### ACRIN Study 6666
**Screening Breast Ultrasound on High Risk Women**

<table>
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<tr>
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<th>Version Date</th>
<th>*Submission Date</th>
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**QC Core Submitted Forms**

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*See next page for Cost Effectiveness Forms*
Cost Effectiveness

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<tr>
<td>TS</td>
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<td>Waiting-Time Trade Off Diagnostic Ultrasound (Telephone)</td>
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<td>Willingness to Pay Ultrasound</td>
<td>10-20-03</td>
</tr>
<tr>
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<tr>
<td>V5</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.

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

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

**Submission date** - This column is intended as a tracking tool for forms submission on individual cases. It is recommended that the RA maintain a printed copy within each case file as a tool to document form submission.
ACRIN 6666
Registration

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.
### Instructions:
The Initial Evaluation Form is either completed through participant interview or self-completed by the participant. In addition, the I2 must be completed. The site RA and participant signature must appear on the completed form. If the participant is eligible based on their lifetime risk %, the printout must be filed within the participant study file.

### 1. Date of birth \____-\____-\____ (mm/dd/yyyy) (age must be \geq 25 years)

### 2. Have you had a prior mammogram?
- No
- 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

### 3. Have you had a prior breast ultrasound?
- No (Proceed to Q4)
- 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

### 4. Have you had a prior MRI of the breast(s) with contrast?
- No
- 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

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

### 6. How long ago was your last menstrual period?
- Within the last month
- Less than 1 year ago
- More than one year ago
- Surgical menopause: year \____-\____ (If year is unknown code "2100")
- Unknown/I cannot remember

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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
    [ ] Tamoxifen Number of years _____ and months_____ used
    [ ] Raloxifene (EVISTA) Number of years _____ and months_____ used
    [ ] Aromatase Inhibitor (e.g. Arimidex) Number of years _____ and months_____ used
    [ ] Birth Control Pills Number of years _____ and months_____ used
    [ ] 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>
</thead>
<tbody>
<tr>
<td>Reduction</td>
<td>(yyyy)</td>
</tr>
<tr>
<td>Lift</td>
<td>(yyyy)</td>
</tr>
<tr>
<td>Implant placed</td>
<td>(yyyy)</td>
</tr>
<tr>
<td>Implant removed</td>
<td>(yyyy)</td>
</tr>
</tbody>
</table>
11. Prior Diagnosis of Breast Cancer
   o No (proceed to Q12)
   o Yes
     o Pathology report is available
     o Pathology report is not available
   o Unknown (proceed to Q12)

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

<table>
<thead>
<tr>
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<th>Breast</th>
<th>Pathology</th>
<th>Lymph nodes involved?</th>
</tr>
</thead>
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<td></td>
<td>(see code table Q11a)</td>
<td>o N o Y o Unknown</td>
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<td></td>
<td>o R o L</td>
<td></td>
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<tr>
<td></td>
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<td>o R o L</td>
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<td></td>
<td></td>
<td>o R o L</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>o R o L</td>
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</tr>
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</table>

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

<table>
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<th>Breast</th>
<th>Treatment</th>
</tr>
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<tr>
<td></td>
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<td>(see treatment code table Q11b)</td>
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<tr>
<td></td>
<td></td>
<td>1 Lumpectomy and radiation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2 Lumpectomy alone (no radiation)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3 Mastectomy and radiation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4 Mastectomy alone</td>
</tr>
</tbody>
</table>

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

12. Prior cyst excision and/or cyst aspiration

<table>
<thead>
<tr>
<th>Right breast</th>
<th>Left breast</th>
</tr>
</thead>
<tbody>
<tr>
<td>o Not on study</td>
<td>o Not on study</td>
</tr>
<tr>
<td>o Never</td>
<td>o Never</td>
</tr>
<tr>
<td>o 1</td>
<td>o 1</td>
</tr>
<tr>
<td>o 2 or 3</td>
<td>o 2 or 3</td>
</tr>
<tr>
<td>o 4 or more</td>
<td>o 4 or more</td>
</tr>
</tbody>
</table>

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

12b. List 4 most significant occurrences
(Record pathology based on worst lesion present, code table is prioritized in decreasing significance; if year of biopsy is unknown, code "2100")

