpendicular measurements as a validation.
26f. Shape
- Oval
- Two or three gentle lobulations
- Round
- Irregular

26g. Orientation
- Parallel to skin
- Not parallel (includes round)

26h. Margin
- Circumscribed
- Not circumscribed (If not circumscribed, choose dominant feature)
  - Indistinct
  - Angular
  - Microlobulated
  - Spiculated

26i. Boundary Zone
- Abrupt Interface
- Echogenic Halo

26j. Echo Pattern
- Anechoic
- Hyperechoic
- Complex cystic
- Hypoechoic with few tiny cystic areas
- Isoechoic to fat
- Mixed hyperechoic and hypoechoic
- Hypoechoic to fat

26k. Posterior Features
- None
- Enhancement
- Combined shadowing/enhancement
- Shadowing

26l. Surrounding Tissue
- No effect
- Effect (check all that apply)
  - Duct changes
  - Edema
  - Cooper’s ligament distortion
  - Architectural distortion
  - Skin thickening
  - Skin retraction

26m. Vascularity (flow)
- None
- Yes (check all that apply)
  - Present in lesion
  - Present immediately adjacent to lesion
  - Increased in surrounding tissue
- Not performed

26n. Calcifications
- None
- Present (check all that apply)
  - Macrocalcifications (> 0.5 mm)
  - Microcalcifications in mass
  - Microcalcifications outside mass

26o. Lesion palpable in retrospect during sonography?
- No
- Yes

27. % Likelihood of malignancy for this lesion (best guess from 0-100)

27a. Assessment for this lesion
- 1 Negative
- 2 Benign (complete Q27b)
- 3 Probably Benign
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion
- 5 Highly Suggestive of Malignancy

27b. Known benign by prior biopsy?
- No (proceed to Q28)
- Yes (complete)
  - < 1 year ago
  - 1-2 years ago
  - > 2 years ago

28. Recommendation for this lesion
- Routine screening in one year
- Diagnostic follow-up in one year
- Short-interval follow-up in 6 months with US
- Intervention and/or Additional Imaging
  (detail intervention and/or additional imaging)
  - Intervention
    - Aspiration w/core biopsy if solid
    - US-guided core biopsy
    - Vacuum-assisted biopsy, guidance by US
    - Vacuum-assisted biopsy, guidance by Mammo
    - Excisional biopsy
  - Additional Imaging (check all that apply)
    - Comparison to current mammogram is required
      (lesion seen on US)
    - Comparison to prior mammograms is required
    - Additional mammographic projections

29. Is this lesion assessed as probably benign AND recommended for intervention?
- No (proceed to Q30)
- Yes (specify dominant reason)
  - Participant preference
  - Cancer present now
  - In this breast
  - In opposite breast
  - Patient risk factors
  - Vaguely palpable
  - Follow-up not reasonable
  - Increased (> 20% in volume for masses)
  - Interval suspicious change
  - Investigator uncertainty
30. For lesion evaluation, techniques used (check all that apply)
- Conventional imaging
- Spatial compounding
- Power Doppler
- Tissue Harmonic Imaging
- Panoramic display

30a. If spatial compounding was used, what was its influence? (please answer the following questions)
- No influence (proceed to Q31)
- Influenced (please answer the following questions in bold)
  - Margin depiction
    - Better
    - Same
    - Worse
  - Internal structure depiction
    - Better
    - Same
    - Worse
  - Posterior feature depiction
    - Better
    - Same
    - Worse
  - Confidence in lesion characterization
    - Better
    - Same
    - Worse

30b. Change in likelihood of malignancy with spatial compounding?
- None
- Looks more benign with spatial compounding
- Looks more malignant with spatial compounding

31. Are there additional lesions you wish to describe?
- No (proceed to Q14)
- Yes (proceed to Q32)
32. Additional lesions other than simple cysts (maximum of 4 per breast)

32a. Lesion # (e.g. UR1, UB1, UL1 etc.)
(Retain lesion numbering from initial study survey sonogram. If this is the first examination, begin with R1 for the first lesion in the right breast, R2 for the second lesion in the right breast etc. If the finding is new since a prior study sonogram, use next sequential #. Describe any new or suspicious findings first. Location, distance from nipple, depth to lesion center and measurements are completed for all reportable findings).

32b. Was this "lesion" seen on a previous sonogram including any sonograms performed prior to study enrollment?
   o Not applicable, no prior breast sonograms
   o No
   o Yes
     o Gone
     o Decreased in size since previous exam
     o Stable in size since previous exam
     o Multiple bilateral circumscribed masses fluctuating in size since previous exam
     o Increased in size since previous exam
     o Other suspicious change
     o Increasing and other suspicious change

Is this "lesion" multiple bilateral circumscribed masses? If yes, describe location and measurement of largest mass.
   o No
   o Yes

Breast

Clockface
(report on the hour)
(e.g. 7:00 = 0700, 12:30 = 1230)

Distance from
the nipple
(to nearest 0.5 cm)

Depth from skin to
center of lesion

R   L

32c. Lesion Size

Largest
Horizontal
Meas (mm) D1

Measured Plane

Trv
Sag
Rad
Arad
Oblique

Vertical
A-P meas (mm) D2

Horiziontal
Perpendicular Meas (mm) D3

X

X

Second
Measured Plane

Trv
Sag
Rad
Arad
Perpendicular Oblique

Volume D1XD2XD3 ÷ 2

mm³

Note: Volume is programmed to be calculated on line; however, as verification, please calculate volume based on horizontal, vertical and perpendicular measurements as a validation.

32d. Is this lesion at the site of prior biopsy?
   o No
   o Yes (if yes, select prior procedure)
     o Core/vacuum biopsy with clip (if procedure performed, select diagnosis)
     o Core/vacuum biopsy without marker (if procedure performed, select diagnosis)
     o Surgical biopsy site (if procedure was performed, select diagnosis)
       o Benign
       o Atypical/high-risk lesion
       o Cancer site
       o Unknown
       o Biopsy details unknown
       o FNAB
     o Not applicable, multiple bilateral circumscribed masses

32e. Special Case (see choices below)
   o No
   o Yes (if yes, detail below then proceed to Q32n)

(Special Case Features)

Complicated Cyst (Note: Do not use this term for "complex cystic masses".
For complex cystic masses code "No" for Q32e, proceed to Q32f and indicate "complex cystic" at Q32j.)
- Homogeneous low-level echoes
- Fluid-Debris Level
- Mobile internal echoes
- Multiple bilateral complicated cysts in company of simple cysts
- Multiple bilateral solid oval, circumscribed masses
- Mass in or on skin
- Clustered microcysts
- Intraductal mass
- Lymph node
- Calcifications without a mass
- Foreign body
- Post-Surgical scar
- Other, specify: ___________________________________
32f. Shape
- Oval
- Two or three gentle lobulations
- Round
- Irregular

32g. Orientation
- Parallel to skin
- Not parallel (includes round)

32h. Margin
- Circumscribed
- Not circumscribed (If not circumscribed, choose dominant feature)
  - Indistinct
  - Angular
  - Microlobulated
  - Spiculated

32i. Boundary Zone
- Abrupt Interface
- Echogenic Halo

32j. Echo Pattern
- Anechoic
- Hyperechoic
- Complex cystic
- Hypoechoic with few tiny cystic areas
- Isoechoic to fat
- Mixed hyperechoic and hypoechoic
- Hypoechoic to fat

32k. Posterior Features
- None
- Enhancement
- Combined shadowing/enhancement
- Shadowing

32l. Surrounding Tissue
- No effect
- Effect (check all that apply)
  - Duct changes
  - Edema
  - Cooper’s ligament distortion
  - Architectural distortion
  - Skin thickening
  - Skin retraction

32m. Vascularity (flow)
- None
- Yes (check all that apply)
  - Present in lesion
  - Present immediately adjacent to lesion
  - Increased in surrounding tissue
- Not performed

32n. Calcifications
- None
- Present (check all that apply)
  - Macroc当地ifications (> 0.5 mm)
  - Microcalcifications in mass
  - Microcalcifications outside mass

32o. Lesion palpable in retrospect during sonography?
- No
- Yes

33. % Likelihood of malignancy for this lesion
   (best guess from 0-100)

33a. Assessment for this lesion
   - Negative
   - Benign (complete Q33b)
   - Probably Benign
   - Low Suspicion of Malignancy
   - Intermediate Suspicion
   - Moderately High Suspicion
   - Highly Suggestive of Malignancy

33b. Known benign by prior biopsy?
   (only complete if Q33a = Benign)
   - No (proceed to Q34)
   - Yes (complete)
     - < 1 year ago
     - 1-2 years ago
     - > 2 years ago

34. Recommendation for this lesion
   - Routine screening in one year
   - Diagnostic follow-up in one year
   - Short-interval follow-up in 6 months with US
   - Intervention and/or Additional Imaging
     (detail intervention and/or additional imaging)
   - Aspiration w/core biopsy if solid
   - US-guided core biopsy
   - Vacuum-assisted biopsy, guidance by US
   - Vacuum-assisted biopsy, guidance by Mammo
   - Excisional biopsy

35. Is this lesion assessed as probably benign AND recommended for intervention?
   - No (proceed to Q36)
   - Yes (specify dominant reason)
     - Participant preference
     - Cancer present now
       - In this breast
       - In opposite breast
     - Patient risk factors
     - Vaguely palpable
     - Follow-up not reasonable
     - Increased (> 20% in volume for masses)
     - Interval suspicious change
     - Investigator uncertainty
36. **For lesion evaluation, techniques used** (check all that apply)
   - Conventional imaging
   - Spatial compounding
   - Power Doppler
   - Tissue Harmonic Imaging
   - Panoramic display

36a. If **spatial compounding** was used, what was its influence? (please answer the following questions)
   - No influence (proceed to Q37)
   - Influenced (please answer the following questions in bold)
     - **Margin depiction**
       - Better
       - Same
       - Worse
     - **Internal structure depiction**
       - Better
       - Same
       - Worse
     - **Posterior feature depiction**
       - Better
       - Same
       - Worse
     - **Confidence in lesion characterization**
       - Better
       - Same
       - Worse

36b. Change in likelihood of malignancy with spatial compounding?
   - None
   - Looks more benign with spatial compounding
   - Looks more malignant with spatial compounding

37. **Are there additional lesions you wish to describe?**
   - No (proceed to Q14)
   - Yes (proceed to Q38)
38. Additional lesions other than simple cysts (maximum of 4 per breast)

38a. Lesion # \( \text{U} \) (e.g. UR1, UB1, UL1 etc.)

(Retain lesion numbering from initial study survey sonogram. If this is the first examination, begin with R1 for the first lesion in the right breast, R2 for the second lesion in the right breast etc. If the finding is new since a prior study sonogram, use next sequential #. Describe any new or suspicious findings first. Location, distance from nipple, depth to lesion center and measurements are completed for all reportable findings).

38b. Was this "lesion" seen on a previous sonogram including any sonograms performed prior to study enrollment?

- Not applicable, no prior breast sonograms
- No
- Yes
  - Decreased in size since previous exam
  - Stable in size since previous exam
  - Multiple bilateral circumscribed masses fluctuating in size since previous exam
  - Increased in size since previous exam
  - Other suspicious change
  - Increasing and other suspicious change

Is this "lesion" multiple bilateral circumscribed masses? If yes, describe location and measurement of largest mass.

- No
- Yes

**Breast**

<table>
<thead>
<tr>
<th>Clockface (report on the hour)</th>
<th>Distance from the nipple (report on hour and 1/2 hour e.g. 7:00 = 0700, 12:30 = 1230)</th>
</tr>
</thead>
<tbody>
<tr>
<td>O R O L</td>
<td>cm</td>
</tr>
</tbody>
</table>

38c. Lesion Size

<table>
<thead>
<tr>
<th>Largest Horizontal Meas (mm)</th>
<th>Measured Plane</th>
<th>Vertical A-P meas (mm)</th>
<th>Horizontal Perpendicular Meas (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>D1</td>
<td>o Trv</td>
<td>o Sag</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>o Rad</td>
<td>o Arad</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Oblique</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

38d. Is this lesion at the site of prior biopsy?

- No
- Yes (if yes, select prior procedure)
  - Core/vacuum biopsy with clip (if procedure performed, select diagnosis)
  - Core/vacuum biopsy without marker (if procedure performed, select diagnosis)
  - Surgical biopsy site (if procedure was performed, select diagnosis)
    - Benign
    - Atypical/high-risk lesion
    - Cancer site
    - Unknown
    - Biopsy details unknown
    - FNAB
  - Not applicable, multiple bilateral circumscribed masses

38e. Special Case (see choices below)

- No
- Yes (if yes, detail below then proceed to Q38n)

**Special Case Features**

- Complicated Cyst (Note: Do not use this term for "complex cystic masses".
  - For complex cystic masses code "No" for Q38e, proceed to Q38f and indicate "complex cystic" at Q38j.)
  - Homogeneous low-level echoes
  - Fluid-Debris Level
  - Mobile internal echoes
  - Multiple bilateral complicated cysts in company of simple cysts
    - Multiple bilateral solid oval, circumscribed masses
    - Mass in or on skin
    - Clustered microcysts
    - Intraductal mass
    - Lymph node
    - Calcifications without a mass
    - Foreign body
    - Post-Surgical scar
    - Other, specify: ____________________________

Note: Volume is programmed to be calculated on line; however, as verification, please calculate volume based on horizontal, vertical and perpendicular measurements as a validation.
38f. Shape
- Oval
- Two or three gentle lobulations
- Round
- Irregular

38g. Orientation
- Parallel to skin
- Not parallel (includes round)

38h. Margin
- Circumscribed
- Not circumscribed (If not circumscribed, choose dominant feature)
  - Indistinct
  - Angular
  - Microlobulated
  - Spiculated

38i. Boundary Zone
- Abrupt Interface
- Echogenic Halo

38j. Echo Pattern
- Anechoic
- Hyperechoic
- Complex cystic
- Hypoechoic with few tiny cystic areas
- Isoechoic to fat
- Mixed hyperechoic and hypoechoic
- Hypoechoic to fat

38k. Posterior Features
- None
- Enhancement
- Combined shadowing/enhancement
- Shadowing

38l. Surrounding Tissue
- No effect
- Effect (check all that apply)
  - Duct changes
  - Edema
  - Cooper’s ligament distortion
  - Architectural distortion
  - Skin thickening
  - Skin retraction

38m. Vascularity (flow)
- None
- Yes (check all that apply)
  - Present in lesion
  - Present immediately adjacent to lesion
  - Increased in surrounding tissue
  - Not performed

38n. Calcifications
- None
- Present (check all that apply)
  - Macrocalcifications (> 0.5 mm)
  - Microcalcifications in mass
  - Microcalcifications outside mass

38o. Lesion palpable in retrospect during sonography?
- No
- Yes

39. _____________% Likelihood of malignancy for this lesion (best guess from 0-100)

39a. Assessment for this lesion
- 1 Negative
- 2 Benign (complete Q39b)
- 3 Probably Benign
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion
- 5 Highly Suggestive of Malignancy

39b. Known benign by prior biopsy?
- No (proceed to Q40)
- Yes (complete)
  - < 1 year ago
  - 1-2 years ago
  - > 2 years ago

40. Recommendation for this lesion
- Routine screening in one year
- Diagnostic follow-up in one year
- Short-interval follow-up in 6 months with US
- Intervention and/or Additional Imaging (detail intervention and/or additional imaging)
  - Intervention
    - Aspiration w/core biopsy if solid
    - US-guided core biopsy
    - Vacuum-assisted biopsy, guidance by US
    - Vacuum-assisted biopsy, guidance by Mammo
    - Excisional biopsy
  - Additional Imaging (check all that apply)
    - Comparison to current mammogram is required
    - Comparison to prior mammograms is required
    - Additional mammographic projections

41. Is this lesion assessed as probably benign AND recommended for intervention?
- No (proceed to Q42)
- Yes (specify dominant reason)
  - Participant preference
  - Cancer present now
    - In this breast
    - In opposite breast
  - Patient risk factors
  - Vaguely palpable
  - Follow-up not reasonable
  - Increased (> 20% in volume for masses)
  - Interval suspicious change
  - Investigator uncertainty
42. **For lesion evaluation, techniques used** (check all that apply)
- Conventional imaging
- Spatial compounding
- Power Doppler
- Tissue Harmonic Imaging
- Panoramic display

42a. **If spatial compounding was used, what was its influence?** (please answer the following questions)
- No influence (proceed to Q43)
- Influenced (please answer the following questions in bold)
  - Margin depiction
    - Better
    - Same
    - Worse
  - Internal structure depiction
    - Better
    - Same
    - Worse
  - Posterior feature depiction
    - Better
    - Same
    - Worse
  - Confidence in lesion characterization
    - Better
    - Same
    - Worse

42b. **Change in likelihood of malignancy with spatial compounding?**
- None
- Looks more benign with spatial compounding
- Looks more malignant with spatial compounding

43. **Are there additional lesions you wish to describe?**
- No (proceed to Q14)
- Yes (proceed to Q44)
44. Additional lesions other than simple cysts (maximum of 4 per breast)

44a. Lesion # U (e.g. UR1, UB1, UL1 etc.)

(Retain lesion numbering from initial study survey sonogram. If this is the first examination, begin with R1 for the first lesion in the right breast, R2 for the second lesion in the right breast etc. If the finding is new since a prior study sonogram, use next sequential #. Describe any new or suspicious findings first. Location, distance from nipple, depth to lesion center and measurements are completed for all reportable findings).

44b. Was this "lesion" seen on a previous sonogram including any sonograms performed prior to study enrollment?
   - No
   - Yes

44c. Lesion Size

<table>
<thead>
<tr>
<th>Breast</th>
<th>Clockface (report on the hour)</th>
<th>Distance from the nipple (to nearest 0.5 cm)</th>
<th>Depth from skin to center of lesion</th>
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</tbody>
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44d. Is this lesion at the site of prior biopsy?
   - No
   - Yes (if yes, select prior procedure)

44e. Special Case (see choices below)
   - No
   - Yes (if yes, detail below then proceed to Q44n)

(Special Case Features)
   - Complicated Cyst (Note: Do not use this term for "complex cystic masses".
     For complex cystic masses code "No" for Q44e, proceed to Q44f and indicate "complex cystic" at Q44j.)
     - Homogeneous low-level echoes
     - Fluid-Debris Level
     - Mobile internal echoes
     - Multiple bilateral complicated cysts in company of simple cysts
     - Multiple bilateral solid oval, circumscribed masses
     - Mass in or on skin
     - Clustered microcysts
     - Intraductal mass
     - Lymph node
     - Calcifications without a mass
     - Foreign body
     - Post-Surgical scar
     - Other, specify: ______________________________
44f. Shape
- Oval
- Two or three gentle lobulations
- Round
- Irregular

44g. Orientation
- Parallel to skin
- Not parallel (includes round)

44h. Margin
- Circumscribed
- Not circumscribed (If not circumscribed, choose dominant feature)
  - Indistinct
  - Angular
  - Microlobulated
  - Spiculated

44i. Boundary Zone
- Abrupt Interface
- Echogenic Halo

44j. Echo Pattern
- Anechoic
- Hyperechoic
- Complex cystic
- Hypoechoic with few tiny cystic areas
- Isoechoic to fat
- Mixed hyperechoic and hypoechoic
- Hypoechoic to fat

44k. Posterior Features
- None
- Enhancement
- Combined shadowing/enhancement
- Shadowing

44l. Surrounding Tissue
- No effect
- Effect (check all that apply)
  - Duct changes
  - Edema
  - Cooper’s ligament distortion
  - Architectural distortion
  - Skin thickening
  - Skin retraction

44m. Vascularity (flow)
- None
- Yes (check all that apply)
  - Present in lesion
  - Present immediately adjacent to lesion
  - Increased in surrounding tissue
- Not performed

44n. Calcifications
- None
- Present (check all that apply)
  - Macrocalcifications (> 0.5 mm)
  - Microlcalcifications in mass
  - Microlcalcifications outside mass

44o. Lesion palpable in retrospect during sonography?
- No
- Yes

45. % Likelihood of malignancy for this lesion (best guess from 0-100)

45a. Assessment for this lesion
- 1 Negative
- 2 Benign (complete Q45b)
- 3 Probably Benign
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion
- 5 Highly Suggestive of Malignancy

45b. Known benign by prior biopsy?
- No (proceed to Q46)
- Yes (complete)
  - < 1 year ago
  - 1-2 years ago
  - > 2 years ago

46. Recommendation for this lesion
- Routine screening in one year
- Diagnostic follow-up in one year
- Short-interval follow-up in 6 months with US
- Intervention and/or Additional Imaging
  - Intervention
    - Aspiration w/core biopsy if solid
    - US-guided core biopsy
    - Vacuum-assisted biopsy, guidance by US
    - Vacuum-assisted biopsy, guidance by Mammo
    - Excisional biopsy
  - Additional Imaging
    - Comparison to current mammogram is required (lesion seen on US)
    - Comparison to prior mammograms is required
    - Additional mammographic projections

47. Is this lesion assessed as probably benign AND recommended for intervention?
- No (proceed to Q48)
- Yes (specify dominant reason)
  - Participant preference
  - Cancer present now
    - In this breast
    - In opposite breast
  - Patient risk factors
  - Vaguely palpable
  - Follow-up not reasonable
  - Increased (> 20% in volume for masses)
  - Interval suspicious change
  - Investigator uncertainty

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48. For lesion evaluation, techniques used (check all that apply)
- Conventional imaging
- Spatial compounding
- Power Doppler
- Tissue Harmonic Imaging
- Panoramic display

48a. If spatial compounding was used, what was its influence? (please answer the following questions)
- No influence (proceed to Q49)
- Influenced (please answer the following questions in bold)
  Margin depiction
  - Better
  - Same
  - Worse
  Internal structure depiction
  - Better
  - Same
  - Worse
  Posterior feature depiction
  - Better
  - Same
  - Worse
  Confidence in lesion characterization
  - Better
  - Same
  - Worse

48b. Change in likelihood of malignancy with spatial compounding?
- None
- Looks more benign with spatial compounding
- Looks more malignant with spatial compounding

49. Are there additional lesions you wish to describe?
- No (proceed to Q14)
- Yes (proceed to Q50)
50. Additional lesions other than simple cysts (maximum of 4 per breast)

50a. Lesion # U (e.g. UR1, UB1, UL1 etc.)
(Retain lesion numbering from initial study survey sonogram. If this is the first examination, begin with R1 for the first lesion in the right breast, R2 for the second lesion in the right breast etc. If the finding is new since a prior study sonogram, use next sequential #. Describe any new or suspicious findings first. Location, distance from nipple, depth to lesion center and measurements are completed for all reportable findings).

50b. Was this "lesion" seen on a previous sonogram including any sonograms performed prior to study enrollment?
- Not applicable, no prior breast sonograms
- No
- Yes
- Decreased in size since previous exam
- Stable in size since previous exam
- Multiple bilateral circumscribed masses fluctuating in size since previous exam
- Increased in size since previous exam
- Other suspicious change
- Increasing and other suspicious change

Is this "lesion" multiple bilateral circumscribed masses? If yes, describe location and measurement of largest mass.
- No
- Yes

Breast
Clockface
(report on the hour)
(report on hour and 1/2 hour e.g. 7:00=0700, 12:30=1230)
O R O L

Distance from the nipple
O cm

Depth from skin to center of lesion
(to nearest 0.5 cm)
O cm

50c. Lesion Size

Largest Horizontal Meas (mm) D1

Horizontal Perpendicular Meas (mm) D3

Vertical A-P meas (mm) D2

Measured Plane
O Try
O Sag
O Rad
O Arad
O Oblique

X mm

X mm

X mm

50d. Is this lesion at the site of prior biopsy?
- No
- Yes (if yes, select prior procedure)
- Core/vacuum biopsy with clip (if procedure performed, select diagnosis)
- Core/vacuum biopsy without marker (if procedure performed, select diagnosis)
- Surgical biopsy site (if procedure was performed, select diagnosis)
  - Benign
  - Atypical/high-risk lesion
  - Cancer site
  - Unknown
  - Biopsy details unknown
  - FNAB
- Not applicable, multiple bilateral circumscribed masses

50e. Special Case (see choices below)
- No
- Yes (if yes, detail below then proceed to Q50n)
  (Special Case Features)
  - Complicated Cyst (Note: Do not use this term for "complex cystic masses"
    For complex cystic masses code "No" for Q50e, proceed to Q50f and indicate "complex cystic" at Q50j.)
    - Homogeneous low-level echoes
    - Fluid-Debris Level
    - Mobile internal echoes
    - Multiple bilateral complicated cysts in company of simple cysts
  - Multiple bilateral solid oval, circumscribed masses
  - Mass in or on skin
  - Clustered microcysts
  - Intraductal mass
  - Lymph node
  - Calcifications without a mass
  - Foreign body
  - Post-Surgical scar
  - Other, specify:

Note: Volume is programmed to be calculated on line; however, as verification, please calculate volume based on horizontal, vertical and perpendicular measurements as a validation.
### 50f. Shape
- Oval
- Two or three gentle lobulations
- Round
- Irregular

### 50g. Orientation
- Parallel to skin
- Not parallel (includes round)

### 50h. Margin
- Circumscribed
- Not circumscribed (If not circumscribed, choose dominant feature)
  - Indistinct
  - Angular
  - Microlobulated
  - Spiculated

### 50i. Boundary Zone
- Abrupt Interface
- Echogenic Halo

### 50j. Echo Pattern
- Anechoic
- Hyperechoic
- Complex cystic
- Hypoechoic with few tiny cystic areas
- Isoechoic to fat
- Mixed hyperechoic and hypoechoic
- Hypoechoic to fat

### 50k. Posterior Features
- None
- Enhancement
- Combined shadowing/enhancement
- Shadowing

### 50l. Surrounding Tissue
- No effect
- Effect (check all that apply)
  - Duct changes
  - Edema
  - Cooper’s ligament distortion
  - Architectural distortion
  - Skin thickening
  - Skin retraction

### 50m. Vascularity (flow)
- None
- Yes (check all that apply)
  - Present in lesion
  - Present immediately adjacent to lesion
  - Increased in surrounding tissue
- Not performed

### 50n. Calcifications
- None
- Present (check all that apply)
  - Macrocalcifications (> 0.5 mm)
  - Microcalcifications in mass
  - Microcalcifications outside mass

### 50o. Lesion palpable in retrospect during sonography?
- No
- Yes

### 51. % Likelihood of malignancy for this lesion (best guess from 0-100)

### 51a. Assessment for this lesion
- 1 Negative
- 2 Benign (complete Q51b)
- 3 Probably Benign
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion
- 5 Highly Suggestive of Malignancy

### 51b. Known benign by prior biopsy?
- No (proceed to Q52)
- Yes (complete)
  - < 1 year ago
  - 1-2 years ago
  - > 2 years ago

### 52. Recommendation for this lesion
- Routine screening in one year
- Diagnostic follow-up in one year
- Short-interval follow-up in 6 months with US
- Intervention and/or Additional Imaging (detail intervention and/or additional imaging)
  - Intervention
    - Aspiration w/core biopsy if solid
    - US-guided core biopsy
    - Vacuum-assisted biopsy, guidance by US
    - Vacuum-assisted biopsy, guidance by Mammo
    - Excisional biopsy
  - Additional Imaging (check all that apply)
    - Comparison to current mammogram is required (lesion seen on US)
    - Comparison to prior mammograms is required
    - Additional mammographic projections

### 53. Is this lesion assessed as probably benign AND recommended for intervention?
- No (proceed to Q54)
- Yes (specify dominant reason)
  - Participant preference
  - Cancer present now
  - In this breast
  - In opposite breast
  - Patient risk factors
  - Vaguely palpable
  - Follow-up not reasonable
  - Increased (> 20% in volume for masses)
  - Interval suspicious change
  - Investigator uncertainty

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54. For lesion evaluation, techniques used (check all that apply)
- Conventional imaging
- Spatial compounding
- Power Doppler
- Tissue Harmonic Imaging
- Panoramic display

54a. If spatial compounding was used, what was its influence? (please answer the following questions)
- No influence (proceed to Q55)
- Influenced (please answer the following questions in bold)
  - Margin depiction
    - Better
    - Same
    - Worse
  - Internal structure depiction
    - Better
    - Same
    - Worse
  - Posterior feature depiction
    - Better
    - Same
    - Worse
  - Confidence in lesion characterization
    - Better
    - Same
    - Worse

54b. Change in likelihood of malignancy with spatial compounding?
- None
- Looks more benign with spatial compounding
- Looks more malignant with spatial compounding

55. Are there additional lesions you wish to describe?
- No (proceed to Q14)
- Yes (proceed to Q56)
56. Additional lesions other than simple cysts (maximum of 4 per breast)

56a. Lesion U (e.g. UR1, UB1, UL1 etc.)
(Retain lesion numbering from initial study survey sonogram. If this is the first examination, begin with R1 for the first lesion in the right breast, R2 for the second lesion in the right breast etc. If the finding is new since a prior study sonogram, use next sequential #. Describe any new or suspicious findings first. Location, distance from nipple, depth to lesion center and measurements are completed for all reportable findings).

56b. Was this "lesion" seen on a previous sonogram including any sonograms performed prior to study enrollment?
- o Not applicable, no prior breast sonograms
- o No
- o Yes
  - o Decreased in size since previous exam
  - o Stable in size since previous exam
  - o Multiple bilateral circumscribed masses fluctuating in size since previous exam
  - o Increased in size since previous exam
  - o Other suspicious change
  - o Increasing and other suspicious change

Is this "lesion" multiple bilateral circumscribed masses?
- o No
- o Yes

Breast

Clockface (report on the hour)
(report on hour and 1/2 hour
e.g. 7:00 = 0700, 12:30 = 1230)

Distance from the nipple
(to nearest 0.5 cm)

Depth from skin to center of lesion

56c. Lesion Size

Largest

Horizontal

Meas (mm) D1

Vertical A-P meas (mm) D2

Horizontal

Perpendicular Meas (mm) D3

Second
Measured Plane

Volume D1XD2XD3 \div 2

Note: Volume is programmed to be calculated on line; however, as verification, please calculate volume based on horizontal, vertical and perpendicular measurements as a validation.

56d. Is this lesion at the site of prior biopsy?
- o No
- o Yes (if yes, select prior procedure)
  - o Core/vacuum biopsy with clip (if procedure performed, select diagnosis)
  - o Core/vacuum biopsy without marker (if procedure performed, select diagnosis)
  - o Surgical biopsy site (if procedure was performed, select diagnosis)
    - o Benign
    - o Atypical/high-risk lesion
    - o Cancer site
    - o Unknown
    - o Biopsy details unknown
    - o FNAB
- o Not applicable, multiple bilateral circumscribed masses

56e. Special Case (see choices below)
- o No
- o Yes (if yes, detail below then proceed to Q56n)

(Special Case Features)
- o Complicated Cyst (Note: Do not use this term for "complex cystic masses". For complex cystic masses code "No" for Q56e, proceed to Q56f and indicate "complex cystic" at Q56j.)
  - o Homogeneous low-level echoes
  - o Fluid-Debris Level
  - o Mobile internal echoes
  - o Multiple bilateral complicated cysts in company of simple cysts
    - o Multiple bilateral solid oval, circumscribed masses
    - o Mass in or on skin
    - o Clustered microcysts
    - o Intraductal mass
    - o Lymph node
    - o Calcifications without a mass
    - o Foreign body
    - o Post-Surgical scar
    - o Other, specify: ________________________________
56f. Shape
- Oval
- Two or three gentle lobulations
- Round
- Irregular

56g. Orientation
- Parallel to skin
- Not parallel (includes round)

56h. Margin
- Circumscribed
- Not circumscribed (If not circumscribed, choose dominant feature)
  - Indistinct
  - Angular
  - Microlobulated
  - Spiculated

56i. Boundary Zone
- Abrupt Interface
- Echogenic Halo

56j. Echo Pattern
- Anechoic
- Hyperechoic
- Complex cystic
- Hypoechoic with few tiny cystic areas
- Isoechoic to fat
- Mixed hyperechoic and hypoechoic
- Hypoechoic to fat

56k. Posterior Features
- None
- Enhancement
- Combined shadowing/enhancement
- Shadowing

56l. Surrounding Tissue
- No effect
- Effect (check all that apply)
  - Duct changes
  - Edema
  - Cooper’s ligament distortion
  - Architectural distortion
  - Skin thickening
  - Skin retraction

56m. Vascularity (flow)
- None
- Yes (check all that apply)
  - Present in lesion
  - Present immediately adjacent to lesion
  - Increased in surrounding tissue
- Not performed

56n. Calcifications
- None
- Present (check all that apply)
  - Macrocalcifications (> 0.5 mm)
  - Microcalcifications in mass
  - Microcalcifications outside mass

56o. Lesion palpable in retrospect during sonography?
- No
- Yes

57. % Likelihood of malignancy for this lesion (best guess from 0-100)

57a. Assessment for this lesion
- 1 Negative
- 2 Benign (complete Q57b)
- 3 Probably Benign
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion
- 5 Highly Suggestive of Malignancy

57b. Known benign by prior biopsy?
(only complete if Q57a = Benign)
- No (proceed to Q58)
- Yes (complete)
  - < 1 year ago
  - 1-2 years ago
  - > 2 years ago

58. Recommendation for this lesion
- Routine screening in one year
- Diagnostic follow-up in one year
- Short-interval follow-up in 6 months with US
- Intervention and/or Additional Imaging
  (detail intervention and/or additional imaging)
  - Intervention
    - Aspiration w/core biopsy if solid
    - US-guided core biopsy
    - Vacuum-assisted biopsy, guidance by US
    - Vacuum-assisted biopsy, guidance by Mammo
    - Excisional biopsy
  - Additional Imaging
    (check all that apply)
    - Comparison to current mammogram is required
    (lesion seen on US)
    - Comparison to prior mammograms is required
    - Additional mammographic projections

59. Is this lesion assessed as probably benign AND recommended for intervention?
- No (proceed to Q60)
- Yes (specify dominant reason)
  - Participant preference
  - Cancer present now
  - In this breast
  - In opposite breast
  - Patient risk factors
  - Vaguely palpable
  - Follow-up not reasonable
  - Increased (> 20% in volume for masses)
  - Interval suspicious change
  - Investigator uncertainty
60. For lesion evaluation, techniques used (check all that apply)

- Conventional imaging
- Spatial compounding
- Power Doppler
- Tissue Harmonic Imaging
- Panoramic display

60a. If spatial compounding was used, what was its influence? (please answer the following questions)

- No influence (proceed to Q61)
- Influenced (please answer the following questions in bold)

  **Margin depiction**
  - Better
  - Same
  - Worse

  **Internal structure depiction**
  - Better
  - Same
  - Worse

  **Posterior feature depiction**
  - Better
  - Same
  - Worse

  **Confidence in lesion characterization**
  - Better
  - Same
  - Worse

60b. Change in likelihood of malignancy with spatial compounding?

- None
- Looks more benign with spatial compounding
- Looks more malignant with spatial compounding

61. Are there additional lesions you wish to describe?

- No (proceed to Q14)
- Yes (proceed to Q62)
62. Additional lesions other than simple cysts (maximum of 4 per breast)

62a. Lesion # [U] (e.g. UR1, UB1, UL1 etc.)
(Retain lesion numbering from initial study survey sonogram. If this is the first examination, begin with R1 for the first lesion in the right breast, R2 for the second lesion in the right breast etc. If the finding is new since a prior study sonogram, use next sequential #. Describe any new or suspicious findings first. Location, distance from nipple, depth to lesion center and measurements are completed for all reportable findings).

62b. Was this "lesion" seen on a previous sonogram including any sonograms performed prior to study enrollment?
- No
- Yes

Is this "lesion" multiple bilateral circumscribed masses?
- No
- Yes

Breast
Clockface (report on the hour)
(e.g. 7:00 = 0700, 12:30 = 1230)
Distance from the nipple (to nearest 0.5 cm)
Depth from skin to center of lesion (to nearest 0.5 cm)

62c. Lesion Size
Largest Measured Plane
Horizontal Meas (mm) D1
Vertical A-P meas (mm) D2
Horizontal Perpendicular Meas (mm) D3
Second Measured Plane

Volume D1XD2XD3 = 2

62d. Is this lesion at the site of prior biopsy?
- No
- Yes (if yes, select prior procedure)

62e. Special Case (see choices below)
- No
- Yes (if yes, detail below then proceed to Q62n)

(Special Case Features)
- Complicated Cyst (Note: Do not use this term for "complex cystic masses". For complex cystic masses code "No" for Q62e, proceed to Q62f and indicate "complex cystic" at Q62j.)
- Homogeneous low-level echoes
- Fluid-Debris Level
- Mobile internal echoes
- Multiple bilateral complicated cysts in company of simple cysts
- Multiple bilateral solid oval, circumscribed masses
- Mass in or on skin
- Clustered microcysts
- Intraductal mass
- Lymph node
- Calcifications without a mass
- Foreign body
- Post-Surgical scar
- Other, specify: ____________________________

Note: Volume is programmed to be calculated on line; however, as verification, please calculate volume based on horizontal, vertical and perpendicular measurements as a validation.
**62f. Shape**
- Oval
- Two or three gentle lobulations
- Round
- Irregular

**62g. Orientation**
- Parallel to skin
- Not parallel (includes round)

**62h. Margin**
- Circumscribed
- Not circumscribed (If not circumscribed, choose dominant feature)
  - Indistinct
  - Angular
  - Microlobulated
  - Spiculated

**62i. Boundary Zone**
- Abrupt Interface
- Echogenic Halo

**62j. Echo Pattern**
- Anechoic
- Hyperechoic
- Complex cystic
- Hypoechoic with few tiny cystic areas
- Isoechoic to fat
- Mixed hyperechoic and hypoechoic
- Hypoechoic to fat

**62k. Posterior Features**
- None
- Enhancement
- Combined shadowing/enhancement
- Shadowing

**62l. Surrounding Tissue**
- No effect
- Effect (check all that apply)
  - Duct changes
  - Edema
  - Cooper’s ligament distortion
  - Architectural distortion
  - Skin thickening
  - Skin retraction

**62m. Vascularity (flow)**
- None
- Yes (check all that apply)
  - Present in lesion
  - Present immediately adjacent to lesion
  - Increased in surrounding tissue
- Not performed

**62n. Calcifications**
- None
- Present (check all that apply)
  - Macrocalcifications (> 0.5 mm)
  - Microcalcifications in mass
  - Microcalcifications outside mass

**62o. Lesion palpable in retrospect during sonography?**
- No
- Yes

**63. % Likelihood of malignancy for this lesion**
(establish a best guess from 0-100)

**63a. Assessment for this lesion**
- 1 Negative
- 2 Benign (complete Q63b)
- 3 Probably Benign
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion
- 5 Highly Suggestive of Malignancy

**63b. Known benign by prior biopsy?**
(only complete if Q63a = Benign)
- No (proceed to Q64)
- Yes (complete)
- < 1 year ago
- 1-2 years ago
- > 2 years ago

**64. Recommendation for this lesion**
- Routine screening in one year
- Diagnostic follow-up in one year
- Short-interval follow-up in 6 months with US
- Intervention and/or Additional Imaging
  (detail intervention and/or additional imaging)
  - Intervention
    - Aspiration w/core biopsy if solid
    - US-guided core biopsy
    - Vacuum-assisted biopsy, guidance by US
    - Vacuum-assisted biopsy, guidance by Mammo
    - Excisional biopsy
  - Additional Imaging
    (check all that apply)
    - Comparison to current mammogram is required
      (lesion seen on US)
    - Comparison to prior mammograms is required
    - Additional mammographic projections

**65. Is this lesion assessed as probably benign AND recommended for intervention?**
- No (proceed to Q66)
- Yes (specify dominant reason)
  - Participant preference
  - Cancer present now
    - In this breast
    - In opposite breast
  - Patient risk factors
  - Vaguely palpable
  - Follow-up not reasonable
  - Increased (> 20% in volume for masses)
  - Interval suspicious change
  - Investigator uncertainty
66. For lesion evaluation, techniques used (check all that apply)
- Conventional imaging
- Spatial compounding
- Power Doppler
- Tissue Harmonic Imaging
- Panoramic display

66a. If spatial compounding was used, what was its influence? (please answer the following questions)
- No influence (proceed to Q14)
- Influenced (please answer the following questions in bold)
  - Margin depiction
    - Better
    - Same
    - Worse
  - Internal structure depiction
    - Better
    - Same
    - Worse
  - Posterior feature depiction
    - Better
    - Same
    - Worse
  - Confidence in lesion characterization
    - Better
    - Same
    - Worse

66b. Change in likelihood of malignancy with spatial compounding? (complete then proceed to Q14, Final Assessment)
- None
- Looks more benign with spatial compounding
- Looks more malignant with spatial compounding
1. Radiologist ID

1a. Same radiologist as survey US?  o No  o Yes

1b. Time point in study of this integration interpretation
   o Initial screening
   o 12 month screening
   o 24 month screening

2. Date of integration interpretation ___-___-______
   (mm-dd-yyyy)

3. Date of study mammogram ___-___-______
   (mm-dd-yyyy)

3a. Date of survey ultrasound ___-___-______
   (mm-dd-yyyy)

3b. Was comparison made to prior studies at time of integration interpretation?
   o No
   o Yes (check all that apply)
     □ Mammogram
     □ US whole breast
     □ Targeted US

When both initial studies are reviewed together:

4. Did any lesion on IA form have a final assessment of BI-RADS 3 or higher, or recommendation for additional evaluation or other than annual follow-up?
   o No
   o Yes (If yes, complete 4a)

4a. If yes, how many lesions? ___

5. Did any lesion on the IS form have a final assessment of BI-RADS 3 or higher, or recommendation for additional evaluation or other than annual follow-up?
   o No
   o Yes (If yes, complete 5a)

5a. If yes, how many lesions? ___

6. When both studies are reviewed together, how many discrete findings are there to be detailed? _____

7. First Lesion Description

7a. Lesion description (dominant feature)
   o Mass
   o Multiple bilateral circumscribed masses
   o Asymmetry
   o Calcifications
   o Architectural distortion
   o Mixed calcifications and mass/asymmetry

7b. Is this lesion seen on mammography?
   o No (proceed to Q7c)
   o Yes, and detailed on form IA (complete)

     7b.1. Lesion ID [M] on form IA
     (e.g. MR1, MB1, ML1 etc.)
     o In retrospect (only after reviewing ultrasound)
     New Lesion # [M] (number sequentially where IA left off, e.g. MR2, MB2, MR3, etc.)

     7b.2. Detail lesion location
     Quadrant - Location (check all that apply)
     □ Right breast  □ upper
     □ Left breast  □ lower
     □ Bilateral/multiple  □ inner
     □ Axillary tail  □ outer
     □ Retroareolar  □ Central

     Distance from the nipple __ cm

7c. Is this lesion seen on ultrasound?
   o No (proceed to Q7d)
   o Yes and detailed on IS (complete)

     7c.1. Lesion ID [U] on form IS
     (e.g. UR1, UB1, UL1 etc.)
     o In retrospect (only after reviewing mammogram)
     New Lesion # [U] (number sequentially where IS left off, e.g. UR2, UB2, UR3, etc.)

     7c.2. Detail lesion location
     o Right breast  o Left breast
     Clockface location: [______] o'clock
     (hour and half hour e.g. 7:00 = 0700, 12:30 = 1230)

     Distance from the nipple __ cm

7d. How certain are you that there is correspondence of the lesion on both mammography and ultrasound? _____% (best guess from 0-100; code 998 if not seen on both modalities)

7e. Combined reading likelihood of malignancy for this lesion _____% (best guess from 0-100)

7f. Final assessment/recommendation for this lesion is based:
   o Primarily on mammogram
   o Primarily on ultrasound
   o On both mammography and ultrasound
   o Primarily on risk factors or clinical history
If this is a revised or corrected form, please check box

ACRIN Study 6666
PLACE LABEL HERE

Institution ________________ Institution No. ________________
Participant Initials __________ Case No. ________________

7g. Assessment for this lesion
- 1 Negative
- 2 Benign
- 3 Probably Benign
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion of Malignancy
- 5 Highly Suggestive of Malignancy

7h. Recommendation for this lesion
- Routine screening in 1 year
- Diagnostic follow-up in 1 year
- Short-interval follow-up in 6 months with US
- Short-interval follow-up in 6 months with mammography
- Intervention and/or Additional Imaging
  (detail intervention and/or additional imaging)
  - Intervention
    - Aspiration with core biopsy if solid
    - US-guided core biopsy
    - Vacuum-assisted biopsy, guidance by US
    - Vacuum-assisted biopsy, guidance by mammography
    - Excisional biopsy
  - Additional Imaging (check all that apply)
    - Additional evaluation
      - Comparison to prior mammogram is required
      - Targeted ultrasound (lesion seen on mammography)
      - Additional mammographic projections
    - Repeat ultrasound
    - Technique/interpretation in question
    - Possibly abnormal
    - Repeat mammogram
    - Incomplete
    - Motion artifact/other technical problem

7i. Is this lesion assessed as probably benign AND recommended for intervention?
- No (proceed to Q7j)
- Yes (check dominant reason)
  - Participant preference
  - Cancer present now
    - In this breast
    - In opposite breast
  - Patient risk factors
  - Vaguely palpable
  - Follow-up not reasonable
  - Interval increase (>20% in volume for masses)
  - Interval suspicious change
  - Investigator uncertainty

7j. Are there additional lesion(s) you wish to describe?
- No (proceed to Q8)
- Yes (proceed to Q10)

Continue onto next page
## 8. Final Assessment of Right Breast

8a. [ ] Not on study (proceed to Q9)

8b. [ ] [ ] [ ] % Combined reading likelihood of malignancy for right breast (best guess from 0-100)

8c. Assessment for right breast
   - 1 Negative
   - 2 Benign
   - 3 Probably Benign
   - 4A Low Suspicion of Malignancy
   - 4B Intermediate Suspicion
   - 4C Moderately High Suspicion
   - 5 Highly Suggestive of Malignancy

8d. Recommendation for right breast
   - Routine screening in 1 year
   - Diagnostic follow-up in 1 year
   - Short-interval follow-up in 6 months with US
   - Short-interval follow-up in 6 months with mammography
   - Intervention and/or Additional Imaging
     - Aspiration with core biopsy if solid
     - US-guided core biopsy
     - Vacuum-assisted biopsy, guidance by US
     - Vacuum-assisted biopsy, guidance by mammography
     - Excisional biopsy
   - Additional Imaging (check all that apply)
     - Additional evaluation
     - Comparison to prior mammogram is required
     - Targeted ultrasound
       (lesion seen on mammography)
     - Additional mammographic projections
     - Repeat ultrasound
       - Technique/interpretation in question
       - Possibly abnormal
     - Repeat mammogram
       - Incomplete
       - Motion artifact/other technical problem

## 9. Final Assessment of Left Breast

9a. [ ] Not on study (stop and sign below)

9b. [ ] [ ] [ ] % Combined reading likelihood of malignancy for left breast (best guess from 0-100)

9c. Assessment for left breast
   - 1 Negative
   - 2 Benign
   - 3 Probably Benign
   - 4A Low Suspicion of Malignancy
   - 4B Intermediate Suspicion
   - 4C Moderately High Suspicion
   - 5 Highly Suggestive of Malignancy

9d. Recommendation for left breast
   - Routine screening in 1 year
   - Diagnostic follow-up in 1 year
   - Short-interval follow-up in 6 months with US
   - Short-interval follow-up in 6 months with mammography
   - Intervention and/or Additional Imaging
     - Aspiration with core biopsy if solid
     - US-guided core biopsy
     - Vacuum-assisted biopsy, guidance by US
     - Vacuum-assisted biopsy, guidance by mammography
     - Excisional biopsy
   - Additional Imaging (check all that apply)
     - Additional evaluation
     - Comparison to prior mammogram is required
     - Targeted ultrasound
       (lesion seen on mammography)
     - Additional mammographic projections
     - Repeat ultrasound
       - Technique/interpretation in question
       - Possibly abnormal
     - Repeat mammogram
       - Incomplete
       - Motion artifact/other technical problem

Stop: Form complete, sign and date below.
10. Additional Lesion Description

10a. Lesion Description (dominant feature)
- Mass
- Multiple bilateral circumscribed masses
- Symmetry
- Calcifications
- Architectural distortion
- Mixed calcifications and mass/density

10b. Is this lesion seen on mammography?
- No (proceed to Q10c)
- Yes, and detailed on form IA (complete)
  - **Lesion ID** [M_____] on form IA
    (e.g. MR1, MB1, ML1 etc.)
  - In retrospect (only after reviewing ultrasound)
  - **New Lesion #** [M_____] (number sequentially
    where IA left off, e.g. MR2, MB2, MR3, etc.)
  - **Detail lesion location**
    - Quadrant - Location (check all that apply)
      - Right breast
      - Left breast
      - Bilateral multiple
      - Axillary tail
      - Retroareolar
      - Central
  - **Distance from the nipple** \_

10c. Is this lesion seen on ultrasound?
- No (proceed to Q10d)
- Yes and detailed on IS (complete)
  - **Lesion ID** [U_____] on form IS
    (e.g. UR1, UB1, UL1 etc.)
  - Yes, cyst, not detailed on form IS
  - In retrospect (only after reviewing mammogram)
  - **New Lesion #** [U_____] (number sequentially
    where IS left off, e.g. UR2, UB2, UR3, etc.)
  - **Detail lesion location**
    - Right breast
    - Left breast
    - **Clockface location:** \_
      (hour and half hour e.g. 7:00 = 0700, 12:30 = 1230)
    - **Distance from the nipple** \_

10d. How certain are you that there is correspondence of the lesion on both mammography and ultrasound? \_

10e. Combined reading likelihood of malignancy for this lesion \_

10f. Final assessment/recommendation for this lesion is based:
- Primarily on mammogram
- Primarily on ultrasound
- On both mammography and ultrasound
- Primarily on risk factors or clinical history

10g. Assessment for this lesion
- 1 Negative
- 2 Benign
- 3 Probably Benign
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion of Malignancy
- 5 Highly Suggestive of Malignancy

10h. Recommendation for this lesion
- Routine screening in 1 year
- Diagnostic follow-up in 1 year
- Short-interval follow-up in 6 months with US
- Short-interval follow-up in 6 months with mammography
- Intervention and/or Additional Imaging
  (detail intervention and/or additional imaging)
  - **Intervention**
    - Aspiration with core biopsy if solid
    - US-guided core biopsy
    - Vacuum-assisted biopsy, guidance by US
    - Vacuum-assisted biopsy, guidance by mammography
    - Excisional biopsy
  - **Additional Imaging** (check all that apply)
    - Additional evaluation
    - Comparison to prior mammogram is required
    - Targeted ultrasound (lesion seen on mammography)
    - Additional mammographic projections
    - Repeat ultrasound
    - Technique/interpretation in question
    - Possibly abnormal
    - Repeat mammogram
    - Incomplete
    - Motion artifact/other technical problem

10i. Is this lesion assessed as probably benign AND recommended for intervention?
- No (proceed to Q10j)
- Yes (specify dominant reason)
  - Participant preference
  - Cancer present now
    - In this breast
    - In opposite breast
  - Patient risk factors
  - Vaguely palpable
  - Follow-up not reasonable
  - Interval increase (>20% in volume for masses)
  - Interval suspicious change
  - Investigator uncertainty

10j. Are there additional lesions you wish to describe?
- No (proceed to Q8)
- Yes (proceed to Q11)
11. Additional Lesion Description

11a. Lesion Description (dominant feature)
- Mass
- Multiple bilateral circumscribed masses
- Asymmetry
- Calcifications
- Architectural distortion
- Mixed calcifications and mass/density

11b. Is this lesion seen on mammography?
- No (proceed to Q11c)
- Yes, and detailed on form IA (complete)
  - Lesion ID [M] on form IA
    (e.g. MR1, MB1, ML1 etc.)
- In retrospect (only after reviewing ultrasound)
  - New Lesion # [M] (number sequentially where IA left off, e.g. MR2, MB2, MR3, etc.)
  - Detail lesion location
    - Quadrant - Location (check all that apply)
      - Right breast
      - Left breast
      - Bilateral multiple
      - Axillary tail
      - Retroareolar
    - Distance from the nipple cm

11c. Is this lesion seen on ultrasound?
- No (proceed to Q11d)
- Yes and detailed on IS (complete)
  - Lesion ID [U] on form IS
    (e.g. UR1, UB1, UL1 etc.)
- In retrospect (only after reviewing mammogram)
  - New Lesion # [U] (number sequentially where IS left off, e.g. UR2, UB2, UR3, etc.)
  - Detail lesion location
    - Right breast
    - Left breast
    - Clockface location: o'clock
      (hour and half hour e.g. 7:00 = 0700, 12:30 = 1230)
    - Distance from the nipple cm

11d. How certain are you that there is correspondence of the lesion on both mammography and ultrasound? % (best guess from 0-100; code 998 if not seen on both modalities)

11e. Combined reading likelihood of malignancy for this lesion % (best guess from 0-100)

11f. Final assessment/recommendation for this lesion is based:
- Primarily on mammogram
- Primarily on ultrasound
- On both mammography and ultrasound
- Primarily on risk factors or clinical history

11g. Assessment for this lesion
- 1 Negative
- 2 Benign
- 3 Probably Benign
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion of Malignancy
- 5 Highly Suggestive of Malignancy

11h. Recommendation for this lesion
- Routine screening in 1 year
- Diagnostic follow-up in 1 year
- Short-interval follow-up in 6 months with US
- Short-interval follow-up in 6 months with mammography
- Intervention and/or Additional Imaging (detail intervention and/or additional imaging)
- Intervention
  - Aspiration with core biopsy if solid
  - US-guided core biopsy
  - Vacuum-assisted biopsy, guidance by US
  - Vacuum-assisted biopsy, guidance by mammography
  - Excisional biopsy
- Additional Imaging (check all that apply)
  - Additional evaluation
  - Comparison to prior mammogram is required
  - Targeted ultrasound (lesion seen on mammography)
  - Additional mammographic projections
  - Repeat ultrasound
  - Technique/interpretation in question
  - Possibly abnormal
  - Repeat mammogram
  - Incomplete
  - Motion artifact/other technical problem

11i. Is this lesion assessed as probably benign AND recommended for intervention?
- No (proceed to Q11j)
- Yes (specify dominant reason)
  - Participant preference
  - Cancer present now
    - In this breast
    - In opposite breast
  - Patient risk factors
  - Vaguely palpable
  - Follow-up not reasonable
  - Interval increase (>20% in volume for masses)
  - Interval suspicious change
  - Investigator uncertainty

11j. Are there additional lesions you wish to describe?
- No (proceed to Q8)
- Yes (proceed to Q12)
12. Additional Lesion Description

12a. Lesion Description (dominant feature)
- Mass
- Multiple bilateral circumscribed masses
- Asymmetry
- Calcifications
- Architectural distortion
- Mixed calcifications and mass/density

12b. Is this lesion seen on mammography?
- No (proceed to Q12c)
- Yes, and detailed on form IA (complete)
  - Lesion ID [M] on form IA (e.g. MR1, MB1, ML1 etc.)
  - In retrospect (only after reviewing ultrasound)
- New Lesion # [M] (number sequentially where IA left off, e.g. MR2, MB2, MR3, etc.)

Detail lesion location
- Quadrant - Location (check all that apply)
  - Right breast
  - Left breast
  - Bilateral multiple
  - Axillary tail
  - Retroareolar
- Distance from the nipple [_____] cm

12c. Is this lesion seen on ultrasound?
- No (proceed to Q12d)
- Yes, and detailed on form IS (complete)
  - Lesion ID [U] on form IS (e.g. UR1, UB1, UL1 etc.)
  - In retrospect (only after reviewing mammogram)
- New Lesion # [U] (number sequentially where IS left off, e.g. UR2, UB2, UR3, etc.)

Detail lesion location
- Right breast
- Left breast
- Clockface location: [_____] o'clock (hour and half hour e.g. 7:00 = 0700, 12:30 = 1230)
- Distance from the nipple [_____] cm

12d. How certain are you that there is correspondence of the lesion on both mammography and ultrasound? [_____] % (best guess from 0-100; code 998 if not seen on both modalities)

12e. Combined reading likelihood of malignancy for this lesion [_____] % (best guess from 0-100)

12f. Final assessment/recommendation for this lesion is based:
- Primarily on mammogram
- Primarily on ultrasound
- On both mammography and ultrasound
- Primarily on risk factors or clinical history

12g. Assessment for this lesion
- 1 Negative
- 2 Benign
- 3 Probably Benign
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion of Malignancy
- 5 Highly Suggestive of Malignancy

12h. Recommendation for this lesion
- Routine screening in 1 year
- Diagnostic follow-up in 1 year
- Short-interval follow-up in 6 months with US
- Short-interval follow-up in 6 months with mammography
- Intervention and/or Additional Imaging (detail intervention and/or additional imaging)
- Intervention
  - Aspiration with core biopsy if solid
  - US-guided core biopsy
  - Vacuum-assisted biopsy, guidance by US
  - Vacuum-assisted biopsy, guidance by mammography
  - Excisional biopsy
- Additional Imaging (check all that apply)
  - Additional evaluation
  - Comparison to prior mammogram is required
  - Targeted ultrasound (lesion seen on mammography)
  - Additional mammographic projections
  - Repeat ultrasound
  - Technique/interpretation in question
  - Possibly abnormal
  - Repeat mammogram
  - Incomplete
  - Motion artifact/other technical problem

12i. Is this lesion assessed as probably benign AND recommended for intervention?
- No (proceed to Q12j)
- Yes (specify dominant reason)
  - Participant preference
  - Cancer present now
  - In this breast
  - In opposite breast
  - Patient risk factors
  - Vaguely palpable
  - Follow-up not reasonable
  - Interval increase (>20% in volume for masses)
  - Interval suspicious change
  - Investigator uncertainty

12j. Are there additional lesions you wish to describe?
- No (proceed to Q8)
- Yes (proceed to Q13)
13. Additional Lesion Description

13a. Lesion Description (dominant feature)
   - Mass
   - Multiple bilateral circumscribed masses
   - Asymmetry
   - Calcifications
   - Architectural distortion
   - Mixed calcifications and mass/density

13b. Is this lesion seen on mammography?
   - No (proceed to Q13c)
   - Yes, and detailed on form IA (complete)
     - Lesion ID [M_____] on form IA
       (e.g. MR1, MB1, ML1 etc.)
     - In retrospect (only after reviewing ultrasound)
       - New Lesion # [M_____] (number sequentially where IA left off, e.g. MR2, MB2, MR3, etc.)

13c. Is this lesion seen on ultrasound?
   - No (proceed to Q13d)
   - Yes, and detailed on IS (complete)
     - Lesion ID [U_____] on form IS
       (e.g. UR1, UB1, UL1 etc.)
     - In retrospect (only after reviewing mammogram)
       - New Lesion # [U_____] (number sequentially where IS left off, e.g. UR2, UB2, UR3, etc.)

13d. How certain are you that there is correspondence of the lesion on both mammography and ultrasound?
   - ___ ___ % (best guess from 0-100; code 998 if not seen on both modalities)

13e. Combined reading likelihood of malignancy for this lesion
   - ___ ___ % (best guess from 0-100)

13f. Final assessment/recommendation for this lesion is based:
   - Primarily on mammogram
   - Primarily on ultrasound
   - On both mammography and ultrasound
   - Primarily on risk factors or clinical history

13g. Assessment for this lesion
   - 1. Negative
   - 2. Benign
   - 3. Probably Benign
   - 4A. Low Suspicion of Malignancy
   - 4B. Intermediate Suspicion
   - 4C. Moderately High Suspicion of Malignancy
   - 5. Highly Suggestive of Malignancy

13h. Recommendation for this lesion
   - Routine screening in 1 year
   - Diagnostic follow-up in 1 year
   - Short-interval follow-up in 6 months with US
   - Short-interval follow-up in 6 months with mammography
   - Intervention and/or Additional Imaging
     (detail intervention and/or additional imaging)
     - Intervention
       - Aspiration with core biopsy if solid
       - US-guided core biopsy
       - Vacuum-assisted biopsy, guidance by US
       - Vacuum-assisted biopsy, guidance by mammography
       - Excisional biopsy
     - Additional Imaging (check all that apply)
       - Additional evaluation
       - Comparison to prior mammogram is required
       - Targeted ultrasound (lesion seen on mammography)
       - Additional mammographic projections
       - Repeat ultrasound
       - Technique/interpretation in question
       - Possibly abnormal
       - Repeat mammogram
       - Incomplete
       - Motion artifact/other technical problem

13i. Is this lesion assessed as probably benign AND recommended for intervention?
   - No (proceed to Q13j)
   - Yes (check dominant reason)
     - Participant preference
     - Cancer present now
       - In this breast
       - In opposite breast
     - Patient risk factors
     - Vaguely palpable
     - Follow-up not reasonable
     - Interval increase (>20% in volume for masses)
     - Interval suspicious change
     - Investigator uncertainty

13j. Are there additional lesions you wish to describe?
   - No (proceed to Q8)
   - Yes (proceed to Q14)
14. Additional Lesion Description

14a. Lesion Description (dominant feature)
- Mass
- Multiple bilateral circumscribed masses
- Asymmetry
- Calcifications
- Architectural distortion
- Mixed calcifications and mass/density

14b. Is this lesion seen on mammography?
- No (proceed to Q14c)
- Yes, and detailed on form IA (complete)
  - Lesion ID [M_____] on form IA
    (e.g. MR1, MB1, ML1 etc.)
  - In retrospect (only after reviewing ultrasound)
  - New Lesion # [M_____] (number sequentially
    where IA left off, e.g. MR2, MB2, MR3, etc.)
- In retrospect (only after reviewing ultrasound)
  - Quadrant - Location (check all that apply)
    - Right breast
    - Left breast
    - Bilateral multiple
    - Axillary tail
    - Retroareolar
  - Distance from the nipple ___ cm

14c. Is this lesion seen on ultrasound?
- No (proceed to Q14d)
- Yes and detailed on IS (complete)
  - Lesion ID [U_____] on form IS
    (e.g. UR1, UB1, UL1 etc.)
  - Yes, cyst, not detailed on form IS
  - In retrospect (only after reviewing mammogram)
  - New Lesion # [U_____] (number sequentially
    where IS left off, e.g. UR2, UB2, UR3, etc.)
- In retrospect (only after reviewing mammogram)
  - Quadrant - Location (check all that apply)
    - Right breast
    - Left breast
  - Clockface location: ___ o'clock
    (hour and half hour e.g. 7:00 = 0700, 12:30 = 1230)
  - Distance from the nipple ___ cm

14d. How certain are you that there is correspondence
of the lesion on both mammography and ultrasound?
___ % (best guess from 0-100; code 998 if
not seen on both modalities)

14e. Combined reading likelihood of malignancy for
this lesion ___ % (best guess from 0-100)

14f. Final assessment/recommendation for this
lesion is based:
- Primarily on mammogram
- Primarily on ultrasound
- On both mammography and ultrasound
- On primarily on risk factors or clinical history

14g. Assessment for this lesion
- 1 Negative
- 2 Benign
- 3 Probably Benign
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion of Malignancy
- 5 Highly Suggestive of Malignancy

14h. Recommendation for this lesion
- Routine screening in 1 year
- Diagnostic follow-up in 1 year
- Short-interval follow-up in 6 months with US
- Short-interval follow-up in 6 months with mammography
- Intervention and/or Additional Imaging
  (detail intervention and/or additional imaging)
  - Intervention
    - Aspiration with core biopsy if solid
    - US-guided core biopsy
    - Vacuum-assisted biopsy, guidance by US
    - Vacuum-assisted biopsy, guidance by mammography
    - Excisional biopsy
  - Additional Imaging (check all that apply)
    - Additional evaluation
    - Comparison to prior mammogram is required
    - Targeted ultrasound (lesion seen on mammography)
    - Additional mammographic projections
    - Repeat ultrasound
    - Technique/interpretation in question
    - Possibly abnormal
    - Repeat mammogram
    - Incomplete
    - Motion artifact/other technical problem

14i. Is this lesion assessed as probably benign AND
recommended for intervention?
- No (proceed to Q14j)
- Yes (specify dominant reason)
  - Participant preference
  - Cancer present now
  - In this breast
  - In opposite breast
  - Patient risk factors
  - Vaguely palpable
  - Follow-up not reasonable
  - Interval increase (>20% in volume for masses)
  - Interval suspicious change
  - Investigator uncertainty

14j. Are there additional lesions you wish to describe?
- No (proceed to Q8)
- Yes (proceed to Q15)
15. Additional Lesion Description

15a. Lesion Description (dominant feature)
- Mass
- Multiple bilateral circumscribed masses
- Asymmetry
- Calcifications
- Architectural distortion
- Mixed calcifications and mass/density

15b. Is this lesion seen on mammography?
- No (proceed to Q15c)
- Yes, and detailed on form IA (complete)
  - Lesion ID [M_____] on form IA
    (e.g. MR1, MB1, ML1 etc.)
  - In retrospect (only after reviewing ultrasound)
  - New Lesion # [M_____] (number sequentially where IA left off, e.g. MR2, MB2, MR3, etc.)
Detail lesion location
  - Quadrant - Location (check all that apply)
    - Right breast
    - Left breast
    - Bilateral multiple
    - Axillary tail
    - Retroareolar
  - Distance from the nipple _____ cm

15c. Is this lesion seen on ultrasound?
- No (proceed to Q15d)
- Yes and detailed on IS (complete)
  - Lesion ID [U_____] on form IS
    (e.g. UR1, UB1, UL1 etc.)
  - Yes, cyst, not detailed on form IS
  - In retrospect (only after reviewing mammogram)
  - New Lesion # [U_____] (number sequentially where IS left off, e.g. UR2, UB2, UR3, etc.)
Detail lesion location
  - Right breast
  - Left breast
  - Clockface location: __________o'clock
    (hour and half hour e.g. 7:00 = 0700, 12:30 = 1230)
  - Distance from the nipple _____ cm

15d. How certain are you that there is correspondence of the lesion on both mammography and ultrasound?
[_________] % (best guess from 0-100; code 998 if not seen on both modalities)

15e. Combined reading likelihood of malignancy for this lesion [_________] % (best guess from 0-100)

15f. Final assessment/recommendation for this lesion is based:
- Primarily on mammogram
- Primarily on ultrasound
- On both mammography and ultrasound
- On risk factors or clinical history

15g. Assessment for this lesion
- 1 Negative
- 2 Benign
- 3 Probably Benign
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion of Malignancy
- 5 Highly Suggestive of Malignancy

15h. Recommendation for this lesion
- Routine screening in 1 year
- Diagnostic follow-up in 1 year
- Short-interval follow-up in 6 months with US
- Short-interval follow-up in 6 months with mammography
- Intervention and/or Additional Imaging
  - Aspiration with core biopsy if solid
  - US-guided core biopsy
  - Vacuum-assisted biopsy, guidance by US
  - Vacuum-assisted biopsy, guidance by mammography
  - Excisional biopsy
- Additional Imaging (check all that apply)
  - Additional evaluation
  - Comparison to prior mammogram is required
  - Targeted ultrasound (lesion seen on mammography)
  - Additional mammographic projections
  - Repeat ultrasound
  - Technique/interpretation in question
  - Possibly abnormal
  - Repeat mammogram
  - Incomplete
  - Motion artifact/other technical problem

15i. Is this lesion assessed as probably benign AND recommended for intervention?
- No (proceed to Q15j)
- Yes (specify dominant reason)
  - Participant preference
  - Cancer present now
    - In this breast
    - In opposite breast
  - Patient risk factors
  - Vaguely palpable
  - Follow-up not reasonable
  - Interval increase (>20% in volume for masses)
  - Interval suspicious change
  - Investigator uncertainty

15j. Are there additional lesions you wish to describe?
- No (proceed to Q8)
- Yes (proceed to Q16)
16. Additional Lesion Description

16a. Lesion Description (dominant feature)
- Mass
- Multiple bilateral circumscribed masses
- Asymmetry
- Calcifications
- Architectural distortion
- Mixed calcifications and mass/density

16b. Is this lesion seen on mammography?
- No (proceed to Q16c)
- Yes, and detailed on form IA (complete)
  - Lesion ID [M] on form IA
  - (e.g., MR1, MB1, ML1 etc.)
- In retrospect (only after reviewing ultrasound)
  - New Lesion # [M] (number sequentially where IA left off, e.g., MR2, MB2, MR3, etc.)
  - Detail lesion location
    - Quadrant - Location (check all that apply)
      - Right breast
      - Left breast
      - Bilateral multiple
      - Axillary tail
      - Retroareolar
    - Distance from the nipple [ ] cm

16c. Is this lesion seen on ultrasound?
- No (proceed to Q16d)
- Yes and detailed on IS (complete)
  - Lesion ID [U] on form IS
  - (e.g., UR1, UB1, UL1 etc.)
- In retrospect (only after reviewing mammogram)
  - New Lesion # [U] (number sequentially where IS left off, e.g., UR2, UB2, UR3, etc.)
  - Detail lesion location
    - Right breast
    - Left breast
    - Clockface location: [ ] o'clock
    - Distance from the nipple [ ] cm

16d. How certain are you that there is correspondence of the lesion on both mammography and ultrasound?
[ ] % (best guess from 0-100; code 998 if not seen on both modalities)

16e. Combined reading likelihood of malignancy for this lesion [ ] % (best guess from 0-100)

16f. Final assessment/recommendation for this lesion is based:
- Primarily on mammogram
- Primarily on ultrasound
- On both mammography and ultrasound
- Primarily on risk factors or clinical history

16g. Assessment for this lesion
- 1 Negative
- 2 Benign
- 3 Probably Benign
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion of Malignancy
- 5 Highly Suggestive of Malignancy

16h. Recommendation for this lesion
- Routine screening in 1 year
- Diagnostic follow-up in 1 year
- Short-interval follow-up in 6 months with US
- Short-interval follow-up in 6 months with mammography
- Intervention and/or Additional Imaging
  - (detail intervention and/or additional imaging)
    - Intervention
      - Aspiration with core biopsy if solid
      - US-guided core biopsy
      - Vacuum-assisted biopsy, guidance by US
      - Vacuum-assisted biopsy, guidance by mammography
      - Excisional biopsy
    - Additional Imaging (check all that apply)
      - Additional evaluation
        - Comparison to prior mammogram is required
        - Targeted ultrasound (lesion seen on mammography)
        - Additional mammographic projections
        - Repeat ultrasound
        - Technique/interpretation in question
        - Possibly abnormal
        - Repeat mammogram
        - Incomplete
        - Motion artifact/other technical problem

16i. Is this lesion assessed as probably benign AND recommended for intervention?
- No (proceed to Final Assessment(s) Q8, Q9)
- Yes (specify dominant reason)
  - Participant preference
  - Cancer present now
    - In this breast
    - In opposite breast
  - Patient risk factors
  - Vaguely palpable
  - Follow-up not reasonable
  - Interval increase (>20% in volume for masses)
  - Interval suspicious change
  - Investigator uncertainty

Proceed to Final Assessment(s), Q8, Q9

"Copyright 2004"
I. GENERAL INFORMATION

1. Is this form IM the continuation from additional evaluations reported on another form IM?
   o No
   o Yes

2. Did participant return for additional evaluation?
   o No (specify reason, STOP and sign form)
   o Second opinion felt not mandated
   o Participant refusal
   o Participant did not return
   o Unable to be performed and rescheduled
   o Yes
   o Completed
   o Incomplete, will return on __________ (mm-dd-yyyy)
   □ Check box if date unknown

3. Indication for exam(s): (check all that apply)
   □ Routine mammogram abnormal
   □ Survey ultrasound abnormal
   □ Clinical abnormalities
   □ MRI abnormalities
   □ CAD abnormalities

4. Date study(ies) performed __________ (mm-dd-yyyy)
   (Report date comparison made if only reporting comparison to prior studies.)

   4a. Date of study interpretation __________ (mm-dd-yyyy)

   4b. Timepoint in study prompting this additional evaluation
   o Initial screening
   o 12 month screening
   o 24 month screening
   o Off study event (see instructions)

5. Radiologist ACRIN ID #__________
   5a. Radiologist performing additional evaluation (last, first)

6. Which breast(s) are reported on this form?
   (check all that apply)
   □ Right Breast
   □ Left Breast

7. How many lesions were recommended for additional evaluation for this breast based on ID forms(s)? [ ]

   Note: enter “0” if participant here for clinical, MRI or off-study (see instructions) abnormalities only.