<table>
<thead>
<tr>
<th>Year</th>
<th>Breast</th>
<th>Biopsy result</th>
<th>Type of Biopsy</th>
</tr>
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<tr>
<td></td>
<td></td>
<td>(see code table A)</td>
<td>(see code table B)</td>
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<td></td>
<td></td>
<td>o R o L</td>
<td></td>
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<tr>
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<td></td>
<td>o R o L</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>o R o L</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>o R o L</td>
<td></td>
</tr>
</tbody>
</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

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. Fibrocystic 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

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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:

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

   | Age at Diagnosis*         | ("99" if unknown) | Breast |
   |---------------------------|-------------------|
   | 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>

<table>
<thead>
<tr>
<th>Age at Diagnosis*</th>
<th>(&quot;99&quot; if unknown)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relative 1 w/ovarian cancer</td>
<td></td>
</tr>
<tr>
<td>Relative 2 w/ovarian cancer</td>
<td></td>
</tr>
<tr>
<td>Relative 3 w/ovarian cancer</td>
<td></td>
</tr>
<tr>
<td>Relative 4 w/ovarian cancer</td>
<td></td>
</tr>
</tbody>
</table>

   * (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:
- HNPCC
- 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

Sign, date and proceed to I2 form

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.

Participant signature

*Copyright 2004*
**ACRIN 6666**
Initial Evaluation Form Supplement

For revised or corrected form check box and fax to 215-717-0936.

**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 (X) 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.

1. Radiologist ID: ____________________________

2. Date of Study Interpretation _______ _______ _______ (mm-dd-yyyy)

3. Time in study
   o Initial screening
   o 12 month screening
   o 24 month screening

   3a. Record actual months since study entry _______

   3b. Was the scheduled mammogram performed?
      o No (complete and stop, sign form)
      o Yes

   3c. Image Presentation
      o Film-Screen
      o Digital

4. Prior Films
   o Present with interpretation (proceed to Q4a)
   o Not present with interpretation (proceed to Q4a)
   o Participant does not have prior films (proceed to Q5)

4a. Date of most Recent Prior Standard View Mammogram _______ _______ _______ (mm-dd-yyyy)
   □ Check box if date of prior Standard View Mammogram is unknown

5. Date of study Mammogram _______ _______ _______ (mm-dd-yyyy)

6. Which breast(s) are included on study?
   o Bilateral
   o Right breast only
   o Left breast only

7. Has patient had breast conservation surgery for cancer?
   o No (proceed to Q8)
   o Yes (provide which breast(s))
      o Right breast only
      o Left breast only
      o Both

8. Density of Breast Parenchyma (current exam)
   8a. Subjective rating of % of breast where tissue is dense.
      □ R
      o Less than 25%
      o 26-40%
      o 41-60%
      o 61-80%
      o Greater than 80%
      o Not applicable
      □ L
      o Less than 25%
      o 26-40%
      o 41-60%
      o 61-80%
      o Greater than 80%
      o Not applicable

   8b. Where is parenchyma dense? (check all that apply)
      □ R
      □ Diffusely dense
      □ Anteriorly
      □ UOQ
      □ Scattered focal areas
      □ Not dense
      □ L
      □ Other, Specify __________________________

9. Mammographic Findings to be reported
   o No (proceed to Q13)
   o Yes (complete and proceed to Q9a)
      o Right breast only
      o Left breast only
      o Bilateral

   9a. Total number of lesion(s) you wish to describe (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.
      □ Right Breast
      □ Left Breast

10. First Lesion Description
    Note: Lesions are numbered sequentially by breast (R = Right, L = Left). Multiple bilateral similar appearing findings to be described as one lesion are coded B for bilateral.

   10a. Lesion # _______ (e.g. MR1, MB1, ML1 etc.)
        (Use # from previous exam if new use next sequential #. Describe any new or suspicious findings first.)

   10b. 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

   10c. mm X mm (largest diameter) X mm (largest perpendicular dimension)
        [NOTE: Code 100 X 100 for diffuse scattered calcifications with no discrete group.]

   10d. 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 Central

   10e. Distance from the nipple _______ cm
        [Code 20 for diffuse scattered calcifications.]