   7a. Were any new lesions seen only on additional mammographic evaluation of this breast? [i.e., not reported on IA]
   o No (proceed to Q7b)
   o Yes (detail how many)
   o Not applicable, not done

   7b. Were any new lesions seen only on additional US evaluation of this breast? [i.e., not reported on IS]
   o No (proceed to Q8)
   o Yes (detail how many)
   o Not applicable, not done

8a. Have there been any clinically significant changes in the right breast since the last annual examination?
   o No
   o Yes (check all clinical changes that apply)
     □ Palpable mass (complete location)
     □ Location of abnormality __________ o’clock or specify location:
       o Axilla
       o Retroareolar
       o Unknown
     □ Nipple discharge (detail):
       o Bloody
       o Clear spontaneous
       o Other
     □ Other, specify: __________
     o Not applicable (not on study) (proceed to Q8b)

8b. Have there been any clinically significant changes in the left breast since the last annual examination?
   o No
   o Yes (check all clinical changes that apply)
     □ Palpable mass (complete location)
     □ Location of abnormality __________ o’clock or specify location:
       o Axilla
       o Retroareolar
       o Unknown
     □ Nipple discharge (detail):
       o Bloody
       o Clear spontaneous
       o Other
     □ Other, specify: __________
     o Not applicable (not on study) (proceed to Q8b)

9. Has the patient had any other evaluation of breast(s) since the last annual study exam(s)?
   o No (proceed to Q10)
   o Yes (check all that apply)
     □ Clinical examination
     □ Biopsy, already reported
     □ Biopsy, not already reported
     □ Note: Complete BX form if core or FNA done, NL form for surgical biopsy and S1 if cancer found.
       □ MRI
       □ Outside US
       □ Outside mammogram

10. Comparison studies other than most recent annual mammogram and study US?
    o Not available (proceed to Section IIA)
    o Available (complete, check all that apply)
      □ Prior mammography
      □ Prior targeted US
      □ Right □ Left
      □ Prior survey US
II. Results (by lesion)

Please complete Mammographic Lesion Description and Sonographic Lesion Description for each lesion to be described based on the ID or MX form, and/or clinical findings even if the additional imaging revealed no abnormalities.

IIA. Lesion # from prior MRI: [G] (e.g. GR1, GL1, GL2, etc.)
(if not applicable code 998)

11. Mammographic Lesion Description

11a. Were additional mammographic views obtained directed to this finding?
   o No (specify reason and proceed to Q12)
   o Not recommended
   o Participant refused
   o Not needed after targeted US
   o Scheduling constraints; participant rescheduled
   o Other
   o Yes (check all that apply)
     R L
     □ Spot compression
     □ True lateral
     □ Laterally exaggerated CC
     □ Magnification views
     □ Rolled views
     □ Repeat CC or MLO or both

11b. Was lesion seen on additional mammographic view(s)?
   o No e.g. resolved on additional views (complete then proceed to Q12)
     Lesion # from prior mammogram: [M]
     (if not applicable code 998)
     Lesion # from prior ultrasound: [U]
     (if not applicable code 998)
   o Yes

11c. Was lesion enumerated on any prior study mammogram?
   o No and not visible in retrospect
     (assign next sequential mammogram lesion #)
   o No but now visible in retrospect
     (assign next sequential mammogram lesion #)
   o Yes
     Lesion # from prior mammogram: [M]
     (e.g. MR1, MB1, ML1, MR2, etc.)

11d. Was lesion enumerated on any prior study ultrasound?
   o No
   o Simple cyst
   o Not a simple cyst
   o Yes (complete)
     Lesion # from ultrasound: [U]
     (e.g. UR1, UB1, UL1, UR2, etc.)

11e. Location on Mammography: (check all that apply)

Note: for multiple bilateral findings with similar appearances, check "bilateral, multiple" and indicate specific location and size of the largest such finding.

   o Right breast
   o Left breast
   o Bilateral, multiple
   o Axillary tail
   o Retroareolar

11f. Distance from nipple ______ cm by Mammography

11g. Size of lesion by Mammography:

   ______ mm X ______ mm
   (largest diameter) (largest perpendicular dimension)

11h. Lesion Description Mammography

(check all that apply)

   Mass (select worse margin feature present)
   o Circumscribed
   o Fat-containing
   o Not fat-containing
   o Microlobulated
   o Obscured
   o Indistinct
   o Sclerulated

   Asymmetry (code type of asymmetry)
   o Focal
   o Asymmetry seen on
     o One view
     o Both views
     o Global

   Calcifications (code morphology and distribution)
   Morphology of calcifications (check all that apply)
   □ Coarse typically benign
   □ Milk of calcium
   □ Coarse heterogeneous
   □ Punctate (<0.5 mm, uniformly round)
   □ Amorphous/Indistinct
   □ Pleomorphic
   □ Branching/Fine linear

   Distribution of calcifications (check all that apply)
   □ Clustered
   □ Multiple clusters (same morphology)
   □ Regional
   □ Linear
   □ Segmental
   □ Diffuse scattered
   □ In mass or asymmetry
   □ Architectural Distortion

12. Sonographic Lesion Description

12a. Was ultrasound performed again directed to this lesion?
   o No (specify reason and proceed to Q13)
   o Not recommended
   o Participant refused
   o Not needed after additional mammographic views
   o Scheduling constraints; participant rescheduled
   o Other
   o Yes (check all that apply)
     Targeted only
     Whole breast

12b. Was lesion seen on this Ultrasound?
   o No (complete then proceed to Q13)
     Lesion # from prior mammogram: [M]
     (if not applicable code 998)
     Lesion # from prior ultrasound: [U]
     (if not applicable code 998)
   o Yes

12c. Was lesion enumerated on any prior study ultrasound?
   o No
   o Simple cyst (proceed to Q13)
   o Not a simple cyst and not visible in retrospect
     (assign next sequential sonogram lesion #)
   o Not a simple cyst and now visible in retrospect
     (assign next sequential sonogram lesion #)
   o New lesion #
   o Yes (complete)
     Lesion # from prior ultrasound: [U]
     (e.g. UR1, UB1, UL1, UR2, etc.)

Was lesion enumerated on any study mammogram (including additional views obtained today)?
   o No
   o Yes (complete)
     Lesion # from mammogram or additional view number: [M]
     (e.g. MR1, MB1, ML1, MR2, etc.)
12d. □ Check if this "lesion" is multiple bilateral circumscribed masses. Describe largest mass in Q12d and Q12e then proceed to Q12f.

Breast Clockface Distance from
(report on 1/2 hour) the nipple
(report on hour and 1/2 hour
e.g. 7:00 = 0700, 12:30 = 1230)

O R O L o’clock cm , , cm

12e. Lesion Size

<table>
<thead>
<tr>
<th>Largest</th>
<th>Measured Plane</th>
<th>Horizontal</th>
<th>Vertical A-P</th>
<th>Horizontal</th>
<th>Second</th>
<th>Volume D1XD2XD3 ÷ 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meas (mm)</td>
<td>D1</td>
<td>D2</td>
<td>meas (mm) D2</td>
<td>Meas (mm)</td>
<td>D3</td>
<td></td>
</tr>
<tr>
<td>mm</td>
<td>o Trv</td>
<td>o Sag</td>
<td>X</td>
<td>o Arad</td>
<td>o Oblique</td>
<td>mm X mm mm mm</td>
</tr>
</tbody>
</table>

12f. Special Case (see choices below)

 □ No
 □ Yes (detail below then proceed to Q12g)
    □ Complicated Cyst (Note: Do not use this term for "complex cystic masses".
    For complex cystic masses code "no" for Q12f, proceed to Q12g and indicate "complex cystic" at 12k).
    □ Homogenous low-level echoes
    □ Fluid debris level
    □ Mobile internal echoes
    □ Multiple bilateral complicated cysts in company of simple cysts
    □ Multiple bilateral solid oval, circumscribed masses
    □ Mass in or on skin
    □ Clustered microcyts
    □ Intraductal mass
    □ Lymph node
    □ Calcfications without a mass
    □ Foreign body
    □ Post-surgical scar
    □ Other, specify ____________________________

12g. Shape

 □ Oval
 □ Two or three gentle lobulations
 □ Round
 □ Irregular

12h. Orientation

 □ Parallel to skin
 □ Not parallel (includes round)

12i. Margin

 □ Circumscribed
 □ Not circumscribed (If not circumscribed, choose dominant feature)
    □ Indistinct
    □ Angular
    □ Microlobulated
    □ Spiculated

12j. Boundary Zone

 □ Abrupt Interface
 □ Echogenic Halo

Note: Volume is programmed to be calculated on line; however, as verification, please calculate volume based on horizontal, vertical and perpendicular measurements as a validation.
12k. Echo Pattern
- Anechoic
- Hyperechoic
- Complex cystic
- Hypoechoic with few tiny cystic areas
- Isoechoic to fat
- Mixed hyperechoic and hypoechoic
- Hypoechoic to fat

12l. Posterior Features
- None
- Enhancement
- Combined shadowing/enhancement
- Shadowing

12m. Surrounding Tissue
- No effect
- Effect (check all that apply)
  - Duct changes
  - Edema
  - Cooper's ligament distortion
  - Architectural distortion
  - Skin thickening
  - Skin retraction

12n. Vascularity (flow)
- None
- Yes (check all that apply)
  - Present in lesion
  - Present immediately adjacent to lesion
  - Increased in surrounding tissue
- Not performed

12o. Calcifications on ultrasound
- None
- Present (check all that apply)
  - Macrocaltifications (> 0.5 mm)
  - Microcaltifications in mass
  - Microcaltifications outside mass

12p. Was lesion palpable in retrospect during sonography?
- No
- Yes, in retrospect
- Yes, participant presented with lump

13. Is this lesion at the site of prior biopsy?
- No (proceed to Q14)
- Yes (If yes, select procedure)
  - Core/vacuum biopsy site with clip
  - Core/vacuum biopsy site without marker
  - Surgical biopsy site (select diagnosis)
    - Benign
    - Atypical/high-risk lesion
    - Cancer site
    - Unknown
    - Biopsy details unknown
    - FNAB
    - Not applicable, multiple bilateral circumscribed masses

14. Assessment/Recommendations (by lesion)

14a. % likelihood of malignancy for this lesion (best guess from 0-100)

14b. Assessment for this lesion
- 1 Negative
- 2 Benign
- 3 Probably Benign
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion
- 5 Highly Suggestive of Malignancy

14c. Recommendation(s) for this lesion
- Routine screening in 1 year
- Diagnostic follow-up in 1 year
- Short-interval follow-up in 6 months with US
- Short-interval follow-up in 6 months with mammo
- Short-interval follow-up in 6 months with MRI
- Intervention and/or Additional Imaging
  - Intervention
    - Aspiration with core biopsy if solid
    - US-guided core biopsy
    - Vacuum-assisted biopsy, guidance by US
    - Vacuum-assisted biopsy, guidance by mammo
    - Excisional biopsy
    - Vacuum-assisted biopsy, guided by MRI
- Additional Imaging
  - Targeted ultrasound (lesion seen on mammography)
  - Comparison to prior mammogram is required
  - Additional mammographic projections

14d. Is this lesion assessed as probably benign AND recommended for intervention?
- No (proceed to Q15)
- Yes (specify dominant reason)
  - Participant preference
  - Cancer present now
    - In this breast
    - In opposite breast
  - Patient risks factors
  - Vaguely palpable
  - Follow-up not reasonable
  - Interval increase (>20% in volume for masses)
  - Interval suspicious change
  - Investigator uncertainty

15. Are there additional lesion(s) you wish to describe?
- No (proceed to Q16)
- Yes (proceed to Section IIB)
### Section IV. Overall Assessment

#### 16. Final Assessment of Right Breast
- **Note:** Final assessment should be based on the worst lesion present, even if that lesion did not undergo additional evaluation.

<table>
<thead>
<tr>
<th>16a.</th>
<th>% Likelihood of malignancy for this breast (best guess from 0-100)</th>
</tr>
</thead>
<tbody>
<tr>
<td>16b.</td>
<td>Assessment for this breast</td>
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<tr>
<td>o 1</td>
<td>Negative</td>
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<td>o 2</td>
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<th>16c.</th>
<th>Recommendation for this breast</th>
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<tbody>
<tr>
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### 17. Final Assessment of Left Breast
- **Note:** Final assessment should be based on the worst lesion present, even if that lesion did not undergo additional evaluation.

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Stop: Form complete, sign and date below.
II. Results (by lesion)

Please complete Mammographic Lesion Description and Sonographic Lesion Description for each lesion to be described based on the ID or MX form, and/or clinical findings even if the additional imaging revealed no abnormalities.

II.B. Lesion # from prior MRI: [G] (e.g. GR1, GL1, GL2, etc.)
(if not applicable code 998)

18. Mammographic Lesion Description

18a. Were additional mammographic views obtained directed to this finding?
   - No (specify reason and proceed to Q19)
   - Not recommended
   - Participant refused
   - Not needed after targeted US
   - Scheduling constraints; participant rescheduled
   - Other
   - Yes (check all that apply)
     - Spot compression
     - True lateral
     - Laterally exaggerated CC
     - Magnification views
     - Rolled views
     - Repeat CC or MLO or both

18b. Was lesion seen on additional mammographic view(s)?
   - No e.g. resolved on additional views (complete then proceed to Q19)
     - Lesion # from prior mammogram: [M]
     - (if not applicable code 998)
     - Lesion # from prior ultrasound: [U]
     - (if not applicable code 998)
   - Yes

18c. Was lesion enumerated on any prior study mammogram?
   - No and not visible in retrospect
   - (assign next sequential mammogram lesion #)
   - No but now visible in retrospect
   - (assign next sequential mammogram lesion #)
   - New lesion: [M]
   - Yes

18d. Was lesion enumerated on any prior study ultrasound?
   - No
   - Simple cyst
   - Not a simple cyst
   - Yes (complete)
     - Lesion # from ultrasound: [U]
     - (e.g. UR1, UB1, UL1, UR2, etc.)

18e. Location on Mammography: (check all that apply)

   Note: for multiple bilateral findings with similar appearances, check "bilateral, multiple" and indicate specific location and size of the largest such finding.

   - Right breast
   - Left breast
   - Bilateral
   - Axillary tail
   - Retroareolar

18f. Distance from nipple: [ ] cm by Mammography

18g. Size of lesion by Mammography:
   [ ] mm X [ ] mm
   (largest diameter) (largest perpendicular dimension)

18h. Lesion Description Mammography
   (check all that apply)

   - Mass (select worse margin feature present)
     - Circumscribed
     - Fat-containing
     - Not fat-containing
     - Microlobulated
     - Obscured
     - Indistinct
     - Spiculated
   - Asymmetry (code type of asymmetry)
     - Focal
     - Asymmetry seen on
       - One view
       - Both views
       - Global
   - Calcifications (code morphology and distribution)
     - Morphology of calcifications (check all that apply)
       - Coarse typically benign
       - Milk of calcium
       - Coarse heterogeneous
       - Punctate (<0.5 mm, uniformly round)
       - Amorphous/Indistinct
       - Pleomorphic
       - Branching/Fine linear
     - Distribution of calcifications (check all that apply)
       - Clustered
       - Multiple clusters (same morphology)
       - Regional
       - Linear
       - Segmental
       - Diffuse scattered
       - In mass or asymmetry
   - Architectural Distortion

19. Sonographic Lesion Description

19a. Was ultrasound performed again directed to this lesion?
   - No (specify reason and proceed to Q20)
   - Not recommended
   - Participant refused
   - Not needed after additional mammographic views
   - Scheduling constraints; participant rescheduled
   - Other
   - Yes (check all that apply)
     - Targeted only
     - Whole breast

19b. Was lesion seen on this Ultrasound?
   - No (complete then proceed to Q20)
     - Lesion # from prior mammogram: [M]
     - (if not applicable code 998)
     - Lesion # from prior ultrasound: [U]
     - (if not applicable code 998)
   - Yes

19c. Was lesion enumerated on any prior study ultrasound?
   - No (complete)
   - Simple cyst (proceed to Q20)
   - Not a simple cyst and not visible in retrospect
     - (assign next sequential sonogram lesion #)
   - New lesion: [U]
   - Yes (complete)
     - Lesion # from prior ultrasound: [U]
     - (e.g. UR1, UB1, UL1, UR2, etc.)

Was lesion enumerated on any study mammogram (including additional views obtained today)?
   - No
   - Yes (complete)
     - Lesion # from mammogram or additional view number: [M]
     - (e.g. MR1, MB1, ML1, MR2, etc.)
19d. □ Check if this "lesion" is multiple bilateral circumscribed masses. Describe largest mass in Q19d and Q19e then proceed to Q19f.

Clockface

Breast (report on 1/2 hour)
Distance from the nipple

Depth from skin to center of lesion
(to nearest 0.5 cm)

o R o L 

o’ clock 

cm 

19e. Lesion Size

Largest Horizontal Meas (mm) D1

Measured Plane

Vertical A-P meas (mm) D2

Horizontal Perpendicular Meas (mm) D3

Second Measured Plane

Volume D1XD2XD3 = 2

mm

mm

mm

mm

mm

Note: Volume is programmed to be calculated on line; however, as verification, please calculate volume based on horizontal, vertical and perpendicular measurements as a validation.

19f. Special Case (see choices below)

○ No

○ Yes (detail below then proceed to Q19o):
  ○ Complicated Cyst (Note: Do not use this term for "complex cystic masses".
    For complex cystic masses code "no" for Q19f, proceed to Q19g and indicate "complex cystic" at 19k).
  □ Homogenous low-level echoes
  □ Fluid debris level
  □ Mobile internal echoes
  □ Multiple bilateral complicated cysts in company of simple cysts
  ○ Multiple bilateral solid oval, circumscribed masses
  ○ Mass in or on skin
  ○ Clustered microcysts
  ○ Intraductal mass
  ○ Lymph node
  ○ Calcifications without a mass
  ○ Foreign body
  ○ Post-surgical scar
  ○ Other, specify _________________________________

19g. Shape

○ Oval

○ Two or three gentle lobulations

○ Round

○ Irregular

19h. Orientation

○ Parallel to skin

○ Not parallel (includes round)

19i. Margin

○ Circumscribed

○ Not circumscribed (If not circumscribed, choose dominant feature)
  □ Indistinct
  □ Angular
  □ Microlobulated
  □ Spiculated

19j. Boundary Zone

○ Abrupt Interface

○ Echogenic Halo
19k. Echo Pattern
- Anechoic
- Hyperechoic
- Complex cystic
- Hypoechoic with few tiny cystic areas
- Isoechoic to fat
- Mixed hyperechoic and hypoechoic
- Hypoechoic to fat

19l. Posterior Features
- None
- Enhancement
- Combined shadowing/enhancement
- Shadowing

19m. Surrounding Tissue
- No effect
- Effect (check all that apply)
  - Duct changes
  - Edema
  - Cooper’s ligament distortion
  - Architectural distortion
  - Skin thickening
  - Skin retraction

19n. Vascularity (flow)
- None
- Yes (check all that apply)
  - Present in lesion
  - Present immediately adjacent to lesion
  - Increased in surrounding tissue
- Not performed

19o. Calcifications on ultrasound
- None
- Present (check all that apply)
  - Macrocalcifications (> 0.5 mm)
  - Microcalcifications in mass
  - Microcalcifications outside mass

19p. Was lesion palpable in retrospect during sonography?
- No
- Yes, in retrospect
- Yes, participant presented with lump

20. Is this lesion at the site of prior biopsy?
- No (proceed to Q21)
- Yes (if yes, select procedure)
  - Core/vacuum biopsy site with clip
  - Core/vacuum biopsy site without marker
  - Surgical biopsy site (select diagnosis)
    - Benign
    - Atypical/high-risk lesion
    - Cancer site
    - Unknown
    - Biopsy details unknown
    - FNAB
    - Not applicable, multiple bilateral circumscribed masses

21. Assessment/Recommendations (by lesion)

21a. % likelihood of malignancy for this lesion (best guess from 0-100)

21b. Assessment for this lesion
- 1 Negative
- 2 Benign
- 3 Probably Benign
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion
- 5 Highly Suggestive of Malignancy

21c. Recommendation(s) for this lesion
- Routine screening in 1 year
- Diagnostic follow-up in 1 year
- Short-interval follow-up in 6 months with US
- Short-interval follow-up in 6 months with mammography
- Short-interval follow-up in 6 months with MRI
- Intervention and/or Additional Imaging
  - Intervention
    - Aspiration with core biopsy if solid
    - US-guided core biopsy
    - Vacuum-assisted biopsy, guidance by US
    - Vacuum-assisted biopsy, guidance by mammography
    - Excisional biopsy
    - Vacuum-assisted biopsy, guided by MRI
  - Additional Imaging
    - Targeted ultrasound (lesion seen on mammography)
    - Comparison to prior mammogram is required
    - Additional mammographic projections

21d. Is this lesion assessed as probably benign AND recommended for intervention?
- No (proceed to Q22)
- Yes (specify dominant reason)
  - Participant preference
  - Cancer present now
    - In this breast
    - In opposite breast
  - Patient risks factors
  - Vaguely palpable
  - Follow-up not reasonable
  - Interval increase (>20% in volume for masses)
  - Interval suspicious change
  - Investigator uncertainty

22. Are there additional lesion(s) you wish to describe?
- No (proceed to Q16)
- Yes (proceed to Section IIC)
II. Results (by lesion)

Please complete Mammographic Lesion Description and Sonographic Lesion Description for each lesion to be described based on the ID or MX form, and/or clinical findings even if the additional imaging revealed no abnormalities.

II C. Lesion # from prior MRI: [G] (e.g. GR1, GL1, GL2, etc.)
(if not applicable code 998)

23. Mammographic Lesion Description

23a. Were additional mammographic views obtained directed to this finding?
- No (specify reason and proceed to Q24)
  - Not recommended
  - Participant refused
  - Not needed after targeted US
  - Scheduling constraints; participant rescheduled
  - Other
- Yes (check all that apply)
  - Spot compression
  - True lateral
  - Laterally exaggerated CC
  - Magnification views
  - Rolled views
  - Repeat CC or MLO or both

23b. Was lesion seen on additional mammographic view(s)?
- No e.g. resolved on additional views (complete then proceed to Q24)
  - Lesion # from prior mammogram [M]
    (if not applicable code 998)
  - Lesion # from prior ultrasound [U]
    (if not applicable code 998)
- Yes

23c. Was lesion enumerated on any prior study mammogram?
- No and not visible in retrospect
  (assign next sequential mammogram lesion #)
- No but now visible in retrospect
  (assign next sequential mammogram lesion #)
  - New lesion # [M]
- Yes
  - Lesion # from prior mammogram: [M]
    (e.g. MR1, MB1, ML1, MR2, etc.)

23d. Was lesion enumerated on any prior study ultrasound?
- No
  - Simple cyst
  - Not a simple cyst
- Yes (complete)
  - Lesion # from ultrasound: [U]
    (e.g. UR1, UB1, UL1, UR2, etc.)

23e. Location on Mammography: (check all that apply)

Note: for multiple bilateral findings with similar appearances, check "bilateral, multiple" and indicate specific location and size of the largest such finding.

- Right breast
- Left breast
- Bilateral, multiple
- Axillary tail
- Retroareolar
- Upper
- Lower
- Inner
- Outer
- Central

23f. Distance from nipple [ ] cm by Mammography

23g. Size of lesion by Mammography:

[ ] mm X [ ] mm
(largest diameter) (largest perpendicular dimension)

23h. Lesion Description Mammography
(check all that apply)

- Mass (select worse margin feature present)
  - Circumscribed
  - Fat-containing
  - Not fat-containing
  - Microlobulated
  - Obscured
  - Indistinct
  - Spiculated
- Asymmetry (code type of asymmetry)
  - Focal
  - Asymmetry seen on
    - One view
    - Both views
  - Global
- Calcifications (code morphology and distribution)
  - Morphology of calcifications (check all that apply)
    - Coarse typically benign
    - Milk of calcium
    - Coarse heterogeneous
    - Punctate (<0.5 mm, uniformly round)
    - Amorphous/Indistinct
    - Pleomorphic
    - Branching/Fine linear
  - Distribution of calcifications (check all that apply)
    - Clustered
    - Multiple clusters (same morphology)
    - Regional
    - Linear
    - Segmental
    - Diffuse scattered
    - In mass or asymmetry
    - Architectural Distortion

24. Sonographic Lesion Description

24a. Was ultrasound performed again directed to this lesion?
- No (specify reason and proceed to Q25)
  - Not recommended
  - Participant refused
  - Not needed after additional mammographic views
  - Scheduling constraints; participant rescheduled
  - Other
- Yes (check all that apply)
  - Targeted only
  - Whole breast

24b. Was lesion seen on this Ultrasound?
- No (complete then proceed to Q25)
  - Lesion # from prior mammogram [M]
    (if not applicable code 998)
  - Lesion # from prior ultrasound [U]
    (if not applicable code 998)
- Yes

24c. Was lesion enumerated on any prior study ultrasound?
- No (complete)
  - Simple cyst (proceed to Q25)
  - Not a simple cyst and not visible in retrospect
    (assign next sequential sonogram lesion #)
  - Not a simple cyst and now visible in retrospect
    (assign next sequential sonogram lesion #)
  - New lesion # [U]
- Yes (complete)
  - Lesion # from prior ultrasound: [U]
    (e.g. UR1, UB1, UL1, UR2, etc.)

Was lesion enumerated on any study mammogram (including additional views obtained today)?

- No
- Yes (complete)
  - Lesion # from mammogram or additional view number: [M]
    (e.g. MR1, MB1, ML1, MR2, etc.)
24d. □ Check if this "lesion" is multiple bilateral circumscribed masses. Describe largest mass in Q24d and Q24e then proceed to Q24f.

Clockface

Breast (report on 1/2 hour)
(report on hour and 1/2 hour
e.g. 7:00 = 0700, 12:30 = 1230)

R o L o' clock cm cm

Distance from
the nipple

Depth from skin to
center of lesion
(to nearest 0.5 cm)

24e. Lesion Size

Largest
Horizontal Meas (mm) D1 Measured Plane

Vertical A–P meas (mm) D2

Horizontal Perpendicular Meas (mm) D3 Second
Measured Plane

Volume D1XD2XD3 ÷ 2

O Sag
O Rad
O Arad
O Oblique

XX

Depth from skin to center of lesion (to nearest 0.5 cm)

24f. Special Case (see choices below)

O No
O Yes (detail below then proceed to Q24o)

- Complicated Cyst (Note: Do not use this term for "complex cystic masses". For complex cystic masses code "no" for Q24f, proceed to Q24g and indicate "complex cystic" at 24k).
- Homogenous low-level echoes
- Fluid debris level
- Mobile internal echoes
- Multiple bilateral complicated cysts in company of simple cysts
- Multiple bilateral solid oval, circumscribed masses
- Mass in or on skin
- Clustered microcysts
- Intraductal mass
- Lymph node
- Calcifications without a mass
- Foreign body
- Post-surgical scar
- Other, specify

24g. Shape

O Oval
O Two or three gentle lobulations
O Round
O Irregular

24h. Orientation

O Parallel to skin
O Not parallel (includes round)

24i. Margin

O Circumscribed
O Not circumscribed (If not circumscribed, choose dominant feature)
○ Indistinct
○ Angular
○ Microlobulated
○ Spiculated

24j. Boundary Zone

O Abrupt Interface
O Echogenic Halo

Note: Volume is programmed to be calculated on line; however, as verification, please calculate volume based on horizontal, vertical and perpendicular measurements as a validation.
### Section III.

#### 26. Assessment/Recommendations (by lesion)

26a. **% likelihood of malignancy for this lesion** (best guess from 0-100)

26b. **Assessment for this lesion**
- 1 Negative
- 2 Benign
- 3 Probably Benign
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion
- 5 Highly Suggestive of Malignancy

26c. **Recommendation(s) for this lesion**
- Routine screening in 1 year
- Diagnostic follow-up in 1 year
- Short-interval follow-up in 6 months with US
- Short-interval follow-up in 6 months with mammography
- Intervention and/or Additional Imaging
  - Aspiration with core biopsy if solid
  - US-guided core biopsy
  - Vacuum-assisted biopsy, guidance by US
  - Vacuum-assisted biopsy, guidance by mammography
  - Excisional biopsy
  - Vacuum-assisted biopsy, guided by MRI
- Additional Imaging
  - Targeted ultrasound (lesion seen on mammography)
  - Comparison to prior mammogram is required
  - Additional mammographic projections

26d. **Is this lesion assessed as probably benign AND recommended for intervention?**
- No (proceed to Q27)
- Yes (specify dominant reason)
  - Participant preference
  - Cancer present now
  - In this breast
  - In opposite breast
  - Patient risks factors
  - Vaguely palpable
  - Follow-up not reasonable
  - Interval increase (>20% in volume for masses)
  - Interval suspicious change
  - Investigator uncertainty

27. **Are there additional lesion(s) you wish to describe?**
- No (proceed to Q16)
- Yes (proceed to Section IID)
II. Results (by lesion)

Please complete Mammographic Lesion Description and Sonographic Lesion Description for each lesion to be described based on the ID or MX form, and/or clinical findings even if the additional imaging revealed no abnormalities.

II.D. Lesion # from prior MRI: [G] (e.g. GR1, GL1, GL2, etc.) (if not applicable code 998)

28. Mammographic Lesion Description

28a. Were additional mammographic views obtained directed to this finding?
- No (specify reason and proceed to Q29)
- Not recommended
- Participant refused
- Not needed after targeted US
- Scheduling constraints; participant rescheduled
- Other
- Yes (check all that apply)
  - Spot compression
  - True lateral
  - Laterally exaggerated CC
  - Magnification views
  - Rolled views
  - Repeat CC or MLO or both

28b. Was lesion seen on additional mammographic view(s)?
- No e.g. resolved on additional views (complete then proceed to Q29)
  - Lesion # from prior mammogram: [M]
    (if not applicable code 998)
  - Lesion # from prior ultrasound: [U]
    (if not applicable code 998)
  - Yes

28c. Was lesion enumerated on any prior study mammogram?
- No and not visible in retrospect
  (assign next sequential mammogram lesion #)
- No but now visible in retrospect
  (assign next sequential mammogram lesion #)
- New lesion: [M]
  - Yes
  - Lesion # from prior ultrasound: [M]
    (e.g. MR1, MB1, ML1, MR2, etc.)

28d. Was lesion enumerated on any prior study ultrasound?
- No
  - Simple cyst
  - Not a simple cyst
  - Yes (complete)
  - Lesion # from ultrasound: [U]
    (e.g. UR1, UB1, UL1, UR2, etc.)

28e. Location on Mammography: (check all that apply)

Note: for multiple bilateral findings with similar appearances, check "bilateral, multiple" and indicate specific location and size of the largest such finding.
- Right breast
- Left breast
- Bilateral, multiple
- Axillary tail
- Retroareolar

28f. Distance from nipple [ ] cm by Mammography

28g. Size of lesion by Mammography:

[ ] mm X [ ] mm

(largest diameter) (largest perpendicular dimension)

28h. Lesion Description Mammography

(check all that apply)

- Mass (select worse margin feature present)
  - Circumscribed
  - Fat-containing
  - Not fat-containing
  - Microlobulated
  - Obscured
  - Indistinct
  - Spiculated
- Asymmetry (code type of asymmetry)
  - Focal
  - Asymmetry seen on
    - One view
    - Both views
    - Global
- Calcifications (code morphology and distribution)
  - Morphology of calcifications (check all that apply)
    - Coarse typically benign
    - Milk of calcium
    - Coarse heterogeneous
    - Punctate (<0.5 mm, uniformly round)
    - Amorphous/Indistinct
    - Pleomorphic
    - Branching/Fine linear
  - Distribution of calcifications (check all that apply)
    - Clustered
    - Multiple clusters (same morphology)
    - Regional
    - Linear
    - Segmental
    - Diffuse scattered
    - In mass or asymmetry
- Architectural Distortion

29. Sonographic Lesion Description

29a. Was ultrasound performed again directed to this lesion?
- No (specify reason and proceed to Q30)
- Not recommended
- Participant refused
- Not needed after additional mammographic views
- Scheduling constraints; participant rescheduled
- Other
- Yes (check all that apply)
  - Targeted only
  - Whole breast

29b. Was lesion seen on this Ultrasound?
- No (complete then proceed to Q30)
  - Lesion # from prior mammogram: [M]
    (if not applicable code 998)
  - Lesion # from prior ultrasound: [U]
    (if not applicable code 998)
  - Yes

29c. Was lesion enumerated on any prior study ultrasound?
- No (complete)
  - Simple cyst (proceed to Q30)
  - Not a simple cyst and not visible in retrospect
    (assign next sequential sonogram lesion #)
  - Not a simple cyst and now visible in retrospect
    (assign next sequential sonogram lesion #)
  - New lesion: [U]
    - Yes (complete)
    - Lesion # from prior ultrasound: [U]
      (e.g. UR1, UB1, UL1, UR2, etc.)

Was lesion enumerated on any study mammogram (including additional views obtained today)?
- No
- Yes (complete)
  - Lesion # from mammogram or additional view number: [M]
    (e.g. MR1, MB1, ML1, MR2, etc.)
29d. □ Check if this "lesion" is multiple bilateral circumscribed masses.

Describe largest mass in Q29d and Q29e then proceed to Q29f.

Breast (report on 1/2 hour)

Distance from the nipple (report on hour and 1/2 hour e.g. 7:00 = 0700, 12:30 = 1230)

Clockface o R o L o’ clock

29e. Lesion Size

<table>
<thead>
<tr>
<th>Largest Horizontal Meas (mm) D1</th>
<th>Measured Plane</th>
<th>Vertical A-P meas (mm) D2</th>
<th>Horizontal Perpendicular Meas (mm) D3</th>
<th>Second Measured Plane</th>
<th>Volume D1XD2XD3 ( \div 2 )</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td>mm(^3)</td>
</tr>
</tbody>
</table>

29f. Special Case (see choices below)

O No

O Yes (detail below then proceed to Q29g)

- Complicated Cyst *(Note: Do not use this term for "complex cystic masses". For complex cystic masses code "no" for Q29f, proceed to Q29g and indicate "complex cystic" at 29k).*
  - Homogenous low-level echoes
  - Fluid debris level
  - Mobile internal echoes
  - Multiple bilateral complicated cysts in company of simple cysts

- Multiple bilateral solid oval, circumscribed masses
- Mass in or on skin
- Clustered microcysts
- Intraductal mass
- Lymph node
- Calcifications without a mass
- Foreign body
- Post-surgical scar
- Other, specify ____________________________

29g. Shape

- Oval
- Two or three gentle lobulations
- Round
- Irregular

29h. Orientation

- Parallel to skin
- Not parallel (includes round)

29i. Margin

- Circumscribed
- Not circumscribed (If not circumscribed, choose dominant feature)
  - Indistinct
  - Angular
  - Microlobulated
  - Spiculated

29j. Boundary Zone

- Abrupt Interface
- Echogenic Halo

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29k. Echo Pattern
- Anechoic
- Hyperechoic
- Complex cystic
- Hypoechoic with few tiny cystic areas
- Isoechoic to fat
- Mixed hyperechoic and hypoechoic
- Hypoechoic to fat

29l. Posterior Features
- None
- Enhancement
- Combined shadowing/enhancement
- Shadowing

29m. Surrounding Tissue
- No effect
- Effect (check all that apply)
  - Duct changes
  - Edema
  - Cooper's ligament distortion
  - Architectural distortion
  - Skin thickening
  - Skin retraction

29n. Vascularity (flow)
- None
- Yes (check all that apply)
  - Present in lesion
  - Present immediately adjacent to lesion
  - Increased in surrounding tissue
- Not performed

29o. Calcifications on ultrasound
- None
- Present (check all that apply)
  - Macrocalcifications (> 0.5 mm)
  - Microcalcifications in mass
  - Microcalcifications outside mass

29p. Was lesion palpable in retrospect during sonography?
- No
- Yes, in retrospect
- Yes, participant presented with lump

30. Is this lesion at the site of prior biopsy?
- No (proceed to Q31)
- Yes (if yes, select procedure)
  - Core/vacuum biopsy site with clip
  - Core/vacuum biopsy site without marker
  - Surgical biopsy site (select diagnosis)
    - Benign
    - Atypical/high-risk lesion
    - Cancer site
    - Unknown
    - Biopsy details unknown
    - FNAB
    - Not applicable, multiple bilateral circumscribed masses

31. Assessment/Recommendations (by lesion)

31a. ___ ___ ___ ___ % likelihood of malignancy for this lesion (best guess from 0-100)

31b. Assessment for this lesion
- 1 Negative
- 2 Benign
- 3 Probably Benign
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion
- 5 Highly Suggestive of Malignancy

31c. Recommendation(s) for this lesion
- Routine screening in 1 year
- Diagnostic follow-up in 1 year
- Short-interval follow-up in 6 months with US
- Short-interval follow-up in 6 months with mammography
- Intervention and/or Additional Imaging
  - Intervention
    - Aspiration with core biopsy if solid
    - US-guided core biopsy
    - Vacuum-assisted biopsy, guidance by US
    - Vacuum-assisted biopsy, guidance by mammography
    - Excisional biopsy
    - Vacuum-assisted biopsy, guided by MRI
  - Additional Imaging
    - Targeted ultrasound (lesion seen on mammography)
    - Comparison to prior mammogram is required
    - Additional mammographic projections

31d. Is this lesion assessed as probably benign AND recommended for intervention?
- No (proceed to Q32)
- Yes (specify dominant reason)
  - Participant preference
  - Cancer present now
    - In this breast
    - In opposite breast
  - Patient risks factors
  - Vaguely palpable
  - Follow-up not reasonable
  - Interval increase (>20% in volume for masses)
  - Interval suspicious change
  - Investigator uncertainty

32. Are there additional lesion(s) you wish to describe?
- No (proceed to Q16)
- Yes (proceed to Section IIE)
II. Results (by lesion)

Please complete Mammographic Lesion Description and Sonographic Lesion Description for each lesion to be described based on the ID or MX form, and/or clinical findings even if the additional imaging revealed no abnormalities.

IIE. Lesion # from prior MRI: [G] (e.g. GR1, GL1, GL2, etc.)

(if not applicable code 998)

33. Mammographic Lesion Description

33a. Were additional mammographic views obtained directed to this finding?
- No (specify reason and proceed to Q34)
- Not recommended
- Participant refused
- Not needed after targeted US
- Scheduling constraints; participant rescheduled
- Other
- Yes (check all that apply)

33b. Was lesion seen on additional mammographic view(s)?
- No e.g. resolved on additional views (complete then proceed to Q34)
- Yes (check all that apply)

33c. Was lesion enumerated on any prior study mammogram?
- No and not visible in retrospect
  (assign next sequential mammogram lesion #)
- No but now visible in retrospect
  (assign next sequential mammogram lesion #)
- New lesion #: [M]
  (if not applicable code 998)
- Yes
  
  Lesion # from prior mammogram: [M]
  (if not applicable code 998)

33d. Was lesion enumerated on any prior study ultrasound?
- No
- Simple cyst
- Not a simple cyst
- Yes (complete)

33e. Location on Mammography: (check all that apply)

Note: for multiple bilateral findings with similar appearances, check "bilateral, multiple" and indicate specific location and size of the largest such finding.

- Right breast
- Left breast
- Bilateral, multiple
- Axillary tail
- Retroareolar

33f. Distance from nipple ______ cm by Mammography

33g. Size of lesion by Mammography:

_______ mm X _______ mm

(largest diameter) (largest perpendicular dimension)

33h. Lesion Description Mammography

(check all that apply)

- Mass (select worse margin feature present)
  - Circumscribed
  - Fat-containing
  - Not fat-containing
  - Microlobulated
  - Obscured
  - Indistinct
  - Spiculated
- Asymmetry (code type of asymmetry)
  - Focal
  - Asymmetry seen on
    - One view
    - Both views
  - Global
- Calcifications (code morphology and distribution)
  - Morphology of calcifications (check all that apply)
    - Coarse typically benign
    - Milk of calcium
    - Coarse heterogeneous
    - Punctate (<0.5 mm, uniformly round)
    - Amorphous/Indistinct
    - Pleomorphic
    - Branching/Fine linear
  - Distribution of calcifications (check all that apply)
    - Clustered
    - Multiple clusters (same morphology)
    - Regional
    - Linear
    - Segmental
    - Diffuse scattered
  - In mass or asymmetry
  - Architectural Distortion

34. Sonographic Lesion Description

34a. Was ultrasound performed again directed to this lesion?
- No (specify reason and proceed to Q35)
- Not recommended
- Participant refused
- Not needed after additional mammographic views
- Scheduling constraints; participant rescheduled
- Other
- Yes (check all that apply)

34b. Was lesion seen on this Ultrasound?
- No (complete then proceed to Q35)
- Yes (complete)

34c. Was lesion enumerated on any prior study ultrasound?
- No (complete)
  - Simple cyst (proceed to Q35)
  - Not a simple cyst
  - Not a simple cyst and not visible in retrospect
  - Not a simple cyst and now visible in retrospect
  - New lesion #: [U]
  (assign next sequential sonogram lesion #)
- Yes (complete)
  
  Lesion # from prior ultrasound: [U]
  (if not applicable code 998)
- Yes

34d. Was lesion enumerated on any prior study mammogram
(including additional views obtained today)?
- No
- Yes (complete)

Was lesion enumerated on any study mammogram
(e.g. MR1, MB1, ML1, MR2, etc.)

“Copyright 2007”
34d. □ Check if this "lesion" is multiple bilateral circumscribed masses. Describe largest mass in Q34d and Q34e then proceed to Q34f.

**Clockface**

- **Breast**
- **Distance from the nipple**
  
  (report on hour and 1/2 hour
e.g. 7:00=0700, 12:30=1230)

<table>
<thead>
<tr>
<th>O R</th>
<th>O L</th>
<th>O' clock</th>
<th>cm</th>
<th>cm</th>
</tr>
</thead>
</table>

34e. **Lesion Size**

<table>
<thead>
<tr>
<th>Largest Horizontal Meas (mm)</th>
<th>D1</th>
<th>Measured Plane</th>
<th>Vertical A-P meas (mm)</th>
<th>D2</th>
<th>Horizontal Perpendicular Meas (mm)</th>
<th>D3</th>
<th>Second Measured Plane</th>
</tr>
</thead>
<tbody>
<tr>
<td>o Trv</td>
<td></td>
<td>o Sag</td>
<td>X</td>
<td></td>
<td>o Rad</td>
<td></td>
<td>o Oblique</td>
</tr>
<tr>
<td>o Sag</td>
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<td>o Rad</td>
<td></td>
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<td>o Arad</td>
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</tr>
<tr>
<td>o Arad</td>
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<td></td>
<td></td>
<td></td>
<td>o Oblique</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

34f. **Special Case** (see choices below)

- O No
- O Yes (detail below then proceed to Q34o)
  - O Complicated Cyst *(Note: Do not use this term for "complex cystic masses". For complex cystic masses code "no" for Q34f, proceed to Q34g and indicate "complex cystic" at 34k)."
  - O Homogenous low-level echoes
  - O Fluid debris level
  - O Mobile internal echoes
  - O Multiple bilateral complicated cysts in company of simple cysts
  - O Multiple bilateral solid oval, circumscribed masses
  - O Mass in or on skin
  - O Clustered microcysts
  - O Intraductal mass
  - O Lymph node
  - O Calcifications without a mass
  - O Foreign body
  - O Post-surgical scar
  - O Other, specify ___________________________

34g. **Shape**

- O Oval
- O Two or three gentle lobulations
- O Round
- O Irregular

34h. **Orientation**

- O Parallel to skin
- O Not parallel (includes round)

34i. **Margin**

- O Circumscribed
- O Not circumscribed (If not circumscribed, choose dominant feature)
  - O Indistinct
  - O Angular
  - O Microlobulated
  - O Spiculated

34j. **Boundary Zone**

- O Abrupt Interface
- O Echogenic Halo
34k. Echo Pattern
- Anechoic
- Hyperechoic
- Complex cystic
- Hypoechoic with few tiny cystic areas
- Isoechoic to fat
- Mixed hyperechoic and hypoechoic
- Hypoechoic to fat

34i. Posterior Features
- None
- Enhancement
- Combined shadowing/enhancement
- Shadowing

34m. Surrounding Tissue
- No effect
- Effect (check all that apply)
  - Duct changes
  - Edema
  - Cooper's ligament distortion
  - Architectural distortion
  - Skin thickening
  - Skin retraction

34n. Vascularity (flow)
- None
- Yes (check all that apply)
  - Present in lesion
  - Present immediately adjacent to lesion
  - Increased in surrounding tissue
- Not performed

34o. Calcifications on ultrasound
- None
- Present (check all that apply)
  - Macrocalcifications (> 0.5 mm)
  - Microcalcifications in mass
  - Microcalcifications outside mass

34p. Was lesion palpable in retrospect during sonography?
- No
- Yes, in retrospect
- Yes, participant presented with lump

35. Is this lesion at the site of prior biopsy?
- No (proceed to Q36)
- Yes (if yes, select procedure)
  - Core/vacuum biopsy site with clip
  - Core/vacuum biopsy site without marker
  - Surgical biopsy site (select diagnosis)
    - Benign
    - Atypical/high-risk lesion
    - Cancer site
    - Unknown
    - Biopsy details unknown
    - FNAB
  - Not applicable, multiple bilateral circumscribed masses

36. Assessment/Recommendations (by lesion)

36a. % likelihood of malignancy for this lesion (best guess from 0-100)

36b. Assessment for this lesion
- 1 Negative
- 2 Benign
- 3 Probably Benign
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion
- 5 Highly Suggestive of Malignancy

36c. Recommendation(s) for this lesion
- Routine screening in 1 year
- Diagnostic follow-up in 1 year
- Short-interval follow-up in 6 months with US
- Short-interval follow-up in 6 months with mammo
- Short-interval follow-up in 6 months with MRI
- Intervention and/or Additional Imaging
  - Intervention
    - Aspiration with core biopsy if solid
    - US-guided core biopsy
    - Vacuum-assisted biopsy, guidance by US
    - Vacuum-assisted biopsy, guidance by mammo
    - Excisional biopsy
    - Vacuum-assisted biopsy, guided by MRI
  - Additional Imaging
    - Targeted ultrasound (lesion seen on mammography)
    - Comparison to prior mammogram is required
    - Additional mammographic projections

36d. Is this lesion assessed as probably benign AND recommended for intervention?
- No (proceed to Q37)
- Yes (specify dominant reason)
  - Participant preference
  - Cancer present now
    - In this breast
    - In opposite breast
  - Patient risks factors
  - Vaguely palpable
  - Follow-up not reasonable
  - Interval increase (>20% in volume for masses)
  - Interval suspicious change
  - Investigator uncertainty

37. Are there additional lesion(s) you wish to describe?
- No (proceed to Q16)
- Yes (proceed to Section IIF)
II. Results (by lesion)

Please complete Mammographic Lesion Description and Sonographic Lesion Description for each lesion to be described based on the ID or MX form, and/or clinical findings even if the additional imaging revealed no abnormalities.

IIF. Lesion # from prior MRI: [G] (e.g. GR1, GL1, GL2, etc.) (if not applicable code 998)

38. Mammographic Lesion Description

38a. Were additional mammographic views obtained directed to this finding?
   o No (specify reason and proceed to Q39)
   o Not recommended
   o Participant refused
   o Not needed after targeted US
   o Scheduling constraints; participant rescheduled
   o Other
   o Yes (check all that apply)
     □ R  □ L
     □ Spot compression
     □ True lateral
     □ Laterally exaggerated CC
     □ Magnification views
     □ Rolled views
     □ Repeat CC or MLO or both

38b. Was lesion seen on additional mammographic view(s)?
   o No e.g. resolved on additional views (complete then proceed to Q39)
   o Yes
     Lesion # from prior mammogram: [M]
     (if not applicable code 998)
     Lesion # from prior ultrasound: [U]
     (if not applicable code 998)
   o Yes (check all that apply)

38c. Was lesion enumerated on any prior study mammogram?
   o No and not visible in retrospect
     (assign next sequential mammogram lesion #)
   o No but now visible in retrospect
     (assign next sequential mammogram lesion #)
   o New lesion #
     Lesion # from prior mammogram: [M]
     (e.g. MR1, MB1, ML1, MR2, etc.)
   ○ Yes

38d. Was lesion enumerated on any prior study ultrasound?
   o No
   o Simple cyst
   o Not a simple cyst
   o Yes (complete)
     Lesion # from ultrasound: [U]
     (e.g. UR1, UB1, UL1, UR2, etc.)

38e. Location on Mammography: (check all that apply)

Note: for multiple bilateral findings with similar appearances, check "bilateral, multiple" and indicate specific location and size of the largest such finding.

   o Right breast  o Upper
   o Left breast  o Lower
   □ Bilateral, multiple  o Inner
   □ Axillary tail  o Outer
   □ Retroareolar  o Central

38f. Distance from nipple [_____] cm by Mammography

38g. Size of lesion by Mammography:

[_____] mm X [_____] mm

(largest diameter)  (largest perpendicular dimension)

38h. Lesion Description Mammography

(check all that apply)

Mass (select worse margin feature present)
   o Circumscribed
   o Fat-containing
   o Not fat-containing
   o Microlobulated
   o Obscured
   o Indistinct
   o Spiculated

Asymmetry (code type of asymmetry)
   o Focal
   o Asymmetry seen on
     o One view
     o Both views
   o Global

Calcifications (code morphology and distribution)
   Morphology of calcifications (check all that apply)
     □ Coarse typically benign
     □ Milk of calcium
     □ Coarse heterogeneous
     □ Punctate (<0.5 mm, uniformly round)
     □ Amorphous/Indistinct
     □ Pleomorphic
     □ Branching/Fine linear

Distribution of calcifications (check all that apply)
   □ Clustered
   □ Multiple clusters (same morphology)
   □ Regional
   □ Linear
   □ Segmental
   □ Diffuse scattered
   □ In mass or asymmetry
   □ Architectural Distortion

39. Sonographic Lesion Description

39a. Was ultrasound performed again directed to this lesion?
   o No (specify reason and proceed to Q40)
   o Not recommended
   o Participant refused
   o Not needed after additional mammographic views
   o Scheduling constraints; participant rescheduled
   o Other
   o Yes (check all that apply)

39b. Was lesion seen on this Ultrasound?
   o No (complete then proceed to Q40)
   o Yes
     Lesion # from prior mammogram: [M]
     (if not applicable code 998)
     Lesion # from prior ultrasound: [U]
     (if not applicable code 998)
   o Yes

39c. Was lesion enumerated on any prior study ultrasound?
   o No (complete)
   o Simple cyst (proceed to Q40)
   o Not a simple cyst and not visible in retrospect
     (assign next sequential sonogram lesion #)
   o Not a simple cyst and now visible in retrospect
     (assign next sequential sonogram lesion #)
   o New lesion #
   o Yes (complete)
     Lesion # from prior ultrasound: [U]
     (e.g. UR1, UB1, UL1, UR2, etc.)

Was lesion enumerated on any study mammogram (including additional views obtained today)?
   o No
   o Yes (complete)

   Lesion # from mammogram or additional view number: [M]
   (e.g. MR1, MB1, ML1, MR2, etc.)
39d. □ Check if this "lesion" is multiple bilateral circumscribed masses. Describe largest mass in Q39d and Q39e then proceed to Q39f.

- **Breast (report on 1/2 hour)**
- **Distance from the nipple (report on hour and 1/2 hour)
  e.g. 7:00 = 0700, 12:30 = 1230**

<table>
<thead>
<tr>
<th>○ R</th>
<th>○ L</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>o' clock cm</td>
</tr>
</tbody>
</table>

39e. **Lesion Size**

- **Horizontal**
  - **Meas (mm) D1**
  - **Measured Plane**
    - ○ Trv
    - ○ Sag
    - ○ Rad
    - ○ Arad
    - ○ Oblique

- **Vertical**
  - **A-P meas (mm) D2**

- **Horizontal Perpendicular Meas (mm) D3**

- **Second Measured Plane**
  - ○ Trv
  - ○ Sag
  - ○ Rad
  - ○ Arad
  - ○ Perpendicular Oblique

39f. **Special Case** (see choices below)

- ○ No
- ○ Yes (detail below then proceed to Q39g)
  - ○ Complicated Cyst (Note: Do not use this term for "complex cystic masses".
    For complex cystic masses code "no" for Q39f, proceed to Q39g and indicate "complex cystic" at 39k).
    - ○ Homogenous low-level echoes
    - ○ Fluid debris level
    - ○ Mobile internal echoes
    - ○ Multiple bilateral complicated cysts in company of simple cysts
  - ○ Multiple bilateral solid oval, circumscribed masses
  - ○ Mass in or on skin
  - ○ Clustered microcysts
  - ○ Intraductal mass
  - ○ Lymph node
  - ○ Calculations without a mass
  - ○ Foreign body
  - ○ Post-surgical scar
  - ○ Other, specify ____________________________

39g. **Shape**

- ○ Oval
- ○ Two or three gentle lobulations
- ○ Round
- ○ Irregular

39h. **Orientation**

- ○ Parallel to skin
- ○ Not parallel (includes round)

39i. **Margin**

- ○ Circumscribed
- ○ Not circumscribed (If not circumscribed, choose dominant feature)
  - □ Indistinct
  - □ Angular
  - □ Microlobulated
  - □ Spiculated

39j. **Boundary Zone**

- ○ Abrupt Interface
- ○ Echogenic Halo

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"Copyright 2007"
39k. Echo Pattern
- Anechoic
- Hyperechoic
- Complex cystic
- Hypoechoic with few tiny cystic areas
- Isoechoic to fat
- Mixed hyperechoic and hypoechoic
- Hypoechoic to fat

39l. Posterior Features
- None
- Enhancement
- Combined shadowing/enhancement
- Shadowing

39m. Surrounding Tissue
- No effect
- Effect (check all that apply)
  - Duct changes
  - Edema
  - Cooper's ligament distortion
  - Architectural distortion
  - Skin thickening
  - Skin retraction

39n. Vascularity (flow)
- None
- Yes (check all that apply)
  - Present in lesion
  - Present immediately adjacent to lesion
  - Increased in surrounding tissue
- Not performed

39o. Calcifications on ultrasound
- None
- Present (check all that apply)
  - Macrocalcifications (> 0.5 mm)
  - Microcalcifications in mass
  - Microcalcifications outside mass

39p. Was lesion palpable in retrospect during sonography?
- No
- Yes, in retrospect
- Yes, participant presented with lump

40. Is this lesion at the site of prior biopsy?
- No (proceed to Q41)
- Yes (If yes, select procedure)
  - Core/vacuum biopsy site with clip
  - Surgical biopsy site (select diagnosis)
    - Benign
    - Atypical/high-risk lesion
    - Cancer site
    - Unknown
    - Biopsy details unknown
    - FNAB
- Not applicable, multiple bilateral circumscribed masses

41a. ___ % likelihood of malignancy for this lesion (best guess from 0-100)

41b. Assessment for this lesion
- 1 Negative
- 2 Benign
- 3 Probably Benign
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion
- 5 Highly Suggestive of Malignancy

41c. Recommendation(s) for this lesion
- Routine screening in 1 year
- Diagnostic follow-up in 1 year
- Short-interval follow-up in 6 months with US
- Short-interval follow-up in 6 months with mammography
- Short-interval follow-up in 6 months with MRI
- Intervention and/or Additional Imaging
  - Intervention
    - Aspiration with core biopsy if solid
    - US-guided core biopsy
    - Vacuum-assisted biopsy, guidance by US
    - Vacuum-assisted biopsy, guidance by mammography
    - Excisional biopsy
    - Vacuum-assisted biopsy, guided by MRI
  - Additional Imaging
    - Targeted ultrasound (lesion seen on mammography)
    - Comparison to prior mammogram is required
    - Additional mammographic projections

41d. Is this lesion assessed as probably benign AND recommended for intervention?
- No (proceed to Q42)
- Yes (specify dominant reason)
  - Participant preference
  - Cancer present now
    - In this breast
    - In opposite breast
  - Patient risks factors
  - Vaguely palpable
  - Follow-up not reasonable
  - Interval increase (>20% in volume for masses)
  - Interval suspicious change
  - Investigator uncertainty

42. Are there additional lesion(s) you wish to describe?
- No (proceed to Q16)
- Yes (proceed to Section IIG)
II. Results (by lesion)

Please complete Mammographic Lesion Description and Sonographic Lesion Description for each lesion to be described based on the ID or MX form, and/or clinical findings even if the additional imaging revealed no abnormalities.

IG. Lesion # from prior MRI: (e.g. GR1, GL1, GL2, etc.) (if not applicable code 998)

43. Mammographic Lesion Description

43a. Were additional mammographic views obtained directed to this finding?
   o No (specify reason and proceed to Q44)
   o Not recommended
   o Participant refused
   o Not needed after targeted US
   o Scheduling constraints; participant rescheduled
   o Other
   o Yes (check all that apply)
   R
   L
   Spot compression
   True lateral
   Laterally exaggerated CC
   Magnification views
   Rolled views
   Repeat CC or MLO or both

43b. Was lesion seen on additional mammographic view(s)?
   o No e.g. resolved on additional views (complete then proceed to Q44)
   
   (if not applicable code 998)
   
   Lesion # from prior mammogram: M
   
   (if not applicable code 998)
   
   Lesion # from prior ultrasound: U
   
   (if not applicable code 998)

   o Yes

43c. Was lesion enumerated on any prior study mammogram?
   o No and not visible in retrospect
     (assign next sequential mammogram lesion #)
   o No but now visible in retrospect
     (assign next sequential mammogram lesion #)
   
   New lesion #

   o Yes

   Lesion # from prior mammogram: M
   
   (e.g. MR1, MB1, ML1, MR2, etc.)

43d. Was lesion enumerated on any prior study ultrasound?
   o No
   o Simple cyst
   o Not a simple cyst
   o Yes (complete)
   
   Lesion # from ultrasound: U
   
   (e.g. UR1, UB1, UL1, UR2, etc.)

43e. Location on Mammography: (check all that apply)
   
   Note: for multiple bilateral findings with similar appearances, check "bilateral, multiple" and indicate specific location and size of the largest such finding.

   o Right breast
   o Left breast
   o Bilateral, multiple
   o Axillary tail
   o Retroareolar

43f. Distance from nipple cm by Mammography

43g. Size of lesion by Mammography:
   mm X mm
   (largest diameter) (largest perpendicular dimension)

43h. Lesion Description Mammography
   (check all that apply)
   Mass (select worse margin feature present)
   o Circumscribed
   o Fat-containing
   o Not fat-containing
   o Microlobulated
   o Obscured
   o Indistinct
   o Spiculated

   Asymmetry (code type of asymmetry)
   o Focal
   o Symmetry seen on
     o One view
     o Both views
     o Global

   Calcifications (code morphology and distribution)
   Morphology of calcifications (check all that apply)
   o Coarse typically benign
   o Milk of calcium
   o Coarse heterogeneous
   o Punctate (<0.5 mm, uniformly round)
   o Amorphous/Indistinct
   o Pleomorphic
   o Branching/Fine linear

   Distribution of calcifications (check all that apply)
   o Clumped
   o Multiple clusters (same morphology)
   o Regional
   o Linear
   o Segmental
   o Diffuse scattered
   o In mass or asymmetry
   o Architectural Distortion

44. Sonographic Lesion Description

44a. Was ultrasound performed again directed to this lesion?
   o No (specify reason and proceed to Q45)
   o Not recommended
   o Participant refused
   o Not needed after additional mammographic views
   o Scheduling constraints; participant rescheduled
   o Other
   o Yes (check all that apply)
   Targeted only
   Whole breast

44b. Was lesion seen on this Ultrasound?
   o No (complete then proceed to Q45)
   Lesion # from prior mammogram: M
   (if not applicable code 998)
   Lesion # from prior ultrasound: U
   (if not applicable code 998)

   o Yes

44c. Was lesion enumerated on any prior study ultrasound?
   o No (complete)
   o Simple cyst (proceed to Q45)
   o Not a simple cyst and not visible in retrospect
     (assign next sequential sonogram lesion #)
   o Not a simple cyst and now visible in retrospect
     (assign next sequential sonogram lesion #)
   
   New lesion #

   o Yes (complete)

   Lesion # from prior ultrasound:

   (e.g. UR1, UB1, UL1, UR2, etc.)

Was lesion enumerated on any study mammogram (including additional views obtained today)?
   o No
   o Yes (complete)
   
   Lesion # from mammogram or additional view number:
   (e.g. MR1, MB1, ML1, MR2, etc.)
44d. □ Check if this "lesion" is multiple bilateral circumscribed masses. Describe largest mass in Q44d and Q44e then proceed to Q44f.

**Breast**  **Clockface**  **Distance from the nipple**

(report on hour and 1/2 hour
(e.g. 7:00 = 7, 12:30 = 12.5)

O R O L

_o_ _o_ clock

_cm_ _cm_

**Depth from skin to center of lesion**

(to nearest 0.5 cm)


44e. **Lesion Size**

<table>
<thead>
<tr>
<th>Largest</th>
<th>Measured Plane</th>
<th>Vertical A-P meas (mm)</th>
<th>Horizontal Perpendicular meas (mm)</th>
<th>Second Measured Plane</th>
</tr>
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<tr>
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</table>

**44f. Special Case (see choices below)**

O No

O Yes (detail below then proceed to Q44o)

□ Complicated Cyst (Note: Do not use this term for "complex cystic masses". For complex cystic masses code "no" for Q44f, proceed to Q44g and indicate "complex cystic" at 44k).

□ Homogenous low-level echoes

□ Fluid debris level

□ Mobile internal echoes

□ Multiple bilateral complicated cysts in company of simple cysts

□ Multiple bilateral solid oval, circumscribed masses

□ Mass in or on skin

□ Clustered microcysts

□ Intraductal mass

□ Lymph node

□ Calcifications without a mass

□ Foreign body

□ Post-surgical scar

□ Other, specify ________________

44g. **Shape**

O Oval

O Two or three gentle lobulations

O Round

O Irregular

44h. **Orientation**

O Parallel to skin

O Not parallel (includes round)

44i. **Margin**

O Circumscribed

O Not circumscribed (If not circumscribed, choose dominant feature)

□ Indistinct

□ Angular

□ Microlobulated

□ Spiculated

44j. **Boundary Zone**

O Abrupt Interface

O Echogenic Halo

*Note: Volume is programmed to be calculated on line; however, as verification, please calculate volume based on horizontal, vertical and perpendicular measurements as a validation.*
44k. Echo Pattern
- Anechoic
- Hyperechoic
- Complex cystic
- Hypoechoic with few tiny cystic areas
- Isoechoic to fat
- Mixed hyperechoic and hypoechoic
- Hypoechoic to fat

44i. Posterior Features
- None
- Enhancement
- Combined shadowing/enhancement
- Shadowing

44m. Surrounding Tissue
- No effect
- Effect (check all that apply)
  - Duct changes
  - Edema
  - Cooper's ligament distortion
  - Architectural distortion
  - Skin thickening
  - Skin retraction

44n. Vascularity (flow)
- None
- Yes (check all that apply)
  - Present in lesion
  - Present immediately adjacent to lesion
  - Increased in surrounding tissue
- Not performed

44o. Calcifications on ultrasound
- None
- Present (check all that apply)
  - Macrocalcifications (> 0.5 mm)
  - Microcalcifications in mass
  - Microcalcifications outside mass

44p. Was lesion palpable in retrospect during sonography?
- No
- Yes, in retrospect
- Yes, participant presented with lump

44. Is this lesion at the site of prior biopsy?
- No (proceed to Q46)
- Yes (if yes, select procedure)
  - Core/vacuum biopsy site with clip
  - Core/vacuum biopsy site without marker
  - Surgical biopsy site (select diagnosis)
    - Benign
    - Atypical/high-risk lesion
    - Cancer site
    - Unknown
    - Biopsy details unknown
    - FNAB
    - Not applicable, multiple bilateral circumscribed masses

Section III.

46. Assessment/Recommendations (by lesion)

46a. % likelihood of malignancy for this lesion (best guess from 0-100)

46b. Assessment for this lesion
- 1 Negative
- 2 Benign
- 3 Probably Benign
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion
- 5 Highly Suggestive of Malignancy

46c. Recommendation(s) for this lesion
- Routine screening in 1 year
- Diagnostic follow-up in 1 year
- Short-interval follow-up in 6 months with US
- Short-interval follow-up in 6 months with mammo
- Short-interval follow-up in 6 months with MRI
- Intervention and/or Additional Imaging
  - Aspiration with core biopsy if solid
  - US-guided core biopsy
  - Vacuum-assisted biopsy, guidance by US
  - Vacuum-assisted biopsy, guidance by mammo
  - Excisional biopsy
  - Vacuum-assisted biopsy, guided by MRI

46d. Is this lesion assessed as probably benign AND recommended for intervention?
- No (proceed to Q47)
- Yes (specify dominant reason)
  - Participant preference
  - Cancer present now
  - In this breast
  - In opposite breast
  - Patient risks factors
  - Vaguely palpable
  - Follow-up not reasonable
  - Interval increase (>20% in volume for masses)
  - Interval suspicious change
  - Investigator uncertainty

47. Are there additional lesion(s) you wish to describe?
- No (proceed to Q16)
- Yes (proceed to Section IIH)
II. Results (by lesion)

Please complete Mammographic Lesion Description and Sonographic Lesion Description for each lesion to be described based on the ID or MX form, and/or clinical findings even if the additional imaging revealed no abnormalities.

IIH. Lesion # from prior MRI: [G] (e.g. GR1, GL1, GL2, etc.) (if not applicable code 998)

48. Mammographic Lesion Description

48a. Were additional mammographic views obtained directed to this finding?
   ○ No (specify reason and proceed to Q49)
   ○ Not recommended
   ○ Participant refused
   ○ Not needed after targeted US
   ○ Scheduling constraints; participant rescheduled
   ○ Other
   ○ Yes (check all that apply)

48b. Was lesion seen on additional mammographic view(s)?
   ○ No e.g. resolved on additional views (complete then proceed to Q49)
   ○ Yes

48c. Was lesion enumerated on any prior study mammogram?
   ○ No and not visible in retrospect (assign next sequential mammogram lesion #)
   ○ No but now visible in retrospect (assign next sequential mammogram lesion #)
   ○ New lesion # [M]
   ○ Yes
   ○ Yes (check all that apply)

48d. Was lesion enumerated on any prior study ultrasound?
   ○ No
   ○ Simple cyst
   ○ Not a simple cyst
   ○ Yes (complete)

48e. Location on Mammography: (check all that apply)

   ○ Right breast
   ○ Left breast
   ○ Bilateral, multiple
   ○ Axillary tail
   ○ Retroareolar

48f. Distance from nipple [___] cm by Mammography

48g. Size of lesion by Mammography:
   [___] mm X [___] mm
   (largest diameter) (largest perpendicular dimension)

48h. Lesion Description Mammography
   (check all that apply)

   □ Mass (select worse margin feature present)
     ○ Circumscribed
     ○ Fat-containing
     ○ Not fat-containing
     ○ Microlobulated
     ○ Obscured
     ○ Indistinct
     ○ Spiculated
   □ Asymmetry (code type of asymmetry)
     ○ Focal
     ○ Asymmetry seen on
     ○ One view
     ○ Both views
     ○ Global
   □ Calcifications (code morphology and distribution)
     Morphology of calcifications (check all that apply)
     ○ Coarse typically benign
     ○ Milk of calcium
     ○ Coarse heterogeneous
     ○ Punctate (<0.5 mm, uniformly round)
     ○ Amorphous/Indistinct
     ○ Pleomorphic
     ○ Branching/Fine linear
     Distribution of calcifications (check all that apply)
     ○ Clustered
     ○ Multiple clusters (same morphology)
     ○ Regional
     ○ Linear
     ○ Segmental
     ○ Diffuse scattered
     ○ In mass or asymmetry
     ○ Architectural Distortion

49. Sonographic Lesion Description

49a. Was ultrasound performed again directed to this lesion?
   ○ No (specify reason and proceed to Q50)
   ○ Not recommended
   ○ Participant refused
   ○ Not needed after additional mammographic views
   ○ Scheduling constraints; participant rescheduled
   ○ Other
   ○ Yes (check all that apply)

49b. Was lesion seen on this Ultrasound?
   ○ No (complete then proceed to Q50)
   ○ Yes

49c. Was lesion enumerated on any prior study ultrasound?
   ○ No (complete)
   ○ Simple cyst (proceed to Q50)
   ○ Not a simple cyst and not visible in retrospect (assign next sequential sonogram lesion #)
   ○ Not a simple cyst and now visible in retrospect (assign next sequential sonogram lesion #)
   ○ New lesion # [U]
   ○ Yes (complete)

49d. Location on Sonography: (check all that apply)

   ○ Right breast
   ○ Lower
   ○ Axillary tail
   ○ Central
   ○ Bilateral, multiple

6666  IMb  01-19-07  24 of 26
49d. □ Check if this "lesion" is multiple bilateral circumscribed masses. Describe largest mass in Q49d and Q49e then proceed to Q49f.

Clockface
Breast
(report on 1/2 hour)

Distance from
the nipple
(report on hour and 1/2 hour e.g. 7:00 = 7, 12:30 = 12.5)

0 O L
	
o' clock

Depth from skin to
center of lesion
(to nearest 0.5 cm)

1

1 cm

49e. Lesion Size

Largest
Horizontal
Meas (mm) D1

Measured Plane

Vertical A-P
meas (mm) D2

Horizontal
Perpendicular Meas
(mm) D3

Second
Measured Plane

Volume D1XD2XD3 ÷ 2

mm

mm

mm

mm

mm

mm

Note: Volume is programmed to be calculated on line; however, as verification, please calculate volume based on horizontal, vertical and perpendicular measurements as a validation.

49f. Special Case (see choices below)

O No

O Yes (detail below then proceed to Q49g)

□ Complicated Cyst (Note: Do not use this term for "complex cystic masses.

For complex cystic masses code "no" for Q49f, proceed to Q49g and indicate "complex cystic" at 49k).

□ Homogenous low-level echoes

□ Mobile internal echoes

□ Multiple bilateral complicated cysts in company of simple cysts

□ Multiple bilateral solid oval, circumscribed masses

□ Mass in or on skin

□ Clustered microcysts

□ Intraductal mass

□ Lymph node

□ Calcifications without a mass

□ Foreign body

□ Post-surgical scar

□ Other, specify ________________

49g. Shape

O Oval

□ Two or three gentle lobulations

□ Round

□ Irregular

49h. Orientation

O Parallel to skin

□ Not parallel (includes round)

49i. Margin

O Circumscribed

□ Not circumscribed (If not circumscribed, choose dominant feature)

□ Indistinct

□ Angular

□ Microlobulated

□ Spiculated

49j. Boundary Zone

O Abrupt Interface

O Echogenic Halo
Section III.