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ACRIN Study 6666

Institution No. _________  Institution No. _________
Participant Initials _________  Case No. ____________

10f. Lesion type (check all that apply)
- Mass (select worst margin feature present)
  0 Circumscribed (select one)
  0 Fat-containing
  0 Not fat-containing
- Microlobulated
- Obscured
- Indistinct
- Spiculated

Associated features
- Yes (check all that apply)
  0 Calcifications (detail below)
  0 Architectural distortion
  0 Skin thickening
  0 Dilated duct(s)

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

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

10g. Is this lesion at the site of prior biopsy?
- No
- Yes (if yes, select procedure)
  0 Core/vacuum biopsy site with clip
  0 Core/vacuum biopsy site without clip
  0 Surgical biopsy site (select diagnosis)
  0 Benign
  0 Atypical/high-risk lesion
  0 Cancer site
  0 Unknown
  0 Biopsy details unknown
  0 FNAB
  0 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)
  0 Aspiration w/core biopsy if solid
  0 US-guided core biopsy
  0 Vacuum-assisted biopsy, guidance by US
  0 Vacuum-assisted biopsy, guidance by mammography
  0 Excisional biopsy
  0 Additional Imaging (check all that apply)
    0 Targeted Ultrasound (lesion seen on mammography)
    0 Comparison to prior mammograms is required
    0 Additional mammographic projections

11d. Is this lesion assessed as probably benign AND recommended for intervention?
- No (proceed to Q12)
- Yes (specify dominant reason)
  0 Participant preference
  0 Cancer present now
  0 In this breast
  0 In opposite breast
  0 Patient risk factors
  0 Vaguely palpable
  0 Follow-up not reasonable
  0 Interval increase (>20% in volume for masses)
  0 Interval suspicious change
  0 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
      (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)
         □ 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
      (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)
         □ 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  

Date Form Completed (mm-dd-yyyy)

Signature of person entering data onto web  

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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
- 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)
    - 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

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
- Fluctuating 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
- Inner
- Upper
- Lower
- 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
        - Dilated duct(s)
      - Skin thickening
      - Asymmetry (code type)
    - Focal (complete)
      - Asymmetry seen on
        - One view
        - Both views
        - Global
    - Calculations (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

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
    - 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. [ ] mm X [ ] 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 [ ] upper [ ] lower
- Left [ ] upper [ ] lower
- Bilateral, multiple [ ] upper [ ] lower [ ] inner [ ] outer
- Axillary tail [ ] upper [ ] lower [ ] inner [ ] outer
- Retroareolar [ ] upper [ ] lower [ ] inner [ ] outer

21e. Distance from the nipple [ ] cm

21f. 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

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. [ ] % 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?**
- New
- Gone
- Decreasing
- Stable
- Fluctuating bilateral circumscribed masses
- Increasing
- Other suspicious change
- Increasing and other suspicious change
- 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.
- Right
- Left
- Bilateral, multiple
- Axillary tail
- Retroareolar
- Central

24e. **Distance from the nipple cm**

24f. **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)
    - Califications (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

24g. **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
- 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**
- 1 Negative
- 2 Benign
- 3 Probably Benign
- 4 Low Suspicion of Malignancy
  - 4A
  - 4B Intermediate Suspicion
  - 4C Moderately High Suspicion
- 5 Highly Suggestive of Malignancy

25c. **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

25d. **Is this lesion assessed as probably benign AND recommended for intervention?**
- No (proceed to Q26)
- 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?
- No (proceed to Q27)
- 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)
   - Right
   - Left
   - Bilateral, multiple
   - Axillary tail
   - Retroareolar
   - Central
   - Upper
   - Lower
   - Inner
   - Outer
   - Bilateral, multiple
   - Axillary tail
   - Retroareolar
   - Central

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)
         - Califications (detail below)
         - Architectural distortion
         - Skin thickening
         - Duct(s)
   - 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

27g. **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

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?
- New
- Gone
- Decreasing
- Stable
- Fluctuating bilateral circumscribed masses
- Increasing
- Other suspicious change
- Increasing and other suspicious change
- 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.
- Right
- Left
- Bilateral, multiple
- Axillary tail
- Retroareolar

30e. Distance from the nipple [ ] cm

30f. 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

30g. 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
  - 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
- 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 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

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 risk factors
  - Vaguely palpable
  - Follow-up not reasonable
  - Interval increase (>20% in volume for masses)
  - Interval suspicious change
  - Investigator uncertainty