51. Assessment/Recommendations (by lesion)

51a. ___________ % likelihood of malignancy for this lesion (best guess from 0-100)

51b. Assessment for this lesion
- 1 Negative
- 2 Benign
- 3 Probably Benign (Q51d required)
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion
- 5 Highly Suggestive of Malignancy

51c. Recommendation(s) for this lesion
- Routine screening in 1 year
- Diagnostic follow-up in 1 year
- Short-interval follow-up in 6 months with US
- Short-interval follow-up in 6 months with mammo
- Short-interval follow-up in 6 months with MRI
- Intervention and/or Additional Imaging (detail intervention and/or additional imaging)
  - Intervention
    - Aspiration with core biopsy if solid
    - US-guided core biopsy
    - Vacuum-assisted biopsy, guidance by US
    - Vacuum-assisted biopsy, guidance by mammo
    - Excisional biopsy
    - Vacuum-assisted biopsy, guided by MRI
  - Additional Imaging
    - Targeted ultrasound (lesion seen on mammography)
    - Comparison to prior mammogram is required
    - Additional mammographic projections

51d. Is this lesion assessed as probably benign AND recommended for intervention?
- No (proceed to Final Assessment(s) Q16, Q17)
- Yes (specify dominant reason)
  - Participant preference
  - Cancer present now
    - In this breast
    - In opposite breast
  - Patient risks factors
  - Vaguely palpable
  - Follow-up not reasonable
  - Interval increase (>20% in volume for masses)
  - Interval suspicious change
  - Investigator uncertainty

Proceed to Final Assessment(s) Q16, Q17.
I. GENERAL INFORMATION

1. Is this form F6 the continuation from additional evaluations reported on another form F6?
   - No
   - Yes

2. Did participant return for the scheduled follow-up?
   - No (specify reason, STOP and sign form)
   - Yes
   - Second opinion, felt not warranted
   - Participant refusal
   - Participant unable to be contacted
   - Unable to be performed and rescheduled
   - Completed
   - Incomplete, will return on __________ (mm-dd-yyyy)

3. Indication for exam(s): (check all that apply)
   - Follow-up mammogram
   - Follow-up ultrasound
   - Clinical abnormalities
   - CAD abnormalities

4. Date study(ies) performed _____-____-______ (mm-dd-yyyy)
   4a. Date of study interpretation _____-____-______ (mm-dd-yyyy)
   4b. Timepoint in study prompting this short-interval follow-up
   - Initial screening
   - 12 month screening
   - 24 month screening
   - Other, specify: ______ months

5. Radiologist ACRIN ID #__________
   5a. Radiologist performing short-interval follow-up (last, first)

6. Which breast(s) are reported on this form?
   - Right Breast
   - Left Breast

7. How many lesions are being followed?
   - For the right breast? [ ] (code 98 if not on study)
   - For the left breast? [ ] (code 98 if not on study)
   7a. Were any new lesions seen on this follow-up mammogram?
      - No (proceed to Q7b)
      - Yes (detail how many)
      - Not applicable, not done (proceed to Q7b)
   7b. Were any new lesions seen on this follow-up ultrasound?
      - No (proceed to Q8a)
      - Yes (detail how many)
      - Not applicable, not done (proceed to Q8a)

8a. Have there been any clinically significant changes in the right breast since the last annual examination?
   - No
   - Yes (check all clinical changes that apply)
   - Palpable mass (complete location)
   - Location of abnormality
     - o Axilla
     - o Retroareolar
     - o Unknown
   - Nipple discharge (detail):
     - o Bloody
     - o Clear spontaneous
     - o Other
   - Other, specify: ______________________
   - Not applicable (not on study) (proceed to Q8b)

8b. Have there been any clinically significant changes in the left breast since the last annual examination?
   - No
   - Yes (check all clinical changes that apply)
   - Palpable mass (complete location)
   - Location of abnormality
     - o Axilla
     - o Retroareolar
     - o Unknown
   - Nipple discharge (detail):
     - o Bloody
     - o Clear spontaneous
     - o Other
   - Other, specify: ______________________
   - Not applicable (not on study) (proceed to Q9)

9. Has the patient had any other evaluation of breast(s) since the last annual study exam(s)?
   - No
   - Yes (check all that apply)
   - Clinical examination
   - Biopsy, already reported
   - Biopsy, not already reported
   - MRI with contrast
     - o Right
     - o Left
     - o Bilateral
     - o Outside US
   - Outside mammogram

10. Comparison studies other than most recent annual mammogram and study US?
    - No available (proceed to Q11)
    - Available (check all that apply)
      - Prior mammography
      - Prior targeted US
      - Prior survey US

"Copyright 2007"
II. Results (by lesion)

Please complete Mammographic Lesion Description and Sonographic Lesion Description for each lesion being followed and for any new findings on this follow-up examination.

11A. Lesion # from prior MRI: [ ] (e.g. GR1, GL1, GL2, etc.)
   (if not applicable code 998)

11. Mammographic Lesion Description

11a. Were mammographic views obtained of this finding on this follow-up evaluation?
   o No (specify reason and proceed to Q12)
   o Not recommended
   o Participant refused
   o Not needed after targeted US
   o Scheduling constraints; participant rescheduled
   o Yes

11b. Change in this lesion from prior mammogram(s)?
   o New
   o Gone (complete then proceed to Q12)
   Lesion # from prior mammogram: [M]
   (if not applicable code 998)
   Lesion # from prior ultrasound: [U]
   (if not applicable code 998)
   o Decreasing
   o Stable
   o Fluctuating bilateral circumscribed masses
   o Increasing
   o Other suspicious change(s)
   o Increasing and other suspicious change(s)

11c. Was lesion enumerated on any prior study mammogram?
   o No and not visible in retrospect
     Assign next sequential mammogram lesion #
   o No but now visible in retrospect
     Assign next sequential mammogram lesion #
   o Yes
     Lesion # from prior mammogram: [M]
     (e.g. MR1, MB1, ML1, MR2, etc.)

11d. Was lesion enumerated on any prior study ultrasound?
   o No
   o Simple cyst
     Assign next sequential ultrasound lesion #
   o Yes (complete)
     Lesion # from ultrasound: [U]
     (e.g. UR1, UB1, UL1, UR2, etc.)

11e. Location on Mammography: (check all that apply)

   Note: for multiple bilateral findings with similar appearances, check “bilateral, multiple” and indicate specific location and size of the largest such finding.

   o Right breast
   o Left breast
   o Bilateral, multiple
   o Axillary tail
   o Retroareolar
   o Upper
   o Lower
   o Inner
   o Outer

11f. Distance from nipple [ ] cm by Mammography

11g. Size of lesion by Mammography:
   [ ] mm x [ ] mm
   (largest diameter) (largest perpendicular dimension)

12. Sonographic Lesion Description

12a. Was ultrasound performed of this lesion on this follow-up evaluation?
   o No (specify reason and proceed to Q13)
   o Not recommended
   o Participant refused
   o Not needed after additional mammographic views
   o Scheduling constraints; participant rescheduled
   o Other
   o Yes (check all that apply)
     o Targeted only
     o Whole breast

12b. Change in this lesion from prior ultrasound?
   o New
   o Gone (complete then proceed to Q13)
   Lesion # from prior mammogram: [M]
   (if not applicable code 998)
   Lesion # from prior ultrasound: [U]
   (if not applicable code 998)
   o Decreasing
   o Stable
   o Fluctuating bilateral circumscribed masses
   o Increasing
   o Other suspicious change(s)
   o Increasing and other suspicious change(s)

12c. Was lesion enumerated on any prior study ultrasound?
   o No (complete)
     Assign next sequential sonogram lesion #
   o Simple cyst
     Proceed to Q13
   o Not a simple cyst and not visible in retrospect
     Assign next sequential sonogram lesion #
   o Not a simple cyst and now visible in retrospect
     Assign next sequential sonogram lesion #
   o Yes (complete)
     Lesion # from prior ultrasound: [U]
     (e.g. UR1, UB1, UL1, UR2, etc.)

12d. Was lesion enumerated on any study mammogram (including views obtained today)?
   o No
   o Yes (complete)
     Lesion # from mammogram: [M]
     (e.g. MR1, MB1, ML1, MR2, etc.)
12e. □ Check if this "lesion" is multiple bilateral circumscribed masses. Describe largest mass in Q12e and Q12f then proceed to Q12g.

Breast (report on hour and 1/2 hour) (report on hour and 1/2 hour

<table>
<thead>
<tr>
<th>Orientation</th>
<th>Distance from the nipple (to nearest 0.5 cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>O R O L</td>
<td>cm</td>
</tr>
</tbody>
</table>

12f. Lesion Size

<table>
<thead>
<tr>
<th>Breast</th>
<th>Largest Horizontal Meas (mm) D1</th>
<th>Measured Plane</th>
<th>Vertical A-P meas (mm) D2</th>
<th>Horizontal Perpendicular Meas (mm) D3</th>
<th>Second Measured Plane</th>
<th>Volume D1XD2XD3 = 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>mm</td>
<td></td>
<td>X mm</td>
<td>mm</td>
<td>mm</td>
<td>mm3</td>
</tr>
</tbody>
</table>

12g. Special Case (see choices below)

- No
- Yes (detail below then proceed to Q12p)
  - Complicated Cyst (Note: Do not use this term for "complex cystic masses". For complex cystic masses code "no" for Q12g, proceed to Q12h and indicate "complex cystic" at 12i).
  - Homogenous low-level echoes
  - Fluid debris level
  - Mobile internal echoes
  - Multiple bilateral complicated cysts in company of simple cysts
  - Multiple bilateral solid oval, circumscribed masses
  - Mass in or on skin
  - Clustered microcysts
  - Intraductal mass
  - Lymph node
  - Calcifications without a mass
  - Foreign body
  - Post-surgical scar
  - Other, specify ____________________________

12h. Shape

- Oval
- Two or three gentle lobulations
- Round
- Irregular

12i. Orientation

- Parallel to skin
- Not parallel (includes round)

12j. Margin

- Circumscribed
- Not circumscribed (If not circumscribed, choose dominant feature)
  - Indistinct
  - Angular
  - Microlobulated
  - Spiculated

12k. Boundary Zone

- Abrupt Interface
- Echogenic Halo

Note: Volume is programmed to be calculated on line; however, as verification, please calculate volume based on horizontal, vertical and perpendicular measurements as a validation.
12. **Echo Pattern**
   - Anechoic
   - Hyperechoic
   - Complex cystic
   - Hypoechoic with few tiny cystic areas
   - Isoechoic to fat
   - Mixed hyperechoic and hypoechoic
   - Hypoechoic to fat

12m. **Posterior Features**
   - None
   - Enhancement
   - Combined shadowing/enhancement
   - Shadowing

12n. **Surrounding Tissue**
   - No effect
   - Effect (check all that apply)
     - Duct changes
     - Edema
     - Cooper's ligament distortion
     - Architectural distortion
     - Skin thickening
     - Skin retraction

12o. **Vascularity (flow)**
   - None
   - Yes (check all that apply)
     - Present in lesion
     - Present immediately adjacent to lesion
     - Increased in surrounding tissue
   - Not performed

12p. **Calcifications on ultrasound**
   - None
   - Present (check all that apply)
     - Macrocalcifications (> 0.5 mm)
     - Microcalcifications in mass
     - Microcalcifications outside mass

12q. **Was lesion palpable in retrospect during sonography?**
   - No
   - Yes, in retrospect
   - Yes, participant presented with lump

13. **Is this lesion at the site of prior biopsy?**
   - No (proceed to Q14)
   - Yes (If yes, select procedure)
     - Core/vacuum biopsy site with clip
     - Core/vacuum biopsy site without marker
     - Surgical biopsy site (select diagnosis)
       - Benign
       - Atypical/high-risk lesion
       - Cancer site
       - Unknown
       - Biopsy details unknown
       - FNAB
     - Not applicable, multiple bilateral circumscribed masses

Section III.

14. **Assessment/Recommendations**

14a. [ ] [ ] [ ] % likelihood of malignancy for this lesion (best guess from 0-100)

14b. **Assessment for this lesion**
   - 1 Negative
   - 2 Benign
   - 3 Probably Benign
   - 4A Low Suspicion of Malignancy
   - 4B Intermediate Suspicion
   - 4C Moderately High Suspicion
   - 5 Highly Suggestive of Malignancy

14c. **Known benign by prior biopsy?**
   - No (proceed to Q14d)
   - Yes (complete)
     - < 1 year ago
     - 1-2 years ago
     - > 2 years ago

14d. **Recommendation(s) for this lesion**
   - Return to routine screening
   - Diagnostic follow-up to coincide with next annual exam
   - Short-interval follow-up in 6 months with US
   - Short-interval follow-up in 6 months with mammography
   - Short-interval follow-up in 6 months with MRI
   - Intervention and/or Additional Imaging
     - detail intervention and/or additional imaging
       - Intervention
         - Aspiration with core biopsy if solid
         - US-guided core biopsy
         - Vacuum-assisted biopsy, guidance by US
         - Vacuum-assisted biopsy, guidance by mammo
         - Excisional biopsy
         - US-guided biopsy, if US negative, MRI guided biopsy
       - Additional Imaging
         - Targeted ultrasound (lesion seen on mammography)
         - Comparison to prior mammogram is required
         - Additional mammographic projections

14e. **Is this lesion assessed as probably benign AND recommended for intervention?**
   - No (proceed to Q15)
   - Yes (specify dominant reason)
     - Participant preference
     - Cancer present now
       - In this breast
       - In opposite breast
       - Patient risks factors
       - Vaguely palpable
       - Follow-up not reasonable
       - Interval increase (>20% in volume for masses)
       - Interval suspicious change
       - Investigator uncertainty

15. **Are there additional lesion(s) you wish to describe?**
   - No (proceed to Q16)
   - Yes (proceed to Q18)
Section IV. Overall Assessment

16. Final Assessment of Right Breast
   □ No additional evaluation of Right Breast, see IA and IS (proceed to Q17)
   
   Note: Final assessment should be based on the worst lesion present, even if that lesion did not undergo additional evaluation.

16a. _______ % Likelihood of malignancy for this breast (best guess from 0-100)

16b. Assessment for this breast
   o 1 Negative
   o 2 Benign
   o 3 Probably Benign
   o 4A Low Suspicion of Malignancy
   o 4B Intermediate Suspicion
   o 4C Moderately High Suspicion
   o 5 Highly Suggestive of Malignancy

16c. Recommendation for this breast
   o Return to routine screening
   o Diagnostic follow-up to coincide with next annual exam
   □ Short-interval follow-up in 6 months with US
   □ Short-interval follow-up in 6 months with mammography
   □ Short-interval follow-up in 6 months with MRI
   o Intervention and/or Additional Imaging
     (detail intervention and/or additional imaging)
     □ Intervention
       o Aspiration with core biopsy if solid
       o US-guided core biopsy
       o Vacuum-assisted biopsy, guidance by US
       o Vacuum-assisted biopsy, guidance by mammo
       o Excisional biopsy
       o US-guided biopsy, if US negative, MRI guided biopsy
     □ Additional Imaging
       □ Additional evaluation
         □ Comparison to prior mammogram is required
         □ Targeted ultrasound
           (lesion seen on mammography)
         □ Additional mammographic projections
       □ Repeat ultrasound
       □ Technique/interpretation in question
       □ Possibly abnormal
       □ Repeat mammogram
       □ Incomplete
       □ Motion artifact/other technical problem

17. Final Assessment of Left Breast
   □ No additional evaluation of Left Breast, see IA and IS (sign and date form)
   
   Note: Final assessment should be based on the worst lesion present, even if that lesion did not undergo additional evaluation.

17a. _______ % Likelihood of malignancy for this breast (best guess from 0-100)

17b. Assessment for this breast
   o 1 Negative
   o 2 Benign
   o 3 Probably Benign
   o 4A Low Suspicion of Malignancy
   o 4B Intermediate Suspicion
   o 4C Moderately High Suspicion
   o 5 Highly Suggestive of Malignancy

17c. Recommendation for this breast
   o Return to routine screening
   o Diagnostic follow-up to coincide with next annual exam
   □ Short-interval follow-up in 6 months with US
   □ Short-interval follow-up in 6 months with mammography
   □ Short-interval follow-up in 6 months with MRI
   o Intervention and/or Additional Imaging
     (detail intervention and/or additional imaging)
     □ Intervention
       o Aspiration with core biopsy if solid
       o US-guided core biopsy
       o Vacuum-assisted biopsy, guidance by US
       o Vacuum-assisted biopsy, guidance by mammo
       o Excisional biopsy
       o US-guided biopsy, if US negative, MRI guided biopsy
     □ Additional Imaging
       □ Additional evaluation
         □ Comparison to prior mammogram is required
         □ Targeted ultrasound
           (lesion seen on mammography)
         □ Additional mammographic projections
           □ Repeat ultrasound
           □ Technique/interpretation in question
           □ Possibly abnormal
           □ Repeat mammogram
           □ Incomplete
           □ Motion artifact/other technical problem

Stop: Form complete, sign and date below.
II. Results (by lesion)

Please complete Mammographic Lesion Description and Sonographic Lesion Description for each lesion being followed and for any new findings on this follow-up examination.

18A. Lesion # from prior MRI: [ ]

(e.g. GR1, GL1, GL2, etc.)

(if not applicable code 998)

18. Mammographic Lesion Description

18a. Were mammographic views obtained of this finding on this follow-up evaluation?

- No (specify reason and proceed to Q19)
  - Not recommended
  - Participant refused
  - Not needed after targeted US
  - Scheduling constraints; participant rescheduled
  - Other
  - Yes

18b. Change in this lesion from prior mammogram(s)?

- New
  - Gone (complete then proceed to Q19)
  - Decreasing
  - Stable
  - Fluctuating bilateral circumscribed masses
  - Increasing
  - Other suspicious change(s)
  - Increasing and other suspicious change(s)

18c. Was lesion enumerated on any prior study mammogram?

- No and not visible in retrospect
  - New lesion #
  - (assign next sequential mammogram lesion #)
- No but now visible in retrospect
  - (assign next sequential mammogram lesion #)
  - New lesion #
  - (assign next sequential mammogram lesion #)
- Yes
  - lesion # from prior mammogram:

18d. Was lesion enumerated on any prior study ultrasound?

- No
  - Simple cyst
  - Not a simple cyst
  - Yes (complete)
  - (assign next sequential mammogram lesion #)
  - (assign next sequential mammogram lesion #)

18e. Location on Mammography: (check all that apply)

Note: for multiple bilateral findings with similar appearances, check “bilateral, multiple” and indicate specific location and size of the largest such finding.

- Right breast
- Left breast
- Bilateral, multiple
- Axillary tail
- Retroareolar
- Upper
- Lower
- Inner
- Outer
- Central

18f. Distance from nipple [ ] cm by Mammography

18g. Size of lesion by Mammography:

[ ] mm X [ ] mm

(largest diameter) (largest perpendicular dimension)

18h. Lesion Description Mammography

(check all that apply)

- Mass (select worse margin feature present)
  - Circumscribed
  - Fat-containing
  - Not fat-containing
  - Microlobulated
  - Obscured
  - Indistinct
  - Spiculated
  - Asymmetry (code type of asymmetry)
  - Focal
  - Asymmetry seen on
  - One view
  - Both views
  - Global
  - Calcinifications (code morphology and distribution)
    - Morphology of calcifications (check all that apply)
      - Coarse typically benign
      - Milk of calcium
      - Coarse heterogeneous
      - Punctate (<0.5 mm, uniformly round)
      - Amorphous/Indistinct
      - Pleomorphic
      - Branching/Fine linear
    - Distribution of calcifications (check all that apply)
      - Clustered
      - Multiple clusters (same morphology)
      - Regional
      - Linear
      - Segmental
      - Diffuse scattered
      - In mass or asymmetry
      - Architectural Distortion

19. Sonographic Lesion Description

19a. Was ultrasound performed of this lesion on this follow-up evaluation?

- No (specify reason and proceed to Q20)
  - Not recommended
  -Participant refused
  - Not needed after additional mammographic views
  - Scheduling constraints; participant rescheduled
  - Other
  - Yes (check all that apply)
    - Targeted only
    - Whole breast

19b. Change in this lesion from prior ultrasound?

- New
  - Gone (complete then proceed to Q20)
  - Decreasing
  - Stable
  - Fluctuating bilateral circumscribed masses
  - Increasing
  - Other suspicious change(s)
  - Increasing and other suspicious change(s)

19c. Was lesion enumerated on any prior study ultrasound?

- No
  - Simple cyst
  - Not a simple cyst
  - Not visible in retrospect
  - (assign next sequential sonogram lesion #)
  - Not a simple cyst and now visible in retrospect
  - (assign next sequential sonogram lesion #)
  - New lesion #
  - (assign next sequential sonogram lesion #)

19d. Was lesion enumerated on any study mammogram (including views obtained today)?

- No
  - Simple cyst (proceed to Q20)
  - Not a simple cyst and not visible in retrospect
  - (assign next sequential sonogram lesion #)
  - Not a simple cyst and now visible in retrospect
  - (assign next sequential sonogram lesion #)
  - New lesion #
  - (assign next sequential sonogram lesion #)

19e. Location on Sonography: (check all that apply)

Note: for multiple bilateral findings with similar appearances, check “bilateral, multiple” and indicate specific location and size of the largest such finding.

- Right breast
- Left breast
- Bilateral, multiple
- Axillary tail
- Retroareolar
- Upper
- Lower
- Inner
- Outer
- Central

19f. Distance from nipple [ ] cm by Sonography

19g. Size of lesion by Sonography:

[ ] mm X [ ] mm

(largest diameter) (largest perpendicular dimension)
19e. □ Check if this "lesion" is multiple bilateral circumscribed masses. Describe largest mass in Q19e and Q19f then proceed to Q19g.

Breast Clockface Distance from Depth from skin to
(report on 1/2 hour) the nipple center of lesion
(report on hour and and 1/2 hour to nearest 0.5 cm)

e.g. 7:00 = 0700, 12:30 = 1230)
0 R 0 L o’ clock cm cm cm

19f. Lesion Size

<table>
<thead>
<tr>
<th>Largest Horizontal Meas (mm) D1</th>
<th>Measured Plane</th>
<th>Vertical A-P meas (mm) D2</th>
<th>Horizontal Perpendicular Meas (mm) D3</th>
<th>Measured Plane</th>
<th>Volume D1XD2XD3 ÷ 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>mm</td>
<td></td>
<td>X mm X</td>
<td>mm</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

19g. Special Case (see choices below)

- No
- Yes (detail below then proceed to Q19p)
  - Complicated Cyst (Note: Do not use this term for "complex cystic masses".
    For complex cystic masses code "no" for Q19g, proceed to Q19h and indicate "complex cystic" at 19l).
    - Homogenous low-level echoes
    - Fluid debris level
    - Mobile internal echoes
    - Multiple bilateral complicated cysts in company of simple cysts
    - Multiple bilateral solid oval, circumscribed masses
    - Mass in or on skin
    - Clustered microcysts
    - Intraductal mass
    - Lymph node
    - Calcifications without a mass
    - Foreign body
    - Post-surgical scar
    - Other, specify _____________________________

19h. Shape

- Oval
- Two or three gentle lobulations
- Round
- Irregular

19i. Orientation

- Parallel to skin
- Not parallel (includes round)

19j. Margin

- Circumscribed
- Not circumscribed (If not circumscribed, choose dominant feature)
  - Indistinct
  - Angular
  - Microlobulated
  - Spiculated

19k. Boundary Zone

- Abrupt Interface
- Echogenic Halo

Note: Volume is programmed to be calculated on line; however, as verification, please calculate volume based on horizontal, vertical and perpendicular measurements as a validation.
19. **Echo Pattern**
   - Anechoic
   - Hyperechoic
   - Complex cystic
   - Hypoechoic with few tiny cystic areas
   - Isoechoic to fat
   - Mixed hyperechoic and hypoechoic
   - Hypoechoic to fat

19m. **Posterior Features**
   - None
   - Enhancement
   - Combined shadowing/enhancement
   - Shadowing

19n. **Surrounding Tissue**
   - No effect
   - Effect (check all that apply)
     - Duct changes
     - Edema
     - Cooper’s ligament distortion
     - Architectural distortion
     - Skin thickening
     - Skin retraction

19o. **Vascularity (flow)**
   - None
   - Yes (check all that apply)
     - Present in lesion
     - Present immediately adjacent to lesion
     - Increased in surrounding tissue
   - Not performed

19p. **Calcifications on ultrasound**
   - None
   - Present (check all that apply)
     - Macrocalcifications (> 0.5 mm)
     - Microcalcifications in mass
     - Microcalcifications outside mass

19q. **Was lesion palpable in retrospect during sonography?**
   - No
   - Yes, in retrospect
   - Yes, participant presented with lump

20. **Is this lesion at the site of prior biopsy?**
   - No (proceed to Q21)
   - Yes (If yes, select procedure)
     - Core/vacuum biopsy site with clip
     - Core/vacuum biopsy site without marker
     - Surgical biopsy site (select diagnosis)
       - Benign
       - Atypical/high-risk lesion
       - Cancer site
       - Unknown
       - Biopsy details unknown
       - FNAB
       - Not applicable, multiple bilateral circumscribed masses

---

**Section III.**

21. **Assessment/Recommendations**

   21a. __________ % likelihood of malignancy for this lesion (best guess from 0-100)

   21b. **Assessment for this lesion**
   - 1 Negative
   - 2 Benign
   - 3 Probably Benign
   - 4A Low Suspicion of Malignancy
   - 4B Intermediate Suspicion
   - 4C Moderately High Suspicion
   - 5 Highly Suggestive of Malignancy

   21c. **Known benign by prior biopsy?**
   - No (proceed to Q21d)
   - Yes (complete)
     - < 1 year ago
     - 1-2 years ago
     - > 2 years ago

   21d. **Recommendation(s) for this lesion**
   - Return to routine screening
   - Diagnostic follow-up to coincide with next annual exam
   - Short-interval follow-up in 6 months with US
   - Short-interval follow-up in 6 months with mammography
   - Intervention and/or Additional Imaging
     - Aspiration with core biopsy if solid
     - US-guided core biopsy
     - Vacuum-assisted biopsy, guidance by US
     - Vacuum-assisted biopsy, guidance by mammography
     - Excisional biopsy
     - US-guided biopsy, if US negative, MRI guided biopsy
   - Targeted ultrasound (lesion seen on mammography)
   - Comparison to prior mammogram is required
   - Additional mammographic projections

   21e. **Is this lesion assessed as probably benign AND recommended for intervention?**
   - No (proceed to Q22)
   - Yes (specify dominant reason)
     - Participant preference
     - Cancer present now
       - In this breast
       - In opposite breast
     - Patient risks factors
     - Vaguely palpable
     - Follow-up not reasonable
     - Interval increase (>20% in volume for masses)
     - Interval suspicious change
     - Investigator uncertainty

22. **Are there additional lesion(s) you wish to describe?**
   - No (proceed to Q16)
   - Yes (proceed to Q23)
II. Results (by lesion)

Please complete Mammographic Lesion Description and Sonographic Lesion Description for each lesion being followed and for any new findings on this follow-up examination.

23A. Lesion # from prior MRI: [ ]

(If not applicable code 998)

23. Mammographic Lesion Description

23a. Were mammographic views obtained of this finding on this follow-up evaluation?

- No (specify reason and proceed to Q24)
  - Not recommended
  - Participant refused
  - Not needed after targeted US
  - Scheduling constraints; participant rescheduled
  - Other
  - Yes

23b. Change in this lesion from prior mammogram(s)?

- New
  - Gone (complete then proceed to Q24)

Lesion # from prior mammogram: [M]

(If not applicable code 998)

Lesion # from prior ultrasound: [U]

(If not applicable code 998)

- Decreasing
- Stable
- Fluctuating bilateral circumscribed masses
- Increasing
- Other suspicious change(s)
- Increasing and other suspicious change(s)

23c. Was lesion enumerated on any prior study mammogram?

- No and not visible in retrospect
  - (assign next sequential mammogram lesion #)
- No but now visible in retrospect
  - (assign next sequential mammogram lesion #)

New lesion #: [M]

- Yes
  - Lesion # from prior mammogram: [M]
    (e.g. MR1, MB1, ML1, MR2, etc.)

23d. Was lesion enumerated on any prior study ultrasound?

- No
  - Simple cyst
  - Not a simple cyst
  - Yes (complete)

Lesion # from ultrasound: [U]

(e.g. UR1, UB1, UL1, UR2, etc.)

23e. Location on Mammography: (check all that apply)

Note: for multiple bilateral findings with similar appearances, check “bilateral, multiple” and indicate specific location and size of the largest such finding.

- Right breast
- Left breast
- Bilateral, multiple
- Axillary tail
- Retroareolar
- Upper
- Lower
- Inner
- Outer
- Central

23f. Distance from nipple _____ cm by Mammography

23g. Size of lesion by Mammography:

[ ] mm X [ ] mm

(largest diameter) (largest perpendicular dimension)

24. Sonographic Lesion Description

24a. Was ultrasound performed of this lesion on this follow-up evaluation?

- No (specify reason and proceed to Q25)
- Not recommended
- Participant refused
- Not needed after additional mammographic views
- Scheduling constraints; participant rescheduled
- Other
  - Yes (check all that apply)
    - Targeted only
    - Whole breast

24b. Change in this lesion from prior ultrasound?

- New
  - Gone (complete then proceed to Q25)

Lesion # from prior mammogram: [M]

(If not applicable code 998)

Lesion # from prior ultrasound: [U]

(If not applicable code 998)

- Decreasing
- Stable
- Fluctuating bilateral circumscribed masses
- Increasing
- Other suspicious change(s)
- Increasing and other suspicious change(s)

24c. Was lesion enumerated on any prior study ultrasound?

- No (complete)
  - Simple cyst (proceed to Q25)
- Not a simple cyst and not visible in retrospect
  - (assign next sequential sonogram lesion #)
- Not a simple cyst and now visible in retrospect
  - (assign next sequential sonogram lesion #)

New lesion #: [U]

- Yes (complete)

Lesion # from prior ultrasound: [U]

(e.g. UR1, UB1, UL1, UR2, etc.)

24d. Was lesion enumerated on any study mammogram (including views obtained today)?

- No
- Yes (complete)

Lesion # from mammogram: [M]

(e.g. MR1, MB1, ML1, MR2, etc.)
24e. Check if this "lesion" is multiple bilateral circumscribed masses. Describe largest mass in Q24e and Q24f then proceed to Q24g.

Breast
(report on 1/2 hour)
(Report on hour and 1/2 hour
e.g. 7:00 = 0700, 12:30 = 1230)

<table>
<thead>
<tr>
<th>Clockface</th>
<th>Distance from</th>
<th>Depth from skin to</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>the nipple</td>
<td>center of lesion</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(to nearest 0.5 cm)</td>
</tr>
</tbody>
</table>

○ R  ○ L  o' clock  cm  cm

24f. Lesion Size

<table>
<thead>
<tr>
<th>Largest Horizontal Meas (mm) D1</th>
<th>Measured Plane</th>
<th>Vertical A-P meas (mm) D2</th>
<th>Horizontal Perpendicular Meas (mm) D3</th>
<th>Second Measured Plane</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>○ Trv</td>
<td>X</td>
<td>○ Arad</td>
<td>○ Arad</td>
</tr>
<tr>
<td></td>
<td>○ Sag</td>
<td></td>
<td>o Rad</td>
<td>o Sag</td>
</tr>
<tr>
<td></td>
<td>○ Rad</td>
<td></td>
<td>o Oblique</td>
<td>o Oblique</td>
</tr>
</tbody>
</table>

24g. Special Case (see choices below)
○ No
○ Yes (detail below then proceed to Q24p)
  ○ Complicated Cyst (Note: Do not use this term for "complex cystic masses".
    For complex cystic masses code "no" for Q24g, proceed to Q24h and indicate "complex cystic" at 24l).
    | Homogenous low-level echoes |
    | Fluid debris level |
    | Mobile internal echoes |
    | Multiple bilateral complicated cysts in company of simple cysts |
    | Multiple bilateral solid oval, circumscribed masses |
    | Mass in or on skin |
    | Clustered microcysts |
    | Intraductal mass |
    | Lymph node |
    | Calcifications without a mass |
    | Foreign body |
    | Post-surgical scar |
    | Other, specify __________________________|

24h. Shape
○ Oval
  ○ Two or three gentle lobulations
  ○ Round
  ○ Irregular

24i. Orientation
○ Parallel to skin
  ○ Not parallel (includes round)

24j. Margin
○ Circumscribed
  ○ Not circumscribed (If not circumscribed, choose dominant feature)
  ○ Indistinct
  ○ Angular
  ○ Microlobulated
  ○ Spiculated

24k. Boundary Zone
○ Abrupt Interface
  ○ Echogenic Halo
### Section III.

**26. Assessment/Recommendations**

26a. ___ ___ % likelihood of malignancy for this lesion (best guess from 0-100)

26b. Assessment for this lesion
   - 1 Negative
   - 2 Benign
   - 3 Probably Benign
   - 4A Low Suspicion of Malignancy
   - 4B Intermediate Suspicion
   - 4C Moderately High Suspicion
   - 5 Highly suggestive of Malignancy

26c. Known benign by prior biopsy?
   - No (proceed to Q26d)
   - Yes (complete)
     - < 1 year ago
     - 1-2 years ago
     - > 2 years ago

26d. Recommendation(s) for this lesion
   - Return to routine screening
   - Diagnostic follow-up to coincide with next annual exam
   - Short-interval follow-up in 6 months with US
   - Short-interval follow-up in 6 months with mammography
   - Short-interval follow-up in 6 months with MRI
   - Intervention and/or Additional Imaging
     - Intervention
       - Aspiration with core biopsy if solid
       - US-guided core biopsy
       - Vacuum-assisted biopsy, guidance by US
       - Vacuum-assisted biopsy, guidance by mammography
       - Excisional biopsy
     - US-guided biopsy, if US negative, MRI guided biopsy
   - Additional Imaging
     - Targeted ultrasound (lesion seen on mammography)
     - Comparison to prior mammogram is required
     - Additional mammographic projections

26e. Is this lesion assessed as probably benign AND recommended for intervention?
   - No (proceed to Q27)
   - Yes (specify dominant reason)
     - Participant preference
     - Cancer present now
     - In this breast
     - In opposite breast
     - Patient risks factors
     - Vaguely palpable
     - Follow-up not reasonable
     - Interval increase (>20% in volume for masses)
     - Interval suspicious change
     - Investigator uncertainty

27. Are there additional lesion(s) you wish to describe?
   - No (proceed to Q16)
   - Yes (proceed to Q28)
II. Results (by lesion)

Please complete Mammographic Lesion Description and Sonographic Lesion Description for each lesion being followed and for any new findings on this follow-up examination.

28a. Lesion # from prior MRI: [ ]

(If not applicable code 998)

28. Mammographic Lesion Description

28a. Were mammographic views obtained of this finding on this follow-up evaluation?

- No (specify reason and proceed to Q29)
  - Not recommended
  - Participant refused
  - Not needed after targeted US
  - Scheduling constraints; participant rescheduled
  - Other
  - Yes

28b. Change in this lesion from prior mammogram(s)?

- New
  - Gone (complete then proceed to Q29)

  Lesion # from prior mammogram: [M]

  (If not applicable code 998)

  Lesion # from prior ultrasound: [U]

  (If not applicable code 998)

- Decreasing
- Stable
- Fluctuating bilateral circumscribed masses
- Increasing
- Other suspicious change(s)
- Increasing and other suspicious change(s)

28c. Was lesion enumerated on any prior study mammogram?

- No and not visible in retrospect
  - New lesion # [M]
    - Yes
      - Lesion # from prior mammogram: [M]
        (E.g. MR1, MB1, ML1, MR2, etc.)

- No but now visible in retrospect
  - New lesion # [M]
    - Yes
      - Lesion # from prior mammogram: [M]
        (E.g. MR1, MB1, ML1, MR2, etc.)

28d. Was lesion enumerated on any prior study ultrasound?

- No
  - Simple cyst
    - Not a simple cyst
      - Yes (complete)

  Lesion # from ultrasound: [U]

  (E.g. UR1, UB1, UL1, UR2, etc.)

28e. Location on Mammography: (Check all that apply)

Note: for multiple bilateral findings with similar appearances, check “bilateral, multiple” and indicate specific location and size of the largest such finding.

- Right breast
- Left breast
- Bilateral, multiple
- Axillary tail
- Retroareolar

28f. Distance from nipple [ ] cm by Mammography

28g. Size of lesion by Mammography:

[ ] mm X [ ] mm

(largest diameter) (largest perpendicular dimension)

II. Results (by lesion)

Please complete Mammographic Lesion Description and Sonographic Lesion Description for each lesion being followed and for any new findings on this follow-up examination.

28a. Lesion # from prior MRI: [ ]

(If not applicable code 998)

28. Mammographic Lesion Description

28a. Were mammographic views obtained of this finding on this follow-up evaluation?

- No (specify reason and proceed to Q29)
  - Not recommended
  - Participant refused
  - Not needed after targeted US
  - Scheduling constraints; participant rescheduled
  - Other
  - Yes

28b. Change in this lesion from prior mammogram(s)?

- New
  - Gone (complete then proceed to Q29)

  Lesion # from prior mammogram: [M]

  (If not applicable code 998)

  Lesion # from prior ultrasound: [U]

  (If not applicable code 998)

- Decreasing
- Stable
- Fluctuating bilateral circumscribed masses
- Increasing
- Other suspicious change(s)
- Increasing and other suspicious change(s)

28c. Was lesion enumerated on any prior study mammogram?

- No and not visible in retrospect
  - New lesion # [M]
    - Yes
      - Lesion # from prior mammogram: [M]
        (E.g. MR1, MB1, ML1, MR2, etc.)

- No but now visible in retrospect
  - New lesion # [M]
    - Yes
      - Lesion # from prior mammogram: [M]
        (E.g. MR1, MB1, ML1, MR2, etc.)

28d. Was lesion enumerated on any prior study ultrasound?

- No
  - Simple cyst
    - Not a simple cyst
      - Yes (complete)

  Lesion # from ultrasound: [U]

  (E.g. UR1, UB1, UL1, UR2, etc.)

28e. Location on Mammography: (Check all that apply)

Note: for multiple bilateral findings with similar appearances, check “bilateral, multiple” and indicate specific location and size of the largest such finding.

- Right breast
- Left breast
- Bilateral, multiple
- Axillary tail
- Retroareolar

28f. Distance from nipple [ ] cm by Mammography

28g. Size of lesion by Mammography:

[ ] mm X [ ] mm

(largest diameter) (largest perpendicular dimension)
29e. □ Check if this "lesion" is multiple bilateral circumscribed masses. Describe largest mass in Q29e and Q29f then proceed to Q29g.

29f. Lesion Size

<table>
<thead>
<tr>
<th>Vertex</th>
<th>Horizontal Meas (mm) D1</th>
<th>Measured Plane</th>
<th>Vertical A-P meas (mm) D2</th>
<th>Horizontal Perpendicular Meas (mm) D3</th>
<th>Measured Plane</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

29g. Special Case (see choices below)

- No
- Yes (detail below then proceed to Q29p)
  - Complicated Cyst (Note: Do not use this term for "complex cystic masses". For complex cystic masses code "no" for Q29g, proceed to Q29h and indicate "complex cystic" at 29i).
    - Homogenious low-level echoes
    - Fluid debris level
    - Mobile internal echoes
    - Multiple bilateral complicated cysts in company of simple cysts
  - Multiple bilateral solid oval, circumscribed masses
  - Mass in or on skin
  - Clustered microcysts
  - Intraductal mass
  - Lymph node
  - Calcifications without a mass
  - Foreign body
  - Post-surgical scar
  - Other, specify ____________________________

29h. Shape

- Oval
- Two or three gentle lobulations
- Round
- Irregular

29i. Orientation

- Parallel to skin
- Not parallel (includes round)

29j. Margin

- Circumscribed
- Not circumscribed (If not circumscribed, choose dominant feature)
  - Indistinct
  - Angular
  - Microlobulated
  - Spiculated

29k. Boundary Zone

- Abrupt Interface
- Echogenic Halo

Breast

Clockface (report on 1/2 hour)

Distance from the nipple

Depth from skin to center of lesion (to nearest 0.5 cm)

O R O L

O' clock cm cm cm

Volume D1XD2XD3 ÷ 2

Horizontal Meas (mm) D1

Vertical A-P meas (mm) D2

Horizontal Perpendicular Meas (mm) D3

Second Measured Plane

Note: Volume is programmed to be calculated on line; however, as verification, please calculate volume based on horizontal, vertical and perpendicular measurements as a validation.
### Section III.

#### 31. Assessment/Recommendations

31a. **% likelihood of malignancy for this lesion** (best guess from 0-100)

31b. **Assessment for this lesion**
- 1 Negative
- 2 Benign
- 3 Probably Benign
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion
- 5 Highly Suggestive of Malignancy

31c. **Known benign by prior biopsy?**
- No (proceed to Q31d)
- Yes (complete)
  - < 1 year ago
  - 1-2 years ago
  - > 2 years ago

31d. **Recommendation(s) for this lesion**
- Return to routine screening
- Diagnostic follow-up to coincide with next annual exam
- Short-interval follow-up in 6 months with US
- Short-interval follow-up in 6 months with mammography
- Intervention and/or Additional Imaging
  - Intervention
    - Aspiration with core biopsy if solid
    - US-guided core biopsy
    - Vacuum-assisted biopsy, guidance by US
    - Vacuum-assisted biopsy, guidance by mammo
    - Excisional biopsy
    - US-guided biopsy, if US negative, MRI guided biopsy
  - Additional Imaging
    - Targeted ultrasound (lesion seen on mammography)
    - Comparison to prior mammogram is required
    - Additional mammographic projections

31e. **Is this lesion assessed as probably benign AND recommended for intervention?**
- No (proceed to Q32)
- Yes (specify dominant reason)
  - Participant preference
  - Cancer present now
  - In this breast
  - In opposite breast
  - Patient risks factors
  - Vaguely palpable
  - Follow-up not reasonable
  - Interval increase (>20% in volume for masses)
  - Interval suspicious change
  - Investigator uncertainty

32. **Are there additional lesion(s) you wish to describe?**
- No (proceed to Q16)
- Yes (proceed to Q33)
II. Results (by lesion)

Please complete Mammographic Lesion Description and Sonographic Lesion Description for each lesion being followed and for any new findings on this follow-up examination.

33A. Lesion # from prior MRI: [Insert] (e.g. GR1, GL1, GL2, etc.) (If not applicable code 998)

33. Mammographic Lesion Description

33a. Were mammographic views obtained of this finding on this follow-up evaluation?
- No (specify reason and proceed to Q34)
  - Not recommended
  - Participant refused
  - Not needed after targeted US
  - Scheduling constraints; participant rescheduled
  - Other
  - Yes

33b. Change in this lesion from prior mammogram(s)?
- New
  - Gone (complete then proceed to Q34)
  - Decreasing
  - Stable
  - Fluctuating bilateral circumscribed masses
  - Increasing
  - Other suspicious change(s)
  - Increasing and other suspicious change(s)

33c. Was lesion enumerated on any prior study mammogram?
- No and not visible in retrospect
  - assign next sequential mammogram lesion #
- No but now visible in retrospect
  - assign next sequential mammogram lesion #
  - New lesion # [M]
  - [Insert]
- Yes
  - assign next sequential mammogram lesion #
  - assign next sequential mammogram lesion #
  - assign next sequential mammogram lesion #

33d. Was lesion enumerated on any prior study ultrasound?
- No
  - Simple cyst
  - Not a simple cyst
  - assign next sequential sonogram lesion #
- Yes
  - assign next sequential sonogram lesion #
  - assign next sequential sonogram lesion #
  - assign next sequential sonogram lesion #
  - assign next sequential sonogram lesion #

33e. Location on Mammography: (check all that apply)
- Right breast
- Left breast
- Bilateral, multiple
- Axillary tail
- Retroareolar
- Upper
- Lower
- Inner
- Outer
- Central

33f. Distance from nipple [Insert] cm by Mammography

33g. Size of lesion by Mammography:
- [Insert] mm (largest diameter)
- [Insert] mm (largest perpendicular dimension)

33h. Lesion Description Mammography
- Mass (select worst margin feature present)
  - Circumscribed
  - Fat-containing
  - Not fat-containing
  - Microlobulated
  - Obscured
  - Indistinct
  - Spiculated
- Asymmetry (code type of asymmetry)
  - Focal
  - Asymmetry seen on
  - One view
  - Both views
  - Global
- Calcifications (code morphology and distribution)
  - Coarse typically benign
  - Milk of calcium
  - Coarse heterogeneous
  - Punctate (<0.5 mm, uniformly round)
  - Amorphous/Indistinct
  - Pleomorphic
  - Branching/Fine linear
- Distribution of calcifications (check all that apply)
  - Clustered
  - Multiple clusters (same morphology)
  - Regional
  - Linear
  - Segmental
  - Diffuse scattered
  - In mass or asymmetry
- Architectural Distortion

34. Sonographic Lesion Description

34a. Was ultrasound performed of this lesion on this follow-up evaluation?
- No (specify reason and proceed to Q35)
  - Not recommended
  - Participant refused
  - Not needed after additional mammographic views
  - Scheduling constraints; participant rescheduled
  - Other
  - Yes
  - assign next sequential sonogram lesion #
  - assign next sequential sonogram lesion #
  - assign next sequential sonogram lesion #
  - assign next sequential sonogram lesion #

34b. Change in this lesion from prior ultrasound?
- New
  - assign next sequential sonogram lesion #
  - assign next sequential sonogram lesion #
  - assign next sequential sonogram lesion #
  - assign next sequential sonogram lesion #
- Decreasing
  - Stable
  - Fluctuating bilateral circumscribed masses
  - Increasing
  - Other suspicious change(s)
  - Increasing and other suspicious change(s)

34c. Was lesion enumerated on any prior study ultrasound?
- No (complete)
  - Simple cyst (proceed to Q35)
  - assign next sequential sonogram lesion #
  - assign next sequential sonogram lesion #
  - assign next sequential sonogram lesion #
  - assign next sequential sonogram lesion #

34d. Was lesion enumerated on any study mammogram (including views obtained today)?
- No
  - assign next sequential mammogram lesion #
  - assign next sequential mammogram lesion #
  - assign next sequential mammogram lesion #
- Yes
  - assign next sequential mammogram lesion #
  - assign next sequential mammogram lesion #
  - assign next sequential mammogram lesion #
34e. □ Check if this "lesion" is multiple bilateral circumscribed masses. Describe largest mass in Q34e and Q34f then proceed to Q34g.

**Breast**
- Clockface (report on 1/2 hour)
  - OR L
  - [ ] o'clock [ ] cm [ ] [ ] cm
- Distance from the nipple
- Depth from skin to center of lesion (to nearest 0.5 cm)

34f. **Lesion Size**

<table>
<thead>
<tr>
<th>Largest Horizontal Meas (mm) D1</th>
<th>Measured Plane</th>
<th>Vertical A-P meas (mm) D2</th>
<th>Horizontal Perpendicular Meas (mm) D3</th>
<th>Second Measured Plane</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] mm [ ] mm [ ] mm</td>
<td>o Trv</td>
<td>X [ ] mm [ ] mm</td>
<td>o Trv</td>
<td>[ ] mm [ ] mm [ ] mm</td>
</tr>
<tr>
<td>o Sag</td>
<td></td>
<td></td>
<td>o Sag</td>
<td></td>
</tr>
<tr>
<td>o Rad</td>
<td></td>
<td></td>
<td>o Rad</td>
<td></td>
</tr>
<tr>
<td>o Arad</td>
<td></td>
<td></td>
<td>o Arad</td>
<td></td>
</tr>
<tr>
<td>o Oblique</td>
<td></td>
<td></td>
<td>o Oblique</td>
<td></td>
</tr>
</tbody>
</table>

34g. **Special Case** (see choices below)
- No
- Yes (detail below then proceed to Q34p)
  - Complicated Cyst (Note: Do not use this term for "complex cystic masses". For complex cystic masses code "no" for Q34g, proceed to Q34h and indicate "complex cystic" at 34l).
    - Homogenous low-level echoes
    - Fluid debris level
    - Mobile internal echoes
    - Multiple bilateral complicated cysts in company of simple cysts
    - Multiple bilateral solid oval, circumscribed masses
    - Mass in or on skin
    - Clustered microcysts
    - Intraductal mass
    - Lymph node
    - Calcifications without a mass
    - Foreign body
    - Post-surgical scar
    - Other, specify __________________________

34h. **Shape**
- [ ] Oval
- [ ] Two or three gentle lobulations
- [ ] Round
- [ ] Irregular

34i. **Orientation**
- [ ] Parallel to skin
- [ ] Not parallel (includes round)

34j. **Margin**
- [ ] Circumscribed
- [ ] Not circumscribed (If not circumscribed, choose dominant feature)
  - [ ] Indistinct
  - [ ] Angular
  - [ ] Microlobulated
  - [ ] Spiculated

34k. **Boundary Zone**
- [ ] Abrupt Interface
- [ ] Echogenic Halo

*Note: Volume is programmed to be calculated on line; however, as verification, please calculate volume based on horizontal, vertical, and perpendicular measurements as a validation.*
### Section III. Assessment/Recommendations

36. **Assessment for this lesion**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Negative</td>
</tr>
<tr>
<td>2</td>
<td>Benign</td>
</tr>
<tr>
<td>3</td>
<td>Probably Benign</td>
</tr>
<tr>
<td>4A</td>
<td>Low Suspicion of Malignancy</td>
</tr>
<tr>
<td>4B</td>
<td>Intermediate Suspicion</td>
</tr>
<tr>
<td>4C</td>
<td>Moderately High Suspicion</td>
</tr>
<tr>
<td>5</td>
<td>Highly Suggestive of Malignancy</td>
</tr>
</tbody>
</table>

36a. **% likelihood of malignancy for this lesion** (best guess from 0-100)

36b. **Assessment for this lesion**

36c. **Known benign by prior biopsy?**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 1 year ago</td>
<td></td>
</tr>
<tr>
<td>1-2 years ago</td>
<td></td>
</tr>
<tr>
<td>&gt; 2 years ago</td>
<td></td>
</tr>
</tbody>
</table>

36d. **Recommended Intervention(s) for this lesion**

- Diagnostic follow-up to coincide with next annual exam
- Short-interval follow-up in 6 months with US
- Short-interval follow-up in 6 months with mammography
- Short-interval follow-up in 6 months with MRI
- Intervention and/or Additional Imaging
  - Aspiration with core biopsy if solid
  - US-guided core biopsy
  - Vacuum-assisted biopsy, guidance by US
  - Vacuum-assisted biopsy, guidance by mammography
  - Excisional biopsy
  - US-guided biopsy, if US negative, MRI guided biopsy

36e. **Is this lesion assessed as probably benign AND recommended for intervention?**

- Participant preference
- Cancer present now
- In this breast
- In opposite breast
- Patient risks factors
- Vaguely palpable
- Follow-up not reasonable
- Interval increase (>20% in volume for masses)
- Interval suspicious change
- Investigator uncertainty

37. **Are there additional lesion(s) you wish to describe?**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>No (not applicable)</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td></td>
</tr>
</tbody>
</table>
II. Results (by lesion)

Please complete Mammographic Lesion Description and Sonographic Lesion Description for each lesion being followed and for any new findings on this follow-up examination.

38A. Lesion # from prior MRI: [ ] (e.g. GR1, GL1, GL2, etc.)

38. Mammographic Lesion Description

38a. Were mammographic views obtained of this finding on this follow-up evaluation?
- No (specify reason and proceed to Q39)
- Not recommended
- Participant refused
- Not needed after targeted US
- Scheduling constraints; participant rescheduled
- Other
- Yes

38b. Change in this lesion from prior mammogram(s)?
- New

38c. Was lesion enumerated on any prior study mammogram?
- No and not visible in retrospect
- No but now visible in retrospect
- New lesion # [ ]
- Yes

38d. Was lesion enumerated on any prior study ultrasound?
- No
- Simple cyst
- Yes (complete)

38e. Location on Mammography: (check all that apply)

Note: for multiple bilateral findings with similar appearances, check “bilateral, multiple” and indicate specific location and size of the largest such finding.
- Right breast
- Left breast
- Bilateral, multiple
- Axillary tail
- Retroareolar

38f. Distance from nipple [ ] cm by Mammography

38g. Size of lesion by Mammography:
[ ] mm X [ ] mm

39. Sonographic Lesion Description

39a. Was ultrasound performed of this lesion on this follow-up evaluation?
- No (specify reason and proceed to Q40)
- Not recommended
- Participant refused
- Not needed after additional mammographic views
- Scheduling constraints; participant rescheduled
- Other
- Yes (check all that apply)

39b. Change in this lesion from prior ultrasound?
- New

39c. Was lesion enumerated on any prior study ultrasound?
- No (complete)
- Simple cyst (proceed to Q40)
- Not a simple cyst and not visible in retrospect
- Not a simple cyst and now visible in retrospect

39d. Was lesion enumerated on any study mammogram (including views obtained today)?
- No
- Yes (complete)
39e. □ Check if this "lesion" is multiple bilateral circumscribed masses. Describe largest mass in Q39e and Q39f then proceed to Q39g.

<table>
<thead>
<tr>
<th>Breast</th>
<th>Clockface (report on 1/2 hour)</th>
<th>Distance from the nipple</th>
<th>Depth from skin to center of lesion (to nearest 0.5 cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>o R</td>
<td>o L</td>
<td>o' clock</td>
<td>cm</td>
</tr>
</tbody>
</table>

39f. Lesion Size

<table>
<thead>
<tr>
<th>Largest Horizontal Meas (mm) D1</th>
<th>Measured Plane</th>
<th>Vertical A-P meas (mm) D2</th>
<th>Horizontal Perpendicular Meas (mm) D3</th>
<th>Second Measured Plane</th>
</tr>
</thead>
<tbody>
<tr>
<td>o Trv</td>
<td>o Sag</td>
<td>X</td>
<td>o Trv</td>
<td>o Sag</td>
</tr>
<tr>
<td>o Sag</td>
<td>o Rad</td>
<td>X</td>
<td>o Rad</td>
<td>o Rad</td>
</tr>
<tr>
<td>o Arad</td>
<td>o Oblique</td>
<td>X</td>
<td>o Oblique</td>
<td></td>
</tr>
</tbody>
</table>

39g. Special Case (see choices below)

- No
- Yes (detail below then proceed to Q39p)
  - Complicated Cyst (Note: Do not use this term for "complex cystic masses". For complex cystic masses code "no" for Q39g, proceed to Q39h and indicate "complex cystic" at 39i).
  - Homogenous low-level echoes
  - Fluid debris level
  - Mobile internal echoes
  - Multiple bilateral complicated cysts in company of simple cysts
  - Multiple bilateral solid oval, circumscribed masses
  - Mass in or on skin
  - Clustered microcysts
  - Intraductal mass
  - Lymph node
  - Calcifications without a mass
  - Foreign body
  - Post-surgical scar
  - Other, specify ________________

39h. Shape
- Oval
- Two or three gentle lobulations
- Round
- Irregular

39i. Orientation
- Parallel to skin
- Not parallel (includes round)

39j. Margin
- Circumscribed
- Not circumscribed (If not circumscribed, choose dominant feature)
  - Indistinct
  - Angular
  - Microlobulated
  - Spiculated

39k. Boundary Zone
- Abrupt Interface
- Echogenic Halo
39i. Echo Pattern
- Anechoic
- Hyperechoic
- Complex cystic
- Hypoechoic with few tiny cystic areas
- Isoechoic to fat
- Mixed hyperechoic and hypoechoic
- Hypoechoic to fat

39m. Posterior Features
- None
- Enhancement
- Combined shadowing/enhancement
- Shadowing

39n. Surrounding Tissue
- No effect
- Effect (check all that apply)
  - Duct changes
  - Edema
  - Cooper’s ligament distortion
  - Architectural distortion
  - Skin thickening
  - Skin retraction

39o. Vascularity (flow)
- None
- Yes (check all that apply)
  - Present in lesion
  - Present immediately adjacent to lesion
  - Increased in surrounding tissue
  - Not performed

39p. Calcifications on ultrasound
- None
- Present (check all that apply)
  - Macrocalcifications (> 0.5 mm)
  - Microcalcifications in mass
  - Microcalcifications outside mass

39q. Was lesion palpable in retrospect during sonography?
- No
- Yes, in retrospect
- Yes, participant presented with lump

40. Is this lesion at the site of prior biopsy?
- No (proceed to Q41)
- Yes (if yes, select procedure)
  - Core/vacuum biopsy site with clip
  - Core/vacuum biopsy site without marker
  - Surgical biopsy site (select diagnosis)
    - Benign
    - Atypical/high-risk lesion
    - Cancer site
    - Unknown
    - Biopsy details unknown
    - FNAB
  - Not applicable, multiple bilateral circumscribed masses

41. Assessment/Recommendations

41a. % likelihood of malignancy for this lesion (best guess from 0-100)

41b. Assessment for this lesion
- 1 Negative
- 2 Benign
- 3 Probably Benign
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion
- 5 Highly Suggestive of Malignancy

41c. Known benign by prior biopsy?
- No (proceed to Q41d)
- Yes (complete)
  - < 1 year ago
  - 1-2 years ago
  - > 2 years ago

41d. Recommendation(s) for this lesion
- Return to routine screening
- Diagnostic follow-up to coincide with next annual exam
- Short-interval follow-up in 6 months with US
- Short-interval follow-up in 6 months with mammography
- Short-interval follow-up in 6 months with MRI
- Intervention and/or Additional Imaging (detail intervention and/or additional imaging)
  - Intervention
    - Aspiration with core biopsy if solid
    - US-guided core biopsy
    - Vacuum-assisted biopsy, guidance by US
    - Vacuum-assisted biopsy, guidance by mammography
    - Excisional biopsy
    - US-guided biopsy, if US negative, MRI guided biopsy
  - Additional Imaging
    - Targeted ultrasound (lesion seen on mammography)
    - Comparison to prior mammogram is required
    - Additional mammographic projections

41e. Is this lesion assessed as probably benign AND recommended for intervention?
- No (proceed to Q42)
- Yes (specify dominant reason)
  - Participant preference
  - Cancer present now
    - In this breast
    - In opposite breast
  - Patient risks factors
  - Vaguely palpable
  - Follow-up not reasonable
  - Interval increase (>20% in volume for masses)
  - Interval suspicious change
  - Investigator uncertainty

42. Are there additional lesion(s) you wish to describe?
- No (proceed to Q16)
- Yes (proceed to Q43)
II. Results (by lesion)
Please complete Mammographic Lesion Description and Sonographic Lesion Description for each lesion being followed and for any new findings on this follow-up examination.

43A. Lesion # from prior MRI: [ ] (e.g. GR1, GL1, GL2, etc.)
   (if not applicable code 998)

43. Mammographic Lesion Description
43a. Were mammographic views obtained of this finding on this follow-up evaluation?
   o No (specify reason and proceed to Q44)
     o Not recommended
     o Participant refused
     o Not needed after targeted US
     o Scheduling constraints; participant rescheduled
     o Other
     o Yes

43b. Change in this lesion from prior mammogram(s)?
   o New
     o Gone (complete then proceed to Q44)
     [ ]
     Lesion # from prior mammogram: [M]
     (if not applicable code 998)
     [ ]
     Lesion # from prior ultrasound: [U]
     (if not applicable code 998)
     o Decreasing
     o Stable
     o Fluctuating bilateral circumscribed masses
     o Increasing
     o Other suspicious change(s)
     o Increasing and other suspicious change(s)

43c. Was lesion enumerated on any prior study mammogram?
   o No and not visible in retrospect
     (assign next sequential mammogram lesion #)
   o No but now visible in retrospect
     (assign next sequential mammogram lesion #)
     New lesion #: [M]
     (e.g. MR1, MB1, ML1, MR2, etc.)
   o Yes
     Lesion # from prior mammogram: [M]
     (e.g. MR1, MB1, ML1, MR2, etc.)

43d. Was lesion enumerated on any prior study ultrasound?
   o No
     o Simple cyst
     o Not a simple cyst
     o Yes (complete)
     Lesion # from ultrasound: [U]
     (e.g. UR1, UB1, UL1, UR2, etc.)

43e. Location on Mammography: (check all that apply)
   Note: for multiple bilateral findings with similar appearances, check "bilateral, multiple" and indicate specific location and size of the largest such finding.
   o Right breast
   o Left breast
   o Bilateral, multiple
   o Axillary tail
   o Retroareolar
   o Upper
   o Lower
   o Inner
   o Outer
   o Central

43f. Distance from nipple [ ] cm by Mammography

43g. Size of lesion by Mammography:
   [ ] mm X [ ] mm
   (largest diameter) (largest perpendicular dimension)

43h. Lesion Description Mammography
   (check all that apply)
   □ Mass (select worse margin feature present)
     o Circumscribed
     o Fat-containing
     o Not fat-containing
     o Microlobulated
     o Obscured
     o Indistinct
     o Spiculated
     o Asymmetry (code type of asymmetry)
       o Focal
       Asymmetry seen on
         o One view
         o Both views
         o Global
   □ Calcifications (code morphology and distribution)
     Morphology of calcifications (check all that apply)
     □ Coarse typically benign
     □ Milk of calcium
     □ Coarse heterogeneous
     □ Punctate (<0.5 mm, uniformly round)
     □ Amorphous/Indistinct
     □ Pleomorphic
     □ Branching/Fine linear
     Distribution of calcifications (check all that apply)
     □ Clustered
     □ Multiple clusters (same morphology)
     □ Regional
     □ Linear
     □ Segmental
     □ Diffuse scattered
     □ In mass or asymmetry
     □ Architectural Distortion

44. Sonographic Lesion Description
44a. Was ultrasound performed of this lesion on this follow-up evaluation?
   o No (specify reason and proceed to Q45)
     □ Not recommended
     □ Participant refused
     □ Not needed after additional mammographic views
     □ Scheduling constraints; participant rescheduled
     □ Other
     o Yes (check all that apply)
     □ Targeted only
     □ Whole breast

44b. Change in this lesion from prior ultrasound?
   o New
     o Gone (complete then proceed to Q45)
     New lesion #: [U]
     (if not applicable code 998)
     o Decreasing
     o Stable
     o Fluctuating bilateral circumscribed masses
     o Increasing
     o Other suspicious change(s)
     o Increasing and other suspicious change(s)

44c. Was lesion enumerated on any prior study ultrasound?
   o No (complete)
     □ Simple cyst (proceed to Q45)
     □ Not a simple cyst and not visible in retrospect
     (assign next sequential sonogram lesion #)
     □ Not a simple cyst and now visible in retrospect
     (assign next sequential sonogram lesion #)
     □ Other suspicious change(s)
     □ Increasing and other suspicious change(s)

44d. Was lesion enumerated on any study mammogram (including views obtained today)?
   o No
     □ Yes (complete)
     New lesion #: [U]
     (e.g. UR1, UB1, UL1, UR2, etc.)

44e. Location on Sonography: (check all that apply)
   Note: for multiple bilateral findings with similar appearances check "bilateral, multiple" and indicate specific location and size of the largest such finding.
   o Right breast
   o Left breast
   o Bilateral, multiple
   o Axillary tail
   o Retroareolar
   o Upper
   o Lower
   o Inner
   o Outer
   o Central

44f. Distance from nipple [ ] cm by Sonography

44g. Size of lesion by Sonography:
   [ ] mm X [ ] mm
   (largest diameter) (largest perpendicular dimension)
44e. □ Check if this "lesion" is multiple bilateral circumscribed masses. Describe largest mass in Q44e and Q44f then proceed to Q44g.

Breast Clockface Distance from Depth from skin to
(report on 1/2 hour) the nipple center of lesion
(e.g. 7:00 = 0700, 12:30 = 1230) (to nearest 0.5 cm)

R L o o’clock cm cm cm

44f. Lesion Size

<table>
<thead>
<tr>
<th>Largest Horizontal Meas (mm) D1</th>
<th>Measured Plane</th>
<th>Vertical A-P meas (mm) D2</th>
<th>Horizontal Perpendicular Meas (mm) D3</th>
<th>Second Measured Plane</th>
<th>Measured Plane</th>
<th>Volume D1XD2XD3 ÷ 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>o Trv</td>
<td>o Sag</td>
<td>X mm</td>
<td>X mm</td>
<td>o Trv</td>
<td>o Sag</td>
<td>mm³</td>
</tr>
<tr>
<td>o Sag</td>
<td>o Rad</td>
<td></td>
<td></td>
<td>o Arad</td>
<td>o Arad</td>
<td></td>
</tr>
<tr>
<td>o Arad</td>
<td>o Oblique</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

44g. Special Case (see choices below)

o No
o Yes (detail below then proceed to Q44p)
  o Complicated Cyst (Note: Do not use this term for "complex cystic masses".
   For complex cystic masses code "no" for Q44g, proceed to Q44h and indicate "complex cystic" at 44l).
    □ Homogenous low-level echoes
    □ Fluid debris level
    □ Mobile internal echoes
    □ Multiple bilateral complicated cysts in company of simple cysts
    o Multiple bilateral solid oval, circumscribed masses
    o Mass in or on skin
    o Clustered microcysts
    o Intraductal mass
    o Lymph node
    o Calcifications without a mass
    o Foreign body
    o Post-surgical scar
    o Other, specify

44h. Shape

o Oval
o Two or three gentle lobulations
o Round
o Irregular

44i. Orientation

o Parallel to skin
o Not parallel (includes round)

44j. Margin

o Circumscribed
o Not circumscribed (If not circumscribed, choose dominant feature)
    □ Indistinct
    □ Angular
    □ Microlobulated
    □ Spiculated

44k. Boundary Zone

o Abrupt Interface
o Echogenic Halo
44. Echo Pattern
   - Anechoic
   - Hyperechoic
   - Complex cystic
   - Hypoechoic with few tiny cystic areas
   - Isoechoic to fat
   - Mixed hyperechoic and hypoechoic
   - Hypoechoic to fat

44m. Posterior Features
   - None
   - Enhancement
   - Combined shadowing/enhancement
   - Shadowing

44n. Surrounding Tissue
   - No effect
   - Effect (check all that apply)
     - Duct changes
     - Edema
     - Cooper’s ligament distortion
     - Architectural distortion
     - Skin thickening
     - Skin retraction

44o. Vascularity (flow)
   - None
   - Yes (check all that apply)
     - Present in lesion
     - Present immediately adjacent to lesion
     - Increased in surrounding tissue
   - Not performed

44p. Calcifications on ultrasound
   - None
   - Present (check all that apply)
     - Macrocalcifications (> 0.5 mm)
     - Microcalcifications in mass
     - Microcalcifications outside mass

44q. Was lesion palpable in retrospect during sonography?
   - No
   - Yes, in retrospect
   - Yes, participant presented with lump

45. Is this lesion at the site of prior biopsy?
   - No (proceed to Q46)
   - Yes (If yes, select procedure)
     - Core/vacuum biopsy site with clip
     - Core/vacuum biopsy site without marker
     - Surgical biopsy site (select diagnosis)
       - Benign
       - Atypical/high-risk lesion
       - Cancer site
       - Unknown
       - Biopsy details unknown
       - FNAB
       - Not applicable, multiple bilateral circumscribed masses

46. Assessment/Recommendations

46a. __________% likelihood of malignancy for this lesion (best guess from 0-100)

46b. Assessment for this lesion
   - 1 Negative
   - 2 Benign
   - 3 Probably Benign
   - 4A Low Suspicion of Malignancy
   - 4B Intermediate Suspicion
   - 4C Moderately High Suspicion
   - 5 Highly Suggestive of Malignancy

46c. Known benign by prior biopsy?
   - No (proceed to Q46d)
   - Yes (complete)
     - < 1 year ago
     - 1-2 years ago
     - > 2 years ago

46d. Recommendation(s) for this lesion
   - Return to routine screening
   - Diagnostic follow-up to coincide with next annual exam
     - Short-interval follow-up in 6 months with US
     - Short-interval follow-up in 6 months with mammography
     - Short-interval follow-up in 6 months with MRI
   - Intervention and/or Additional Imaging
     (detail intervention and/or additional imaging)
     - Intervention
       - Aspiration with core biopsy if solid
       - US-guided core biopsy
       - Vacuum-assisted biopsy, guidance by US
       - Vacuum-assisted biopsy, guidance by mamm
       - Excisional biopsy
       - US-guided biopsy, if US negative, MRI guided biopsy
     - Additional Imaging
       - Targeted ultrasound (lesion seen on mammography)
       - Comparison to prior mammogram is required
       - Additional mammographic projections

46e. Is this lesion assessed as probably benign AND recommended for intervention?
   - No (proceed to Q47)
   - Yes (specify dominant reason)
     - Participant preference
     - Cancer present now
       - In this breast
       - In opposite breast
     - Patient risks factors
     - Vaguely palpable
     - Follow-up not reasonable
     - Interval increase (>20% in volume for masses)
     - Interval suspicious change
     - Investigator uncertainty

47. Are there additional lesion(s) you wish to describe?
   - No (proceed to Q16)
   - Yes (proceed to Q48)
II. Results (by lesion)

Please complete Mammographic Lesion Description and Sonographic Lesion Description for each lesion being followed and for any new findings on this follow-up examination.

48A. Lesion # from prior MRI: __________ (e.g. GR1, GL1, GL2, etc.)
(Fit not applicable code 998)

48. Mammographic Lesion Description

48a. Were mammographic views obtained of this finding on this follow-up evaluation?
- No (specify reason and proceed to Q49)
  - Not recommended
  - Participant refused
  - Not needed after targeted US
  - Scheduling constraints; participant rescheduled
  - Other
  - Yes

48b. Change in this lesion from prior mammogram(s)?
- New
- Gone (complete then proceed to Q49)
  - Lesion # from prior mammogram: M
  - Lesion # from prior ultrasound: U
- Decreasing
- Stable
- Fluctuating bilateral circumscribed masses
- Increasing
- Other suspicious change(s)
- Increasing and other suspicious change(s)

48c. Was lesion enumerated on any prior study mammogram?
- No and not visible in retrospect
  - assign next sequential mammogram lesion #
  - New lesion # M
- Yes
  - Lesion # from prior mammogram: M
  (e.g. MR1, MB1, ML1, MR2, etc.)

48d. Was lesion enumerated on any prior study ultrasound?
- No
- Simple cyst
- Not a simple cyst
- Yes (complete)
  - Lesion # from ultrasound: U
  (e.g. UR1, UB1, UL1, UR2, etc.)

48e. Location on Mammography: (check all that apply)

   Note: for multiple bilateral findings with similar appearances, check “bilateral, multiple” and indicate specific location and size of the largest such finding.

   - Right breast
   - Left breast
   - Bilateral, multiple
   - Axillary tail
   - Retroareolar

48f. Distance from nipple _______ cm by Mammography

48g. Size of lesion by Mammography:

   __________ mm X __________ mm
   (largest diameter) (largest perpendicular dimension)

49. Sonographic Lesion Description

49a. Was ultrasound performed of this lesion on this follow-up evaluation?
- No (specify reason and proceed to Q50)
- Not recommended
- Participant refused
- Not needed after additional mammographic views
- Scheduling constraints; participant rescheduled
- Other
- Yes (check all that apply)
  - Targeted only
  - Whole breast

49b. Change in this lesion from prior ultrasound?
- New
- Gone (complete then proceed to Q50)
  - Lesion # from prior mammogram: M
  - Lesion # from prior ultrasound: U
  - Decreasing
  - Stable
  - Fluctuating bilateral circumscribed masses
  - Increasing
  - Other suspicious change(s)
  - Increasing and other suspicious change(s)

49c. Was lesion enumerated on any prior study ultrasound?
- No (complete)
  - Simple cyst (proceed to Q50)
- Not a simple cyst
  - Not visible in retrospect
  - assign next sequential sonogram lesion #
- Not a simple cyst and now visible in retrospect
  - assign next sequential sonogram lesion #
  - New lesion # U
- Yes (complete)
  - Lesion # from ultrasound: U
  (e.g. UR1, UB1, UL1, UR2, etc.)

49d. Was lesion enumerated on any study mammogram (including views obtained today)?
- No
- Yes (complete)
  - Lesion # from mammogram: M
  (e.g. MR1, MB1, ML1, MR2, etc.)
49e. □ Check if this "lesion" is multiple bilateral circumscribed masses. Describe largest mass in Q49e and Q49f then proceed to Q49g.

<table>
<thead>
<tr>
<th>Breast</th>
<th>Clockface (report on 1/2 hour)</th>
<th>Distance from the nipple</th>
<th>Depth from skin to center of lesion (to nearest 0.5 cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

49f. Lesion Size

<table>
<thead>
<tr>
<th>Largest Meas (mm) D1</th>
<th>Measured Plane</th>
<th>Vertical A-P meas (mm) D2</th>
<th>Horizontal Meas (mm) D3</th>
<th>Second Measured Plane</th>
<th>Volume D1XD2XD3 ÷ 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

49g. Special Case (see choices below)

- No
- Yes (detail below then proceed to Q49p)
  - Complicated Cyst (Note: Do not use this term for "complex cystic masses". For complex cystic masses code "no" for Q49g, proceed to Q49h and indicate "complex cystic" at 49i).
    - Homogenous low-level echoes
    - Fluid debris level
    - Mobile internal echoes
    - Multiple bilateral complicated cysts in company of simple cysts
    - Multiple bilateral solid oval, circumscribed masses
    - Mass in or on skin
    - Clustered microcysts
    - Intraductal mass
    - Lymph node
    - Calcifications without a mass
    - Foreign body
    - Post-surgical scar
    - Other, specify ________________________________

49h. Shape

- Oval
- Two or three gentle lobulations
- Round
- Irregular

49i. Orientation

- Parallel to skin
- Not parallel (includes round)

49j. Margin

- Circumscribed
- Not circumscribed (If not circumscribed, choose dominant feature)
  - Indistinct
  - Angular
  - Microlobulated
  - Spiculated

49k. Boundary Zone

- Abrupt Interface
- Echogenic Halo
49l. Echo Pattern
- Anechoic
- Hyperechoic
- Complex cystic
- Hypoechoic with few tiny cystic areas
-Isoechoic to fat
- Mixed hyperechoic and hypoechoic
- Hypoechoic to fat

49m. Posterior Features
- None
- Enhancement
- Combined shadowing/enhancement
- Shadowing

49n. Surrounding Tissue
- No effect
- Effect (check all that apply)
  - Duct changes
  - Edema
  - Cooper's ligament distortion
  - Architectural distortion
  - Skin thickening
  - Skin retraction

49o. Vascularity (flow)
- None
- Yes (check all that apply)
  - Present in lesion
  - Present immediately adjacent to lesion
  - Increased in surrounding tissue
- Not performed

49p. Calcifications on ultrasound
- None
- Present (check all that apply)
  - Macrocalcifications (> 0.5 mm)
  - Microcalcifications in mass
  - Microcalcifications outside mass

49q. Was lesion palpable in retrospect during sonography?
- No
- Yes, in retrospect
- Yes, participant presented with lump

50. Is this lesion at the site of prior biopsy?
- No (proceed to Q51)
- Yes (if yes, select procedure)
  - Core/vacuum biopsy site with clip
  - Core/vacuum biopsy site without marker
  - Surgical biopsy site (select diagnosis)
    - Benign
    - Atypical/high-risk lesion
    - Cancer site
    - Unknown
    - Biopsy details unknown
    - FNAB
  - Not applicable, multiple bilateral circumscribed masses

Section III.

51. Assessment/Recommendations

51a. ____________ % likelihood of malignancy for this lesion (best guess from 0-100)

51b. Assessment for this lesion
- 1 Negative
- 2 Benign
- 3 Probably Benign
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion
- 5 Highly Suggestive of Malignancy

51c. Known benign by prior biopsy?
- No (proceed to Q51d)
- Yes (complete)
- < 1 year ago
- 1-2 years ago
- > 2 years ago

51d. Recommendation(s) for this lesion
- Return to routine screening
- Diagnostic follow-up to coincide with next annual exam
- Short-interval follow-up in 6 months with US
- Short-interval follow-up in 6 months with mammography
- Short-interval follow-up in 6 months with MRI
- Intervention and/or Additional Imaging
  - Intervention
    - Aspiration with core biopsy if solid
    - US-guided core biopsy
    - Vacuum-assisted biopsy, guidance by US
    - Vacuum-assisted biopsy, guidance by mammo
    - Excisional biopsy
    - US-guided biopsy, if US negative, MRI guided biopsy
  - Additional Imaging
    - Targeted ultrasound (lesion seen on mammography)
    - Comparison to prior mammogram is required
    - Additional mammographic projections

51e. Is this lesion assessed as probably benign AND recommended for intervention?
- No (proceed to Final Assessment(s) Q16, Q17)
- Yes (specify dominant reason)
  - Participant preference
  - Cancer present now
    - In this breast
    - In opposite breast
  - Patient risks factors
  - Vaguely palpable
  - Follow-up not reasonable
  - Interval increase (>20% in volume for masses)
  - Interval suspicious change
  - Investigator uncertainty

Proceed to Final Assessment(s) Q16, Q17.
I. GENERAL INFORMATION

1. Was any percutaneous procedure performed?
   - No; If no, specify reason from code table (STOP and sign form)
   - Yes (continue)

2. Date of Procedure ______-_____-_______ (mm-dd-yyyy)
   
   2a. Time point in study prompting this biopsy
   - Initial screening
   - 6 month follow-up
   - 12 month screening
   - 18 month follow-up
   - 24 month screening
   - 30 month follow-up
   - 36 month follow-up
   - Other, specify __________________________

3. Radiologist name ______________________________

4. Total number of lesions biopsied ______ (please complete a separate BX form for each lesion biopsied)

5. Pathology Specimen ID# _________ (If no specimen, code xxxx)

   5a. Were slides sent for central review and results obtained?
   - No (proceed to Q6)
   - Yes (complete Q5b)
   - Pending (proceed to Q6)

   5b. Did central review change management?
   - No (proceed to Q6) Local result | Central result (reference code table)
   - Yes (complete)
     - Upgrade from □ □
     - Downgrade from □ □

6a. Guidance method:
   - US
   - Stereotactic prone
   - Stereotactic upright
   - Mammographic
   - MRI
   - No image guidance (e.g. palpable or duct excision)
   - Other, specify __________________________

6b. Biopsy of this lesion prompted by (check all that apply)
   - □ Mammogram
   - □ US
   - □ MRI
   - □ Clinical
   - □ Patient concern
   - □ Other, specify __________________________
II. DETAILS OF PROCEDURE

7. Lesion Details

Lesion # seen on any Mammogram (e.g. MR1, MB1, ML1, etc.)
If not applicable, code 998

Lesion # seen on any Ultrasound (e.g. UR1, UB1, UL1, etc.)
If not applicable, code 998

Finding # seen on MRI and reported on M3 or M4 (e.g. GR1, GL1, etc.)
If not applicable, code 998

Breast

[ ] [ ] [ ] o'clock OR

Clockface or specify Location

Distance from Nipple

Size (largest dimension)

o axilla
o retroareolar
o central

8. Lesion type (check all that apply)

☐ Mass
☐ Asymmetry
☐ Calcifications
☐ Architectural distortion
☐ Focus on MRI
☐ Non-mass enhancement on MRI
☐ Not seen on any imaging

9. Was procedure performed at study site?

☐ No, performed at (facility name then proceed to Section III)
☐ Yes (proceed to Q10)

10. Type of procedure

10a. ☐ US guided aspiration w/ -g needle

☐ Lesion resolved (proceed to Q12)
☐ Lesion did not resolve, core also done (complete Q10b)
☐ Lesion did not resolve, core not done (complete and proceed to Q12)

Reason

10b. ☐ US-guided core biopsy w/ -g biopsy gun or -g vacuum - assisted biopsy

☐ number of passes/specimens

☐ Stereotactically guided biopsy w/ -g biopsy gun or -g vacuum - assisted biopsy

☐ number of passes/specimens

☐ MRI guided biopsy w/ -g vacuum - assisted biopsy

☐ number of passes/specimens

10c. Specimen radiograph

☐ Not performed (proceed to Q10d)
☐ Performed (provide number of specimens with calcifications or number of specimens felt to include the lesion)

☐ number of specimens with calcifications or

☐ number of specimens felt to include lesion

10d. Was the lesion felt to be well sampled at the time of procedure?

☐ No
☐ Yes
☐ Unsure

10e. Was a clip placed?

☐ No
☐ Yes (complete placement location)

☐ Felt to be at site
☐ Within 1 cm of site
☐ 1-2 cm from lesion
☐ >2 cm from lesion

11. Any clinically significant complications from the biopsy procedure?

☐ No
☐ Yes

If yes, specify ________________________________
III. PATHOLOGY

12. Fluid analysis
   - No fluid obtained (proceed to Q13)
   - Fluid typical of benign cyst fluid and discarded (proceed to Q13)
   - Fluid not sent for cytology (proceed to Q12b)
   - Fluid sent for cytology (proceed to Q12a)

12a. Cytology (complete and proceed to Q12b)
   - Benign
   - Insufficient sample
   - Atypical/indeterminate
   - Suspicious
   - Malignant

12b. Culture/gram stain (complete and proceed to Q13)
   - Fluid not sent for this
   - Consistent with abscess
   - No organism/no growth

13. Histopathology of Core
   □ No core sent (proceed to Q15)

   Note: Please report all relevant discrete diagnoses with histopathology: e.g. If the main diagnosis was fibroadenoma but LCIS was also present, please include both.

13a. Core biopsy benign
   - No (proceed to Q13b)
   - Yes (check all that apply)
     - Fibroadenoma
     - Fibrosis
     - Fibroadenomatoid
     - Usual ductal hyperplasia
     - Duct ectasia
     - Sclerosing adenosis
     - Adenosis
     - Fibrocystic changes
     - Apocrine Metaplasia
     - Fat necrosis
     - Papilloma without atypia
     - Abscess
     - Lymph Node
     - Ruptured Cyst/Duct +/- Inflammation
     - Tubular Adenoma
     - PASH
     - Hypersecretory hyperplasia
     - Columnar alteration without atypia
     - Other, specify: __________________________

13b. Core biopsy high-risk/atypical
   - No (proceed to Q13c)
   - Yes (check all that apply)
     - Complex sclerosing lesion/radial scar
     - Atypical ductal hyperplasia
     - Atypical lobular hyperplasia
     - Check if ductal extension
     - Lobular carcinoma in situ
     - Check if ductal extension
     - Atypical papilloma
     - Columnar alteration with atypia
     - Other, specify: __________________________

13c. Core biopsy malignant
   - No (proceed to Q15)
   - Yes (check all that apply)
     - Invasive (infiltrating) ductal carcinoma
       - Grade
         - Grade cannot be assessed/ not reported
         - Low (Grade I)
         - Intermediate (Grade II)
         - High (Grade III)
         - Insufficient specimen
       - Pattern(s)
         □ Tubular
         □ Colloid/Mucinous
         □ Medullary
         □ Cribriform
         □ Micropapillary
         □ NOS
         □ Unknown
         □ Other, specify: __________________________

     - Invasive lobular carcinoma
     - Invasive with mixed ductal/lobular features
     - Ductal carcinoma in situ (DCIS)
       - Grade
         - Grade cannot be assessed/ not reported
         - Low (Grade I)
         - Intermediate (Grade II)
         - High (Grade III)
         - Insufficient specimen
       - Central necrosis
         □ Present
         □ Absent
         □ Unknown
       - Number of cores with DCIS [___] (code 99 if unknown)
       □ check if cancerization of lobules present
       □ Other Malignant, specify __________________________

14. Lymphovascular invasion on core?
   - Possible or definite
   - Not reported
   - Not applicable

15. Microcalcifications
   - Not present
   - Not detailed
   - In cancer
   - In benign areas only
   - In benign and malignant areas
IV. MANAGEMENT

16. Are the pathology results concordant with imaging findings?
   - No
   - Yes
   - Not sure

17. Recommendation
   - Return to annual screening
   - 12 month diagnostic follow-up
   - 6 month follow-up due on _____-_______ (mm-yyyy)
     - Mammography
     - US
     - MRI
   - Re-biopsy with (complete and provide reason)
     - Core
     - Surgery
     - Reason for rebiopsy
       - insufficient sample
       - atypical or high risk lesion
       - discordant
       - patient desires excision
       - other
     - Definitive surgery
     - Treatment for cancer, no surgery (complete S1 form)

18. Do you recommend MRI be performed now?
   - No
   - Yes (complete)
     - Bilateral
     - Right
     - Left

Stop. Form complete. Sign and date below.

Comments: ____________________________________________________________
_______________________________________________________________________
_______________________________________________________________________

Signature of Radiologist responsible for the data 1 __________________________ Date Form Completed (mm-dd-yyyy)

Signature of person entering data onto web 2 _______________________________
I. GENERAL INFORMATION

1. Was procedure performed?
   - No; If no, specify reason from code table [ ] (stop and sign form)
   - Yes

2. Date of procedure _____ - _____ - _____ (mm-dd-yyyy)

2a. Time point in study prompting this surgical biopsy
   - Initial screening
   - 6 month follow-up
   - 12 month screening
   - 18 month follow-up
   - 24 month screening
   - 30 month follow-up
   - 36 month follow-up
   - Other, specify ____________________________

3. Radiologist name ____________________________

4. Total number of lesions localized on this date _____ (submit a separate NL form for each separate lesion localized)

5. Pathology specimen ID # ____________

5a. Were slides from surgery sent for central review and results obtained?
   - No (proceed to Q6)
   - Yes (complete Q5b)
   - Pending (proceed to Q6)

5b. Did central review change management?
   - No (proceed to Q6)
   - Yes (complete)
   - Upgrade from Local result ____________
   - Downgrade from Central result ____________ (reference code table)

6. Guidance method:
   - US
   - Stereotactic prone
   - Stereotactic upright
   - Mammographic
   - MRI
   - No image guidance (e.g. palpable or duct excision)
   - Other, specify ____________________________

II. DETAILS OF PROCEDURE

7. Lesion Details
   - Lesion # seen on any Mammogram _______ (e.g. MR1, MB1, ML1 etc.)
     If not applicable, code 998
   - Lesion # seen on any Ultrasound _______ (e.g. UR1, UB1, UL1 etc.)
     If not applicable, code 998
   - Finding # seen on MRI and reported on M3 or M4 _______ (e.g. GR1, GL1, etc.)
     If not applicable, code 998

   Breast
   - R
   - L
   - Clockface or specify Location o’clock
   - Distance from Nipple cm
   - Size (largest dimension) mm

   OR

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8. **Lesion type** (check all that apply)
   - Mass
   - Asymmetry
   - Calcifications
   - Architectural distortion
   - Focus on MRI
   - Non Mass enhancement on MRI
   - Not seen on any imaging

9. **Was procedure performed at study site?**
   - No, performed at ____________ (facility name then proceed to Section III)
   - Yes (proceed to Q10)

10. **Target**
   10a. **Is this the first procedure to sample this lesion?**
       - No (please complete BX as appropriate)
       - Yes (proceed to Q10d)
   10b. **Is there a clip?**
       - No (proceed to Q10c)
       - Yes (detail all that apply then proceed to Q10d)
         - Clip only, no residual lesion apparent
         - Clip is remote (>2cm) from lesion
         - Residual lesion and clip
   10c. **Prior core biopsy site without clip**
       - Lesion readily visualized
       - Lesion difficult to visualize
   10d. **Was this a bracketed localization?**
       - No (proceed to Q10e)
       - Yes, detail number of needles/wires
         - 2
         - 3
         - 4 or more

10e. **Length of longest needle used** __________ cm

10f. **Shortest distance from lesion to wire:**
    (If bracketed, give average distance to wires)
    - ≤ 0.5 cm
    - 0.6–1.0 cm
    - 1.1–2.0 cm
    - > 2 cm

10g. **How was the specimen imaged?**
    - Mammogram only
    - US only
    - Both US and mammo
    - Neither US nor mammo

10h. **Assessment of specimen**
    - Includes lesion
    - Equivocal
    - Does not include lesion

11. **Any clinically significant complications from the localization procedure?**
    - No (proceed to Q12)
    - Yes (check all that apply)
      - Vasovagal reaction
      - Needle had to be repositioned
      - Other, specify: __________________________

12. **Benign**
    - No (proceed to Q13)
    - Yes (If yes, check all that apply)
      - Fibroadenoma
      - Fibrosis
      - Fibroadenomatoic
      - Usual ductal hyperplasia
      - Duct ectasia
      - Sclerosing adenosis
      - Adenosis
      - Fibrocystic changes
      - Apocrine metaplasia
      - Fat necrosis
      - Papilloma without atypia
      - Abscess
      - Lymph node
      - Ruptured Cyst/Duct +/- Inflammation
      - Tubular Adenoma
      - PASH
      - Hypersecretory hyperplasia
      - Columnar alteration without atypia
      - Other __________________________

13. **High-risk/atypia**
    - No (proceed to Q14)
    - Yes (If yes, check all that apply)
      - Complex sclerosing lesion/radial scar
      - Atypical ductal hyperplasia
      - Atypical lobular hyperplasia
        - Check if ducal extension
      - Lobular carcinoma in situ
        - Check if ducal extension
      - Atypical papilloma
      - Columnar alteration with atypia
      - Other __________________________
14. Malignant
   - No (proceed to Q16)
   - Yes (check all that apply)

   NOTE: If core or excision malignant and no further treatment surgery for cancer is planned, please complete form S1 also at this time.
   □ Invasive (infiltrating) ductal carcinoma
     Grade
     - Grade cannot be assessed/ not reported
     - Low (Grade I)
     - Intermediate (Grade II)
     - High (Grade III)
     - Insufficient specimen
     Pattern(s)
     - Tubular
     - Colloid/Mucinous
     - Medullary
     - Cribriform
     - Micropapillary
     - NOS
     - Unknown
     - Other
     □ Invasive lobular carcinoma
     □ Invasive with mixed ductal/lobular features
     □ Ductal carcinoma in situ
     Grade
     - Grade cannot be assessed/ not reported
     - Low (Grade I)
     - Intermediate (Grade II)
     - High (Grade III)
     - Insufficient specimen
     Central Necrosis
     - Present
     - Absent
     - Unknown
     □ Check if cancerization of lobules present
     □ Other malignant (specify): __________________________

15. Lymphovascular invasion present?
   - Possible or definite
   - Not reported
   - Not applicable

16. Microcalcifications
   - Not present
   - Not detailed
   - In cancer
   - In benign areas only
   - In benign and malignant areas

17. Are the excisional histopathology results concordant with imaging findings?
   - No
   - Yes
   - Not sure

18. Recommendation
   - Return to annual screening
   - 12 month diagnostic follow-up
     - 6 month follow-up due ___________, __________ (mm-yyyy)
       □ Mammography
       □ US
       □ MRI
   - Re-excision for diagnosis (initial surgery inadequate)
   - Definitive surgery (Complete S1 when performed)
   - Treatment for cancer, no further surgery (complete S1 form)
   - Mammogram as soon as feasible

19. Do you recommend MRI be performed now?
   - No
   - Yes (complete)
     - Bilateral
     - Right
     - Left

20. Are there additional lesions to be reported on another form NL at this time?
   - No
   - Yes

Stop, form complete, sign and date below.

Comments: __________________________________________
_____________________________________________________
_____________________________________________________
_____________________________________________________
_____________________________________________________
Signature of Radiologist responsible for the data 1 ____________________________
Date Form Completed (mm-dd-yyyy) ___________, __________

Signature of person entering data onto web 2 ____________________________
## ACRIN Study 6666

### Therapeutic Surgery Form

**Instructions:** Complete a separate S1 form for each separate area of each breast excised with the intent to treat a cancer (e.g., each lumpectomy or mastectomy). May be completed by study RA or study Radiologist; original pathology report should be submitted. Lymph nodes excised on the same date as the breast treatment surgery can be reported on the same S1 form as the main breast surgery. If an axillary dissection is performed at a later date or re-excision of margins is performed, please complete a separate form S1.

1. **Is participant known to have distant metastases from breast cancer?**
   - No (proceed to Q1a)
   - Yes (detail then proceed to Q1a)
     - Primary Cancer was in:
       - Right breast
       - Left breast
       - Both breasts
       - Unknown
   1a. **Has an S1 form previously been submitted for this breast?**
     - No
     - Yes
   1b. **Was therapeutic surgical procedure performed?**
     - No; If no, specify reason from code table □ (proceed to Q11)
     - Yes

2. **Date of treatment surgery** (mm-dd-yyyy) __________-

2a. **Name of facility where surgery performed** __________

2b. **Time point in study when this cancer was detected?**
   - Initial screening
   - 6 month follow-up
   - 12 month screening
   - 18 month follow-up
   - 24 month screening
   - 30 month follow-up
   - 36 month follow-up
   - Other, specify __________
   - No cancer known preoperatively this breast

3. **What surgery was performed?**

3a. **Tumor Excision**
   - Single lumpectomy
   - Double lumpectomy
   - Quadrantectomy/Wide excision/Segmentectomy
   - Mastectomy
   - Prophylactic mastectomy
   - Other, specify __________

3b. **Lymph node evaluation**

   **Sentinel Node(s)**
   - Not done (proceed to Q3c)
   - Already performed, reported previously (on prior S1 form, proceed to Q3c)
   - Performed (complete)
   - □ Number of nodes retrieved
   - □ Number malignant
   - Check if micrometastasis (< 2 mm) only by (detail)
     - IHC
     - H + E
     - Both
     - Unknown
   - Already performed, reported previously (on prior S1 form)

3c. **Axillary dissection**
   - Not done (proceed to Q4)
   - Performed (complete)
   - □ Number of nodes retrieved
   - □ Number malignant
   - □ Check if extracapsular invasion

---

**Code Table for Q1b**

1. Not indicated (other medical problems)
2. Participant refusal
3. Participant did not return
4. Unable to be performed and rescheduled
5. Other

---

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4. **Pathology Specimen ID#**

4a. Were slides sent for central review and results obtained?
- No (proceed to Q5)
- Yes (complete Q4b)
- Pending (proceed to Q5)

4b. Did central review change management?
- No (proceed to Q5)
- Yes (complete)
  - Upgrade from __________ to __________
  - Downgrade from __________ to __________

5. How many previously enumerated lesions were excised with this surgical specimen (i.e. lumpectomy or mastectomy)? [ ]

5a. **Lesion Location**

   - Check if this lesion ONLY seen on MRI

   - Breast [ ]
   - Clockface or specify Location [ ]
   - Clockface or specify Location [ ]
   - Distance from Nipple [ ]
   - Size (largest dimension) cm [ ] mm [ ]
   - Lesion number [ ]

   - Provide pathology at this surgery for the lesion described above
   - Cancer
   - Atypical/high-risk
   - Benign
   - Unsure of correlation with final surgical specimen

5b. Was there another previously enumerated lesion removed from this breast during this surgery?
- No (proceed to Q6)
- Yes (proceed to Q13)

6. **Final Margin Status**

   - Margins clear
     - 10 mm or more
     - 4-9 mm
     - 1-3 mm
     - < 1 mm
     - Unknown
   - Margins equivocal
   - Invasive tumor at margin
   - DCIS at margin
   - Not applicable, no cancer found

7. Will additional surgery be needed for this breast or axilla (other than cosmetic surgery)?
- No
- Yes (please complete another S1 when performed)
- Unknown

---

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8. Final Histopathology

8a. Is cancer present at excision?
- No (complete Q8b-9d based on core information)
- Felt to have been excised at core
- S/P neoadjuvant chemotherapy
- Felt to have been missed by surgeon or pathologist
- Prophylactic mastectomy (skip to Q12)
- Yes (complete Q8b-9d based on worst applicable information from combination of core and excision)

8b. Are multiple tumors present?
- No
- Yes
  - Multifocal (< 4 cm apart)
  - Multicentric (≥ 4 cm apart)
  - Diffuse throughout breast
  - Unknown

8c. Is invasive cancer present?
- No (proceed to Q9)
- Yes (provide largest diameter)
  - [ ] [ ] [ ] mm Largest diameter of invasive component
    (per pathology report) (code 999 if unknown or not reported)
- Unknown

8d. Is lymphovascular invasion present?
- No
- Yes
- Unknown

8e. Detail invasive cancer (check all that apply)
- Invasive ductal carcinoma
  (complete grade and pattern)
  Grade
  - Grade cannot be assessed
  - Low (Grade I)
  - Intermediate (Grade II)
  - High (Grade III)
  - Insufficient specimen
- Pattern(s)
  - Tubular
  - Colloid/mucinous
  - Medullary
  - Cribriform
  - Micropapillary
  - NOS
  - Unknown
  - Other, specify __________________________

- Invasive lobular carcinoma
- Invasive with mixed ductal/lobular features
- Invasive, not of breast origin, (specify and then STOP, sign form ________)

8f. Were Receptors done?
- No (proceed to Q9)
- Yes (detail then proceed to Q8g)
  - From core biopsy
  - From surgical specimen
- Unknown (proceed to Q9)

8g. What is the ER status?
- Positive
- Negative
- Not assessed
- Unknown

8h. What is the PR status?
- Positive
- Negative
- Not assessed
- Unknown

8i. What is the Her-2/neu (c-erb2) status?
- Negative
- 1 +
- 2 +
- 3 +
- Not assessed
- Unknown

8j. What is the CA-125 level?
- Normal
- Abnormal
- Unknown

9. Is Ductal Carcinoma in situ present?
- No (proceed to Q10)
- Yes (proceed to Q9a)
- Unknown (proceed to Q10)

9a. Grade
- Grade cannot be assessed
- Low (Grade I)
- Intermediate (Grade II)
- High (Grade III)
- Insufficient specimen

9b. Is central necrosis present?
- No
- Yes
- Unknown

9c. Histologic type(s) __________________________
  Number of slides with DCIS [ ] [ ] (code 999 if unknown)
  Total number of slides [ ] [ ] (code 999 if unknown)

9d. Extensive Intraductal component (invasive cancer and DCIS where DCIS is at least 25% of tumor with additional DCIS foci outside main tumor mass)
- No
- Yes
- Unknown

10. Were all pathologically proven cancers in this breast identified on either mammography or US preoperatively?
- No (detail)
  Number of additional malignant foci: [ ] [ ] (code 999 if unknown)
  (Detail below. Note: code mixed invasive and intraductal as invasive)
  - Invasive ductal carcinoma
  - Invasive lobular carcinoma
  - Invasive with mixed ductal/lobular features
  - DCIS only
  - Invasive, not of breast origin
  - Unknown
  - Yes (proceed to Q11)
  - Unknown (proceed to Q11)
11. **TNM Stage**

11a. **Has staging already been reported on another S1?**
- o No (proceed to Q11c)
- o Yes

11b. **Did the results of this surgery change the staging of this cancer?**
- o No (proceed to Q12)
- o Yes (proceed to Q11c)

11c. **T Stage (Primary Tumor)**

- o **TX** Primary Tumor cannot be assessed
- o **T0** No evidence of primary tumor
- o **Tis** Ductal carcinoma in situ
- o **T1** Tumor 2 cm or less in greatest dimension
  - o **T1a** Microinvasive tumor, ≤ 0.1 cm in greatest diameter
  - o **T1b** Invasive tumor, 0.1 < x ≤ 0.5 cm in greatest diameter
  - o **T1c** Invasive tumor, 0.5 < x ≤ 1.0 cm in greatest diameter
- o **T2** Invasive tumor, 1.0 < x ≤ 2.0 cm in greatest diameter
- o **T3** Invasive tumor, > 5 cm in greatest diameter

11d. **N Stage (Regional Lymph Nodes)**

- o **NX** Regional lymph nodes cannot be assessed (e.g., previously removed)
- o **N0** No regional lymph node metastasis
  - o **pN0** No regional lymph node metastasis histologically, no additional examination for isolated tumor cells (ITC)
  - o **pN0(i-)** No regional lymph node metastasis histologically, negative IHC
  - o **pN0 (i+)** No regional lymph node metastasis histologically, positive IHC cluster greater than 0.2 mm
- o **N1** Metastasis in moveable ipsilateral lymph node(s)
  - o **pN1** Micrometastasis (greater than 0.2 mm, none greater than 2.0 mm)
  - o **pN1a** Metastasis in 1 to 3 axillary lymph nodes
  - o **pN1b** Metastasis in internal mammary lymph nodes with microscopic disease detected by sentinel lymph node dissection but not clinically apparent
  - o **pN1c** Metastasis in 1 to 3 axillary lymph nodes and in internal mammary lymph nodes with microscopic disease detected by sentinel lymph node dissection but not clinically apparent
- o **N2** Metastases in ipsilateral axillary lymph nodes fixed or matted, or in clinically apparent ipsilateral internal mammary lymph nodes in the absence of clinically evident axillary lymph node metastasis
  - o **N2a** Metastasis in ipsilateral axillary lymph nodes fixed to one another (matted) or to other structures
  - o **pN2** Metastasis in 4-9 axillary lymph nodes, or in clinically apparent internal mammary lymph nodes in the absence of axillary lymph node metastasis
  - o **pN2a** Metastasis in 4-9 axillary lymph nodes (at least one tumor deposit greater than 2.0 mm )
  - o **pN2b** Metastasis in clinically apparent internal mammary lymph nodes in the absence of axillary lymph node metastasis
- o **N3** Metastasis in ipsilateral infraclavicular lymph node(s) with or without axillary lymph node involvement, or in clinically apparent ipsilateral internal mammary lymph node(s) and in the presence of clinically evident axillary lymph node metastasis; or metastasis in ipsilateral supraclavicular lymph node(s) with or without axillary or internal mammary lymph node involvement
  - o **N3a** Metastasis in ipsilateral infraclavicular lymph node(s) and axillary lymph node(s)
  - o **N3b** Metastasis in ipsilateral internal mammary lymph node(s) and axillary lymph node(s)
  - o **N3c** Metastasis in ipsilateral supraclavicular lymph node(s)
  - o **pN3** Metastasis in 10 or more axillary lymph nodes, or in infraclavicular lymph nodes, or in clinically apparent ipsilateral internal mammary lymph nodes in the presence of 1 or more positive axillary lymph nodes; or in more than 3 axillary lymph nodes with clinically negative microscopic metastasis in internal mammary lymph nodes; or in ipsilateral supraclavicular lymph nodes
  - o **pN3a** Metastasis in 10 or more axillary lymph nodes (at least one tumor deposit greater than 2.0 mm), or metastasis to the infraclavicular lymph nodes
  - o **pN3b** Metastasis in clinically apparent ipsilateral internal mammary lymph nodes in the presence of 1 or more positive axillary lymph nodes; or in more than 3 axillary lymph nodes and in internal mammary lymph nodes with microscopic disease detected by sentinel lymph node dissection but not clinically apparent
  - o **pN3c** Metastasis in ipsilateral supraclavicular lymph node(s)

11e. **M Stage (Distant Metastasis)**

- o **MX** Presence of distant metastasis cannot be assessed
- o **M0** No evidence of distant metastasis
- o **M1** Distant metastasis (includes metastasis to ipsilateral supraclavicular lymph node(s)
Foot Notes

1. Clinically apparent is defined as detected by imaging studies (excluding lymphoscintigraphy) or by clinical examination.
2. Classification is based on axillary lymph node dissection with or without sentinel lymph node dissection. Classification based solely on sentinel lymph node dissection without subsequent axillary lymph node dissection is designated (sn) for "sentinel node," e.g., pN0 (i+) (sn).
3. Isolated tumor cells (ITC) are defined as single tumor cell or small cell clusters not greater than 0.2 mm, usually detected only by immunohistochemical (IHC) or molecular methods but which may be verified on H&E stains. ITCs do not usually show evidence of metastatic activity (e.g., proliferation or stromal reaction.)
4. RT-PCR: reverse transcriptase/polymerase chain reaction.
5. Not clinically apparent is defined as not detected by imaging studies (excluding lymphoscintigraphy) or by clinical examination.
6. If associated with greater than 3 positive axillary lymph nodes, the internal mammary nodes are classified as pN3b to reflect increased tumor burden.
7. T1 includes T1mic

12. Will another form S1 be completed for this breast at this time (e.g. double lumpectomy)?
   o No
   o Yes

Comments:__________________________________________________________

____________________________________________________________________

____________________________________________________________________

____________________________________________________________________

____________________________________________________________________

STOP: Sign and date form

Signature of person responsible for the data _____________________________ Date Form Completed (mm-dd-yyyy) ___________________

Signature of person entering data on web ______________________________

"Copyright 2007"
13. Detail additional enumerated lesion this specimen

13a. **Lesion Location**  □ Check if this lesion **ONLY** seen on MRI

<table>
<thead>
<tr>
<th>Breast</th>
<th>Clockface or specify Location</th>
<th>Distance from Nipple</th>
<th>Size (largest dimension)</th>
<th>Lesion number</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 R O L</td>
<td>• o’ clock</td>
<td>• cm</td>
<td>• mm</td>
<td>•</td>
</tr>
</tbody>
</table>

Provide pathology at this surgery for the lesion described above
- Cancer
- Atypical/high-risk
- Benign
- Unsure of correlation with final surgical specimen

13b. Was there another previously enumerated lesion removed from this breast during this surgery?
- No (proceed to Q6)
- Yes (proceed to Q14)

14. Detail additional enumerated lesion this specimen

14a. **Lesion Location**  □ Check if this lesion **ONLY** seen on MRI

<table>
<thead>
<tr>
<th>Breast</th>
<th>Clockface or specify Location</th>
<th>Distance from Nipple</th>
<th>Size (largest dimension)</th>
<th>Lesion number</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 R O L</td>
<td>• o’ clock</td>
<td>• cm</td>
<td>• mm</td>
<td>•</td>
</tr>
</tbody>
</table>

Provide pathology at this surgery for the lesion described above
- Cancer
- Atypical/high-risk
- Benign
- Unsure of correlation with final surgical specimen

14b. Was there another previously enumerated lesion removed from this breast during this surgery?
- No (proceed to Q6)
- Yes (proceed to Q15)

15. Detail additional enumerated lesion this specimen

15a. **Lesion Location**  □ Check if this lesion **ONLY** seen on MRI

<table>
<thead>
<tr>
<th>Breast</th>
<th>Clockface or specify Location</th>
<th>Distance from Nipple</th>
<th>Size (largest dimension)</th>
<th>Lesion number</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 R O L</td>
<td>• o’ clock</td>
<td>• cm</td>
<td>• mm</td>
<td>•</td>
</tr>
</tbody>
</table>

Provide pathology at this surgery for the lesion described above
- Cancer
- Atypical/high-risk
- Benign
- Unsure of correlation with final surgical specimen

Proceed to Q6
I. GENERAL INFORMATION

1a. Breast reported on this form
   - Right Breast
   - Left Breast

1b. Is this form M3 a continuation of another M3 for this breast?
   - No, proceed to Q2
   - Yes, proceed to Q5

2. Was an MRI done?
   - No; If no, specify reason from code table (stop and sign form)
   - Yes (complete Q2a and continue with form)

2a. Are there any findings in the breast reported in Q1a for which recommendation is other than routine follow-up?
   - No
   - Yes

3. Date of MRI Scan
   - ______-____-_______ (mm-dd-yyyy)

3a. Participant's last menstrual period
   - ______-____-_______ (mm-dd-yyyy)
   * If < 1 month ago. Note: Code 12-12-2100 if not applicable or unknown

3b. Date of MRI Interpretation
   - ______-____-_______ (mm-dd-yyyy)

3c. Reader ID# ____________________________
   Radiologist Name ____________________________ (Last, First)

3d. Background tissue enhancement
   - None/minimal
   - Moderate, patchy
   - Moderate, uniform
   - Marked

3e. Significant artifacts for this breast?
   - No (proceed to Q4)
   - Yes (check all that apply then proceed to Q4)
   - Motion
   - Large breast, abuts coil
   - Inhomogeneous fat suppression
   - Clips/sutures
   - Other, specify ____________________________

4. ____ Total number of findings for this breast on MRI.
   (If zero (0), skip to Q12) (Note: Multiple foci can be reported as one lesion if all felt to be the same process)

5. □ Data recorded represents finding #.
   (A separate form must be completed for each finding. Note: Code GR1 for the first lesion in right breast, GL1 for the first lesion in the left breast, etc.)

II. FINDING

6a. Signal on T2 for this finding
   - Purely cystic/fluid
   - Moderately hyperintense (at least partially solid)
   - Slightly hyperintense
   - Hypointense or not seen

6b. Finding type (study breast)
   - Focus/foci < 5 mm (proceed to Q6c)
   - Mass (answer Q7 then skip to Q9)
   - Non mass enhancement (skip to Q8)
   - Scar (skip to Q10)

6c. If focus/foci (detail then proceed to Q10)
   - Solitary
   - If Solitary, ______ largest diameter in mm
   - 2-3
   - ≥ 4

7. Mass size encompassed by Gd enhancement
   (record three dimensions)
   - _______ x _______ x _______ mm
   - med-lat sup-inf ant-post

7a. Mass Shape
   - Round
   - Oval
   - Lobulated
   - Irregular

7b. Mass Margin
   - Smooth
   - Irregular
   - Spiculated

7c. Mass Internal Enhancement
   - Homogeneous
   - Heterogeneous
   - Rim enhancement
   - Dark internal septation(s)
   - Enhanced internal septation(s)
   - Central internal enhancement

7d. Fat containing
   - No
   - Yes

7e. Mass Degree of Enhancement
   - Minimal
   - Moderate
   - Marked

   * * * proceed to question 9 * * *
8. Type of non-mass enhancement
   - Focal area
   - Linear
   - Ductal
   - Segmental
   - Regional
   - Multiple regions
   - Diffuse

8a. Largest diameter ____________ mm

8b. Non-Mass enhancement symmetry
   - Not applicable
   - Symmetric
   - Asymmetric

8c. Non-Mass enhancement internal characteristics
   - Homogeneous
   - Heterogeneous
   - Stippled/punctate
   - Clumped
   - Reticular/dendritic

III. ASSOCIATED FINDINGS

9. Associated findings (finding noted in Q5)
   - No (skip to Q10)
   - Yes (complete Q9A and continue)

9a. Characterization of Associated findings
   (Check all that apply)
   - Nipple retraction or inversion
   - Skin retraction
   - Pre-contrast high duct signal
   - Skin thickening
   - Skin invasion
   - Edema
   - Lymphadenopathy
   - Pectoralis muscle invasion
   - Chest wall invasion
   - Hematoma / blood
   - Abnormal signal void
     (absence of signal due to artifact)
   - Cyst(s)
   - Other, specify __________________________

IV. Finding Location (location of finding noted in Q5)

10. Location of finding
    - Nipple
    - Central Region
    - UIQ
    - LIQ
    - UOQ
    - LOQ
    - Axillary Tail
    - Breast, NOS
    - Subareolar
    - Multiple scattered areas
    - Other, Specify __________________________

V. KINETIC CURVE ASSESSMENT

11. CAD used for this lesion
    - No
    - Yes, for kinetics only
    - Lesion only detected after CAD

11a. Initial enhancement phase
    - Not applicable
    - Slow
    - Medium
    - Rapid

11b. Delayed enhancement phase
    (after 2 minutes or after curve begins to change)
    - Not applicable
    - Persistent
    - Plateau
    - Washout
VI. OVERALL ASSESSMENT OF FINDING

Questions 12 and 13 record recommendations specific to the finding # reported in Q5.
Note: If no lesion recorded in Q5, code assessments and recommendation for this breast.

12. Assessment
- 1 Negative, no abnormal enhancement
- 2 Benign
- 3 Probably Benign finding
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion of Malignancy
- 4C Moderately High Suspicion of Malignancy
- 5 Highly Suggestive of Malignancy

12a. Recommendation for this lesion
- Routine follow-up
- Short-interval follow-up with MRI in _____ months
- Biopsy (detail)
  - US-guided biopsy; if US negative, MRI-guided biopsy
  - MRI guided biopsy directly
  - Other, specify; ____________________________
- Additional Imaging
  - Additional mammographic views
  - Ultrasound targeted to finding
    - If US negative, routine follow-up
    - If US negative, short-interval follow-up with MRI in _____ months
- Repeat MRI due to
  - Technical problem or motion (detail in comments)
  - Incomplete
  - Abnormalities likely due to phase in cycle
  - Other, specify; ____________________________

13. Likelihood of malignancy for this finding, 0-100% _______ _______

COMMENTS: _______________________________________________________________
__________________________________________________________________________
__________________________________________________________________________

Date form completed3 _____-_____-____ (mm-dd-yyyy)

Signature of person responsible for the data 1

Signature of person entering data onto the web 2

6666 M3 06-08-06 3 of 3
INSTRUCTIONS: This form is completed only for the follow-up MRI of the study breast and submitted to the ACR. 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; in addition a separate form is to be completed for EACH breast even if no finding is identified in that breast. Reports are dated MM/DD/YYYY. Measurements are reported in mm. Nonenhancing cysts and nonenhancing scars do not have to be numbered; use comments.

I. GENERAL INFORMATION

1a. Breast reported on this form
   - Right Breast
   - Left Breast

1b. Is this form M4 a continuation of another M4 for this breast?
   - No, proceed to Q2
   - Yes, proceed to Q5

2. Was an MRI done?
   - No; If no, specify reason from code table (stop and sign form)
   - Yes (complete Q2a and continue with form)

2a. Follow-up MRI timepoint
   - 3 months
   - 6 months
   - Other, specify ____________________________

2b. Are there any findings in the breast reported in Q1a for which recommendation is other than routine follow-up?
   - No
   - Yes

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

3a. Participant's last menstrual period
   _____-_____-(mm-dd-yyyy)
   If < 1 month ago. Note: Code 12-12-2100 if not applicable or unknown

3b. Date of MRI Interpretation
   _____-_____-(mm-dd-yyyy)

3c. Reader ID# ____________________________
   Radiologist Name ____________________________
   (Last, First)

3d. Background tissue enhancement
   - None/minimal
   - Moderate, patchy
   - Moderate, uniform
   - Marked

3e. Significant artifacts for this breast?
   - No (proceed to Q4)
   - Yes (check all that apply then proceed to Q4)
     - Motion
     - Large breast, abuts coil
     - Inhomogeneous fat suppression
     - Clips/sutures
     - Other, specify ____________________________

4. __________ Total number of findings for this breast on MRI.
   (If zero (0), skip to Q12) (Note: Multiple foci can be reported as one lesion if all felt to be the same process)

5. G __________ Data recorded represents finding #.
   (A separate form must be completed for each finding. Note: Code GR1 for the first lesion in right breast, GL1 for the first lesion in the left breast, etc.)

II. FINDING

6a. Signal on T2 for this finding
   - Purely cystic/fluid
   - Moderately hyperintense (at least partially solid)
   - Slightly hyperintense
   - Hypointense or not seen

6b. Finding type (study breast)
   - Focus/foci < 5 mm (proceed to Q6c)
   - Mass (answer Q7 then skip to Q9)
   - Non mass enhancement (skip to Q8)
   - Scar (skip to Q10)

6c. If focus/foci (detail then proceed to Q10)
   - Solitary
   - If Solitary, ______ largest diameter in mm
   - 2-3
   - > 4

7. Mass size encompassed by Gd enhancement
   (record three dimensions)
   _____-_____ (mm/dd/yyyy)
   med-lat x mm sup-inf y mm ant-post z mm

7a. Mass Shape
   - Round
   - Oval
   - Lobulated
   - Irregular

7b. Mass Margin
   - Smooth
   - Irregular
   - Spiculated

7c. Mass Internal Enhancement
   - Homogeneous
   - Heterogeneous
   - Rim enhancement
   - Dark internal septation(s)
   - Enhanced internal septation(s)
   - Central internal enhancement

7d. Fat Containing
   - No
   - Yes

7e. Mass Degree of Enhancement
   - Minimal
   - Moderate
   - Marked

   * * * proceed to question 9 * * *

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8. Type of non-mass enhancement
   - Focal area
   - Linear
   - Ductal
   - Segmental
   - Regional
   - Multiple regions
   - Diffuse

8a. Largest diameter ______ mm

8b. Non-Mass enhancement symmetry
   - Not applicable
   - Symmetric
   - Asymmetric

8c. Non-Mass enhancement internal characteristics
   - Homogeneous
   - Heterogeneous
   - Stippled/punctate
   - Clumped
   - Reticular/dendritic

III. ASSOCIATED FINDINGS

9. Associated findings (finding noted in Q5)
   - No (skip to Q10)
   - Yes (complete Q9A and continue)

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

[ ] Nipple retraction or inversion
[ ] Skin retraction
[ ] Pre-contrast high duct signal
[ ] Skin thickening
[ ] Skin invasion
[ ] Edema
[ ] Lymphadenopathy
[ ] Pectoralis muscle invasion
[ ] Chest wall invasion
[ ] Hematoma/blood
[ ] Abnormal signal void
   (absence of signal due to artifact)
[ ] Cyst(s)
[ ] Other, specify ____________________________

IV. Finding Location (location of finding noted in Q5)

10. Location of finding
    - Nipple
    - Central Region
    - UIQ
    - LIQ
    - UOQ
    - LOQ
    - Axillary Tail
    - Breast, NOS
    - Subareolar
    - Multiple scattered areas
    - Other, Specify ____________________________

10a. Maximum distance of Finding From the Nipple

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

      Cranio-Caudal
                    Medio-Lateral

      Cranio-Caudal
      Medio-Lateral

      Cranio-Caudal
      Medio-Lateral

      Cranio-Caudal
      Medio-Lateral

      Cranio-Caudal
      Medio-Lateral

      Cranio-Caudal
      Medio-Lateral

V. KINETIC CURVE ASSESSMENT

11. CAD used for this lesion
    - No
    - Yes, for kinetics only
    - Lesion only detected after CAD

11a. Initial enhancement phase
     - Not applicable
     - Slow
     - Medium
     - Rapid

11b. Delayed enhancement phase
     (after 2 minutes or after curve begins to change)
     - Not applicable
     - Persistent
     - Plateau
     - Washout
VI. OVERALL ASSESSMENT OF FINDING

Questions 12 and 13 record recommendations specific to the finding # reported in Q5.
Note: If no lesion recorded in Q5, code assessments and recommendation for this breast.

12. Assessment
   - 1. Negative, no abnormal enhancement
   - 2. Benign
   - 3. Probably Benign finding
   - 4A. Low Suspicion of Malignancy
   - 4B. Intermediate Suspicion of Malignancy
   - 4C. Moderately High Suspicion of Malignancy
   - 5. Highly Suggestive of Malignancy

12a. Recommendation for this lesion
   - Routine follow-up
   - Short-interval follow-up with MRI in _____ months
   - Biopsy (detail)
     - US-guided biopsy; if US negative, MRI-guided biopsy
     - MRI guided biopsy directly
     - Other, specify; __________________________
   - Additional Imaging
     - Additional mammographic views
     - Ultrasound targeted to finding
       - If US negative, short-interval follow-up with MRI in _____ months
     - Repeat MRI due to
       - Technical problem or motion (detail in comments)
       - Incomplete
       - Abnormalities likely due to phase in cycle
       - Other, specify; __________________________

13. Likelihood of malignancy for this finding, 0-100% [ ] [ ] [ ]

COMMENTS:

________________________________________
________________________________________
________________________________________
________________________________________

________________________________________
Date form completed 3 _____-_____-(mm-dd-yyyy)

Signature of person responsible for the data 1

________________________________________

Signature of person entering data onto the web 2

"Copyright 2007"
1. Radiologist ID ___________ 
   
   1a. Radiologist Name ____________________________
       (Last, First)

2. Date of Integration Interpretation: _______ - _______ - _______
   mm-dd-yyyy
   
   2a. Date of Mammogram _______ - _______ - _______
       mm-dd-yyyy
   
   2b. Date of US _______ - _______ - _______
       mm-dd-yyyy
   
   2c. Date of MRI _______ - _______ - _______
       mm-dd-yyyy

3. When all current breast imaging is reviewed together:
   Are there any findings seen ONLY on MRI:
   
   3a. Requiring additional evaluation?
       o None
       o Right breast only
       o Left breast only
       o Both breasts

   3b. Requiring short interval follow-up?
       o None
       o Right breast only
       o Left breast only
       o Both breasts

   3c. Requiring biopsy?
       o None
       o Right breast only
       o Left breast only
       o Both breasts

4. Are any findings considered benign or probably benign by US that require biopsy based on MRI?
   o No
   o Yes

5. Are any findings considered benign or probably benign by Mammography that require biopsy based on MRI?
   o No
   o Yes
6. Taking together all breast imaging on this participant, final assessment by breast:

Final Assessment of Right Breast

6a. □ Not on study (proceed to Q7)

6b. □ □ □ % Combined reading likelihood of malignancy for right breast (best guess from 0-100)

6c. Assessment for right breast

- 1 Negative
- 2 Benign
- 3 Probably Benign
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion
- 5 Highly Suggestive of Malignancy

6d. Recommendation for right breast

Follow-up
- Routine screening in 1 year
- Diagnostic follow-up in 1 year
- Short-interval follow-up in 6 months with US
- Short-interval follow-up in 6 months with mammography
- Short-interval follow-up MRI in 6 months
- Intervention and/or Additional Imaging (detail intervention and/or additional imaging)
  □ Intervention
  - Aspiration with core biopsy if solid
  - US-guided core biopsy
  - Vacuum-assisted biopsy, guidance by US
  - Vacuum-assisted biopsy, guidance by mammography
  - Excisional biopsy
  - MRI-guided vacuum assisted biopsy if not US biopsy
  □ Additional Imaging (check all that apply)
    □ Additional evaluation
    - Comparison to prior mammogram is required
    - Targeted ultrasound (lesion seen on mammography)
    - Ultrasound targeted to MRI abnormality
    - Additional mammographic projections
    □ Repeat ultrasound
    - Technique/interpretation in question
    - Possibly abnormal
    □ Repeat mammogram
    - Incomplete
    - Motion artifact/other technical problem
    □ Repeat MRI
    - Motion artifact or other technical problem
    - Incomplete
    - Abnormalities likely due to phase in cycle

7. Final Assessment of Left Breast

7a. □ Not on study (stop and sign below)

7b. □ □ □ % Combined reading likelihood of malignancy for left breast (best guess from 0-100)

7c. Assessment for left breast

- 1 Negative
- 2 Benign
- 3 Probably Benign
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion
- 5 Highly Suggestive of Malignancy

7d. Recommendation for left breast

Follow-up
- Routine screening in 1 year
- Diagnostic follow-up in 1 year
- Short-interval follow-up in 6 months with US
- Short-interval follow-up in 6 months with mammography
- Short-interval follow-up MRI in 6 months
- Intervention and/or Additional Imaging (detail intervention and/or additional imaging)
  □ Intervention
  - Aspiration with core biopsy if solid
  - US-guided core biopsy
  - Vacuum-assisted biopsy, guidance by US
  - Vacuum-assisted biopsy, guidance by mammography
  - Excisional biopsy
  - MRI-guided vacuum assisted biopsy if not US biopsy
  □ Additional Imaging (check all that apply)
    □ Additional evaluation
    - Comparison to prior mammogram is required
    - Targeted ultrasound (lesion seen on mammography)
    - Ultrasound targeted to MRI abnormality
    - Additional mammographic projections
    □ Repeat ultrasound
    - Technique/interpretation in question
    - Possibly abnormal
    □ Repeat mammogram
    - Incomplete
    - Motion artifact/other technical problem
    □ Repeat MRI
    - Motion artifact or other technical problem
    - Incomplete
    - Abnormalities likely due to phase in cycle

COMMENTS:

________________________________________

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

Signature of person responsible for the data

________________________________________

Signature of person entering data onto the web
1. Time point of this follow-up
   - 12 months
   - 24 months
   - 36 months

1a. Record actual elapsed months since study entry [ ]

2. Date of follow-up contact or attempt [ ]
   - mm dd yyyy

3. Method of contact
   - At appointment
   - By telephone
   - Other, specify __________________________

4. Participant Status
   - Alive (proceed to Q5)
   - Dead (complete Q4a)
   - Lost to follow-up; unable to contact (proceed to Q4b)

4a. Date of death [ ]
   - mm dd yyyy
   - If date of death unknown code 12-12-2100
   - If exact date is unknown, choose the 15th of that month.

4b. Date of last contact [ ]
   - mm dd yyyy

Section I. Clinical Status

5. Was a clinical breast exam of the breast(s) performed since the last annual screening visit?
   - No (provide reason in Q5a)
   - Yes (complete then proceed to Q5b and Q5c)

5a. Provide reason CBE not done (then proceed to Q6):
   - Patient missed appointment
   - Patient unable to be located
   - Patient pregnant or lactating
   - Patient refused
   - Referring physician's choice
   - Expired
   - Other, specify ____________________________

5b. Date of follow-up CBE [ ]
   - mm yyyy

5c. Have there been any clinically significant changes in the right breast since the last annual examination?
   - No or breast not on study
   - Yes (check all clinical changes that apply)

5d. Have there been any clinically significant changes in the left breast since the last annual examination?
   - No or breast not on study
   - Yes (check all clinical changes that apply)

6. Current use of hormones?
   - No (proceed to Q7)
   - Yes (complete Q6a)

6a. Specify hormone(s) __________________________

7. Has any interval breast imaging been performed since last visit? (consider only items not previously reported on forms IM, F6, etc., per instructions.)
   - No (proceed to Section III)
   - Yes (complete Q7a)

7a. Check all breast imaging performed since last visit:
   - Mammogram (complete Q8)
   - Ultrasound (complete Q11)
   - MRI (complete Q14)
   - Other (complete Q17)
   - Do not recall details (proceed to Q20)
Section II. Interval Imaging

8. Mammogram

(If no mammogram performed proceed to Q11)

Identify the study breast(s) on which a mammogram was performed in the past 11 months.

NOTE: Interval mammography at study site should be reported on forms IM and/or F6 as appropriate.
- Right (Complete Qs 8a, 8b and 9)
- Left (Complete Qs 8a, 8b and 10)
- Both (Complete Qs 8a-10a)

8a. Date of most recent mammogram ______ mm yyyy

8b. Specify basis for decision to obtain the Mammogram

Recommended by:
- Screening site
- MD who referred you for screening
- Another physician
  - (identify type of physician)
- Internist
- Surgeon
- Ob/Gyn
- Other or unknown
- Family Member
- Someone else
  - (specify relationship of this person to you)

9. Mammographic Assessment of Right Breast

If No evaluation of Right Breast performed, proceed to Q10
If outside study codes "4, suspicious", code as 4B.

9a. Reported Assessment for right breast
- 1 Negative
- 2 Benign
- 3 Probably Benign
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion
- 5 Highly Suggestive of Malignancy
- Assessment unknown or incomplete
  - (unable to obtain reported assessment, done at another imaging facility, BIRADS 0, or partial report)

10. Mammographic Assessment of Left Breast

If No evaluation of Left Breast performed, proceed to Q11
If outside study codes "4, suspicious", code as 4B

10a. Reported Assessment for left breast
- 1 Negative
- 2 Benign
- 3 Probably Benign
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion
- 5 Highly Suggestive of Malignancy
- Assessment unknown or incomplete
  - (unable to obtain reported assessment, done at another imaging facility, BIRADS 0, or partial report)

11. Ultrasound

(If no ultrasound performed proceed to Q14)

Identify the study breast(s) on which an Ultrasound was performed in the past 11 months.

NOTE: Interval ultrasound at study site should be reported on forms IM and/or F6 as appropriate.
- Right (Complete Qs 11a, 11b and 12)
- Left (Complete Qs 11a, 11b and 13)
- Both (Complete Qs 11a-13a)

11a. Date of most recent ultrasound ______ mm yyyy

11b. Specify basis for decision to obtain the Ultrasound

Recommended by:
- Screening site
- MD who referred you for screening
- Another physician
  - (identify type of physician)
- Internist
- Surgeon
- Ob/Gyn
- Other or unknown
- Family Member
- Someone else
  - (specify relationship of this person to you)

12. Ultrasound Assessment of Right Breast

If No evaluation of Right Breast performed, proceed to Q13
If outside study codes "4, suspicious", code as 4B

12a. Assessment for right breast
- 1 Negative
- 2 Benign
- 3 Probably Benign
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion
- 5 Highly Suggestive of Malignancy
- Assessment unknown or incomplete
  - (unable to obtain reported assessment, done at another imaging facility, BIRADS 0, or partial report)

13. Ultrasound Assessment of Left Breast

If No evaluation of Left Breast performed, proceed to Q14
If outside study codes "4, suspicious", code as 4B

13a. Assessment for left breast
- 1 Negative
- 2 Benign
- 3 Probably Benign
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion
- 5 Highly Suggestive of Malignancy
- Assessment unknown or incomplete
  - (unable to obtain reported assessment, done at another imaging facility, BIRADS 0, or partial report)
14. Contrast-enhanced breast MRI  
*(If no breast MRI performed proceed to Q17)*  
Identify the study breast(s) on which an MRI was performed in the past 11 months?  
- Right (Complete Qs 14a, 14b, and 15)  
- Left (Complete Qs 14a, 14b and 16)  
- Both (Complete Qs 14a-16a)  

14a. Date of most recent breast MRI ______-______ mm yyyy  
14b. Specify basis for decision to obtain the MRI  
Recommended by:  
- Screening site  
- MD who referred you for screening  
- Another physician  
  (identify type of physician)  
  - Internist  
  - Surgeon  
  - Ob/Gyn  
  - Other or unknown  
- Family Member  
- Someone else  
  (specify relationship of this person to you)  

15. MRI Assessment of Right Breast  
If No evaluation of Right Breast performed, proceed to Q16  
If outside study codes as "4, suspicious", code as 4B  
15a. Assessment for right breast  
- 1 Negative  
- 2 Benign  
- 3 Probably Benign  
- 4A Low Suspicion of Malignancy  
- 4B Intermediate Suspicion  
- 4C Moderately High Suspicion  
- 5 Highly Suggestive of Malignancy  
- Assessment unknown or incomplete  
  (unable to obtain reported assessment, done at another imaging facility, BI-RADS 0, or partial report)  

16. MRI Assessment of Left Breast  
If No evaluation of Left Breast performed, proceed to Q17  
If outside study codes as "4, suspicious", code as 4B  
16a. Assessment for left breast  
- 1 Negative  
- 2 Benign  
- 3 Probably Benign  
- 4A Low Suspicion of Malignancy  
- 4B Intermediate Suspicion  
- 4C Moderately High Suspicion  
- 5 Highly Suggestive of Malignancy  
- Assessment unknown or incomplete  
  (unable to obtain reported assessment, done at another imaging facility, BI-RADS 0, or partial report)  

17. Other Breast Imaging  
*(If no other breast imaging performed proceed to section III)*  
Identify other imaging performed of the study breast(s) performed in the past 11 months.  
NOTE: Use forms IM or F6 to report additional mammographic or sonographic imaging at this site as appropriate  
- Right (Complete Qs 17a, 17b, 17c and 18)  
- Left (Complete Qs 17a, 17b, 17c and 19)  
- Both (Complete Qs 17a-19a)  
- Unknown (proceed to Q20)  

17a. Specify type ____________________________  
17b. Date of most recent other imaging ______-______ mm yyyy  
17c. Specify basis for decision to obtain other imaging  
Recommended by:  
- Screening site  
- MD who referred you for screening  
- Another physician  
  (identify type of physician)  
  - Internist  
  - Surgeon  
  - Ob/Gyn  
  - Other or unknown  
- Family Member  
- Someone else  
  (specify relationship of this person to you)  

18. Other Imaging Assessment of Right Breast  
If No evaluation of Right Breast performed, proceed to Q19  
If outside study codes as "4, suspicious", code as 4B  
18a. Assessment for right breast  
- 1 Negative  
- 2 Benign  
- 3 Probably Benign  
- 4A Low Suspicion of Malignancy  
- 4B Intermediate Suspicion  
- 4C Moderately High Suspicion  
- 5 Highly Suggestive of Malignancy  
- Assessment unknown or incomplete  
  (unable to obtain reported assessment, done at another imaging facility, BI-RADS 0, or partial report)  

19. Other Imaging Assessment of Left Breast  
If No evaluation of Left Breast performed, proceed to Q20  
If outside study codes as "4, suspicious", code as 4B  
19a. Assessment for left breast  
- 1 Negative  
- 2 Benign  
- 3 Probably Benign  
- 4A Low Suspicion of Malignancy  
- 4B Intermediate Suspicion  
- 4C Moderately High Suspicion  
- 5 Highly Suggestive of Malignancy  
- Assessment unknown or incomplete  
  (unable to obtain reported assessment, done at another imaging facility, BI-RADS 0, or partial report)
Section III. Intervention

20. Were there any cyst aspirations, biopsies or surgeries on the study breast(s) in the past 11 months?
   - No (Proceed to Q21)
   - Yes, not previously reported (Complete Q20a)
   - Yes, previously reported (Proceed to Q21)
   - Unknown (Proceed to Q21)

   NOTE: If yes and the procedures have not previously been reported, complete Q20a and Form(s) BX, NL, and S1 as appropriate.

   20a. Specify intervention and date (list all that apply below)
   If an intervention is on both breasts, list each breast on a separate line.

<table>
<thead>
<tr>
<th>Intervention Code Table (Q20a)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Cyst Aspiration</td>
</tr>
<tr>
<td>2. FNAB (complete BX)</td>
</tr>
<tr>
<td>3. Core Needle Biopsy (complete BX)</td>
</tr>
<tr>
<td>4. Excisional Biopsy (complete NL)</td>
</tr>
<tr>
<td>5. Lumpectomy (complete S1)</td>
</tr>
<tr>
<td>6. Sentinel Lymph Node (complete S1)</td>
</tr>
<tr>
<td>7. Axillary Lymph Node Dissection (complete S1)</td>
</tr>
<tr>
<td>8. Mastectomy (complete S1)</td>
</tr>
<tr>
<td>10. Other, specify (in details)</td>
</tr>
<tr>
<td>99. Specifics Unknown</td>
</tr>
</tbody>
</table>

Section IV. Summary/Treatment

21. Was a breast cancer diagnosed in the past 11 months?
   - No (Complete Q21a)
   - Yes, not already reported (Proceed to Q21b and complete BX and S1 forms)
   - Yes, already reported on BX and/or, NL and S1 (Proceed to Q22)
   - Unknown (Proceed to Q22)

21a. Most reliable source regarding Negative breast cancer status for this participant. (complete then proceed to Q22)
   - Participant herself says she has not been diagnosed with breast cancer
   - No findings reported in participant's medical chart
   - Participant's Primary Care Physician (PCP) reports (no abnormality found at last clinical exam)
   - Report of clinical exam
   - Other Physician
   - No abnormality found at last clinical exam
   - Relative or friend stated that participant has not been diagnosed with breast cancer
   - Participant is not listed on the cancer registry for the area in which she lives
   - Hospital billing department reports no charges for breast cancer treatment
   - Other, specify ________________________________

21b. Most reliable source regarding Positive breast cancer status for this participant.
   - Pathology report
   - Cancer diagnosis is reported in participant's medical chart
   - Participant's Primary Care Physician (PCP) reports breast cancer
   - Participant herself says she has been diagnosed with breast cancer
   - Death certificate in municipality of last known address that lists cause of death as breast cancer
   - Relative or friend states that participant has been diagnosed with breast cancer
   - Participant is listed on the cancer registry for the area in which she lives
   - Hospital billing department reports charges for breast cancer treatment
   - Other, specify ________________________________

21c. Site of breast cancer
   - Right
   - Left
   - Bilateral
22. Additional treatment for disease of the study breast(s)
   o No (Proceed to Q23)
   o Yes, not previously reported (Complete Q22a)
   o Yes, previously reported (Proceed Q23)
   o Unknown (Proceed to Q23)

   NOTE: Report all treatment that is continuing or new since last contact. Provide the start date for each, details and site.

22a. Specify treatment and date (list all that apply below)
   If an intervention is on both breasts, list each breast on a separate line.

<table>
<thead>
<tr>
<th>Intervention Code Table (Q22a)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Radiation Therapy</td>
</tr>
<tr>
<td>2 Systemic Chemotherapy</td>
</tr>
<tr>
<td>3 Other hormone manipulation</td>
</tr>
<tr>
<td>9 Other, specify (in details)</td>
</tr>
<tr>
<td>99 Specifics Unknown</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Date (mm-yyyy)</th>
<th>Details</th>
<th>R</th>
<th>L</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
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<td>_______</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
</tbody>
</table>

23. Has patient enrolled into a breast imaging trial in the past 11 months other than the Screening Breast Ultrasound in High Risk Women Trial?
   o No (Stop and sign form)
   o Yes (Complete Q23a)
   o Unknown (Stop and sign form)

23a. Provide name of trial ________________

Comments: ____________________________________________________________

_____________________________________________________________________

_____________________________________________________________________

_____________________________________________________________________

Signature of person responsible for the data ¹ ____________________________

Date Form Completed (mm-dd-yyyy) ________________________________________

Signature of person entering data onto web ² ______________________________
Instructions: This form is designed to capture the results of screening and any follow-up imaging performed at 36 months after study entry. This form is to be completed by the RA or a study radiologist based on images and/or reports.

1. What type of imaging was performed of study breasts at the 36 month time point? (check all that apply)
   - Standard-view mammography, date: _____-____-_____ (mm-dd-yyyy)
   - Additional mammographic views, date: _____-____-_____ (mm-dd-yyyy)
   - Whole breast ultrasound, date: _____-____-_____ (mm-dd-yyyy)
   - Targeted ultrasound, date: _____-____-_____ (mm-dd-yyyy)
     - Right
     - Left
     - Both breasts
   - Contrast-enhanced MRI, date: _____-____-_____ (mm-dd-yyyy)
     - Right
     - Left
     - Both breasts
   - None
   - Unknown

2. Was there a suspicious abnormality (BI-RADS 4 or 5) identified in any study breast(s) at the 36 month time point?
   - No (STOP and sign form)
   - Yes, detail which breast (check all that apply):
     - Right, suspicious by (check all that apply):
       - Mammography
       - US
       - MRI
       - Clinically
       - Unknown
     - Left, suspicious by (check all that apply):
       - Mammography
       - US
       - MRI
       - Clinically
       - Unknown
   - Unknown (STOP and sign form)
3. Does the suspicious abnormality correspond to a finding previously reported?
   - O No (create a new lesion number on the BX form to report)
   - O Yes, detail lesion number: [Lesion Number] (e.g. UR3, ML2, GR1, etc.)

4. Will any biopsies be performed on any study breast(s) at this time?
   - O No, detail reason: [Reason] (STOP and sign form)
   - O Yes, detail which breast (check all that apply):
     - □ Right (please complete a BX form for each biopsy)
     - □ Left (please complete a BX form for each biopsy)
   - O Unknown (STOP and sign form)

Comments:________________________________________________________
_________________________________________________________________
_________________________________________________________________
_________________________________________________________________
_________________________________________________________________
_________________________________________________________________
_________________________________________________________________

Signature of person responsible for the data ____________________________ Date Form Completed (mm-dd-yyyy)

Signature of person entering data on web _____________________________
All questions regarding Adverse Events should be directed to ACRIN. All Adverse Events (AEs) and Serious Adverse Events (SAEs) as defined in the protocol require routine reporting via web entry of the AE CRF. In addition, SAEs meeting the criteria for expedited reporting, as specified in the protocol, require (a) telephone report to both NCI and ACRIN within 24 hours of knowledge, (b) AdEERS report completed and submitted as specified in the protocol, and (c) completed AE case report form with investigator's signature submitted to ACRIN via web and filed in the participant chart.

<table>
<thead>
<tr>
<th>AE Description</th>
<th>AE Short Name</th>
<th>CTCAE v3.0</th>
<th>CTCAE Grade</th>
<th>Attribution</th>
<th>AdEERS Submitted for SAEs</th>
<th>Action Taken</th>
<th>Outcome</th>
<th>Date of AE Onset and Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start date:</td>
<td>Resolution date:</td>
<td>On-going</td>
<td></td>
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</tr>
<tr>
<td>Start date:</td>
<td>Resolution date:</td>
<td>On-going</td>
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<tr>
<td>Start date:</td>
<td>Resolution date:</td>
<td>On-going</td>
<td></td>
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</tr>
</tbody>
</table>

Comments - for each comment, identify the AE number from above (#1-3):

If there are more than 3 AEs for a visit, check this box and use another form.

*copyright 2005*
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)
   - Ineligible participant registered to main (US) study
   - Duplicate case registration
   - Site not currently qualified to accrue participants
   - Randomization > 2 business days after consent
   - Imaging not performed per randomization sequence
   - Same radiologist interpreted both images
   - Recommended biopsy not performed
   - Excision not performed
   - Participant withdrew main (US) study consent, provide documentation. Date of withdrawal: _____ - _____ - _______ (mm-dd-yyyy)
     - No further contact or follow-up per participant
     - No further contact, follow-up or permission to use data per participant
   - Mammogram not performed per protocol specified time point
     - Initial
     - 12 months
     - 24 months
   - Survey US not performed per protocol specified time point
     - Initial
     - 12 months
     - 24 months
   - Survey US or Mammogram interpretation done by radiologist not approved as a qualified investigator in protocol 6666
     - Initial
     - 12 months
     - 24 months
   - Recommended targeted US not done - enter date of imaging study that recommended US
     _____ - _____ - _______ (mm-dd-yyyy)
   - Recommended additional mammography views not done - enter date of imaging study that recommended these
     _____ - _____ - _______ (mm-dd-yyyy)
   - Lesion # changed. Previously reported lesion # ______________ at time point: o Initial
     - 12 months
     - 24 months
   - Annual follow-up mammogram performed at outside facility.
   - CAD used on study mammogram
   - Bilateral mastectomies
     Note: Please complete S1 form for each breast. Fax a copy of anonymized pathology reports to ACRIN Headquarters. All pages must be labeled with study number, case number, and participant initials.
   - Screening MRI performed prior to 24 month screening US. Note: If the participant is diagnosed with breast cancer during the trial period, it is then acceptable for the participant to undergo contrast-enhanced breast MR to evaluate the extent of disease for treatment planning.
Breast US # 6666 Institution ________ Case # ________ Revision [ ]

- Participant withdrew consent for MRI substudy only. Date of withdrawal: ______ - ______ - ______ (mm-dd-yyyy)
  - No further contact or follow-up per participant
  - No further contact, follow-up or permission to use data per participant
- MRI ineligible participant registered for MRI substudy
- 24 month study screening MRI interpretation done by radiologist not approved as a qualified MRI investigator in protocol 6666
- MRI participant had MRI more than 8 weeks after 24 month study ultrasound and mammogram (detail reason in Q2)
- Case enrolled under expired IRB approval/FWA
- Other, specify: ________________________________

2. Describe The Protocol Event Reported Above

________________________________________________________________________________________

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

3. Deviations
- None
- Breast density insufficient
- Incorrect US transducer utilized
- No images documenting flow
- Images without spatial compounding not performed
- Images with spatial compounding not performed
- Mammogram image quality insufficient
- US image quality insufficient
- MRI image quality insufficient
- Imaging not done within 2 weeks of each other
- Mammogram images lost, unable to archive, date of exam ______ - ______ - ________ (mm-dd-yyyy)
- US images lost, unable to archive, date of exam ______ - ______ - ________ (mm-dd-yyyy)
- Fewer than the required number of mammogram images received, date of exam ______ - ______ - ________ (mm-dd-yyyy)
- Fewer than the required number of US images received, date of exam ______ - ______ - ________ (mm-dd-yyyy)

4. Comments

________________________________________________________________________________________

________________________________________________________________________________________

________________________________________________________________________________________

__________________________________________ Date form completed ______ - ______ - ________ (mm-dd-yyyy)

Person responsible for data

[ ] HQ Use Only

__________________________________________ Date form completed ______ - ______ - ________ (mm-dd-yyyy)

HQ Research Associate
1. ACRIN READER ID __________________________
2. DATE OF STUDY _____-____-____
3. DATE IMAGES REVIEWED _____-____-____
4. IF IMAGES ARE RESUBMISSION, DATES OF PREVIOUS REVIEW(S) AND OUTCOME(S)
   4a. 1st review date _____-____-____
        Acceptable
        O 1 No
        O 2 Yes
   4b. 2nd review date _____-____-____
        Acceptable
        O 1 No
        O 2 Yes
5. US SYSTEM UNDER REVIEW:
   O Philips/ATL Model _________________________
   O Siemens/Acuson Model _____________________
   O GE Model ________________________________
   O Toshiba Model ____________________________
   O Other specify _____________________________

IMAGE QUALITY

6. DOES IMAGING MEET PROTOCOL SPECIFICATIONS?
   O 1 No, Detail ______________________________
   O 2 Yes
7. ARE THERE FINDINGS ON THIS STUDY?
   O 1 No (proceed to Q8)
   O 2 Yes
7a. Simple cyst only:
    O 1 No
    O 2 Yes
7b. Are lesions other than cyst(s) or scar(s) present?
    O 1 No
    O 2 Yes
7c. Are lesion(s) imaged with spatial compounding
    O 1 No
    O 2 Yes
7d. Are lesion(s) imaged without spatial compounding
    O 1 No
    O 2 Yes
7e. Are lesion(s) imaged with power Doppler?
    O 1 No
    O 2 Yes
8. ARE IMAGES PROPERLY LABELED?
   O 1 No, Detail ______________________________
   O 2 Yes
   O 3 Yes except survey images only indicate quadrant
9. ARE IMAGES PRESENT FROM EACH QUADRANT?
   Right Breast
   O 1 No
   O 2 Yes
   O 3 Not on study
   Left Breast
   O 1 No
   O 2 Yes
   O 3 Not on study
10. OVERALL US IMAGE QUALITY
    O Unacceptable (proceed to Q10a)
    O Minor deficiencies, but acceptable (proceed to Q10a)
    O Acceptable (proceed to Q11)
    O Good (proceed to Q11)
10a. Image size or field of view
    □ Too shallow
    □ Too deep
    □ Meets Standards
10b. Focal Zones
    □ Too anterior
    □ Too posterior
    □ Too many
    □ Meets Standards
10c. Gain
    □ Too Low
    □ Too high
    □ Meets Standards
10d. Transducer frequency
- Too Low
- Too high
- Meets Standards

10e. Artifacts present?
- No
- Yes
  Details: __________________________

10f. Other __________________________

11. IS SPATIAL COMPOUNDING USED?
(Check all that apply:)
- Survey Images
- Images of lesion(s)
- None of the images

12. OVERALL MAMMOGRAM IMAGE QUALITY
- Unacceptable, Detail: __________________________
- Minor deficiencies, but acceptable Detail: __________________________
- Acceptable
- Good

12a. Does mammographic density meet protocol?
- 1 No, Detail __________________________
- 2 Yes
- 3 Borderline

13. REVIEWER HAS CONTACTED P.I. OF ORIGINATING SITE:
- 1 No
- 2 Yes

13a. Name of the P.I contacted __________________________

13b. Phone date _____-____-____ E-mail date _____-____-____

14. IF CLINICAL IMAGE UNACCEPTABLE OR BELOW AVERAGE:
Remedial plan by site __________________________

  Resubmission
- No
- Yes

15. COMMENTS: __________________________

16. SIGNATURE OF REVIEWER: __________________________

17. DATE FORM COMPLETED _____-____-____

18. PERSON ENTERING INFORMATION INTO DATABASE: __________________________

19. DATE ENTERED _____-____-____