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

33a. Lesion # \( \text{M} \) (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
- Gone
- Decreasing
- Stable
- Fluctuating bilateral circumscribed masses
- Increasing
- Other suspicious change
- Increasing and other suspicious change
- Not applicable, no prior

33c. \( \text{mm} \times \text{mm} \)
(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 \( \text{cm} \)

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 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

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
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:
   [ ] MHz (high end) MHz to
   [ ] MHz (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
   [ ] MHz (high end) MHz to
   [ ] MHz (low end) MHz

2e. Transducer width of second transducer
   - 38 mm
   - 50 mm
   - Other, specify mm

3. Reader ID #
   (Last, First)

3a. Radiologist performing exam

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)
   - Specify
   - 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. Time Radiologist entered room.
   Time scan initiated
   Time scan completed
   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: mm-dd-yyyy
       Date of prior study: mm-dd-yyyy (if different from right)
10. Greatest depth (thickness) of Breast by ultrasound

<table>
<thead>
<tr>
<th></th>
<th>Right</th>
<th>Left</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 2 cm</td>
<td>o</td>
<td>o</td>
</tr>
<tr>
<td>2.0-2.9 cm</td>
<td>o</td>
<td>o</td>
</tr>
<tr>
<td>3.0-3.9 cm</td>
<td>o</td>
<td>o</td>
</tr>
<tr>
<td>4.0-4.9 cm</td>
<td>o</td>
<td>o</td>
</tr>
<tr>
<td>5.0-5.9 cm</td>
<td>o</td>
<td>o</td>
</tr>
<tr>
<td>6.0-6.9 cm</td>
<td>o</td>
<td>o</td>
</tr>
<tr>
<td>&gt;7 cm</td>
<td>o</td>
<td>o</td>
</tr>
<tr>
<td>not applicable</td>
<td>o</td>
<td>not applicable</td>
</tr>
</tbody>
</table>

11. Background Echotexture

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

<table>
<thead>
<tr>
<th></th>
<th>Right</th>
<th>Left</th>
</tr>
</thead>
<tbody>
<tr>
<td>UOQ</td>
<td></td>
<td>UOQ</td>
</tr>
<tr>
<td>UIQ</td>
<td></td>
<td>UIQ</td>
</tr>
<tr>
<td>LOQ</td>
<td></td>
<td>LOQ</td>
</tr>
<tr>
<td>LIQ</td>
<td></td>
<td>LIQ</td>
</tr>
</tbody>
</table>

12. Were any simple cysts identified?

- No (proceed to Q12c)
- Yes (If yes, proceed to Q12a)

12a. 
- Right: o Solitary, o 2-3, o numerous (>4)
- Left: o Solitary, o 2-3, o numerous (>4)

12b. Detail Largest Cyst

<table>
<thead>
<tr>
<th>Breast</th>
<th>Clockface</th>
<th>Distance from the nipple</th>
<th>Depth from skin to center of cyst</th>
<th>Largest Dimension</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>(to nearest 0.5 cm)</td>
<td></td>
</tr>
<tr>
<td>R L</td>
<td>o'clock</td>
<td>cm</td>
<td>cm</td>
<td>mm</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Lesion #</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
</table>

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 (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 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 (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 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  __________________________

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### Part B. Positive Findings (pages 4-27) as needed

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

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>20a. Number of solid findings/lesions other than simple cysts: <strong>Right Breast</strong></td>
<td><strong>Left Breast</strong></td>
</tr>
<tr>
<td>(Note: If there are multiple bilateral similar-appearing circumscribed masses, code this as one bilateral lesion).</td>
<td></td>
</tr>
</tbody>
</table>

20b. 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).

**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?** If yes, describe location and measurement of largest mass.

- No
- Yes

**Breast**

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

**20c. Lesion Size**

<p>| | |</p>
<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>Largest Horizontal Meas (mm) D1</strong></td>
<td><strong>Vertical A-P meas (mm) D2</strong></td>
</tr>
<tr>
<td>X mm</td>
<td></td>
</tr>
<tr>
<td>X mm</td>
<td></td>
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</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)

**Special Case Features**

- Complicated Cyst (Note: Do not use this term for "complex cystic masses". For complex cystic masses code "No" for Q20e, proceed to Q20f and indicate "complex cystic" at Q20j.)
  - 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.

---

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### 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)
  - Macrocalcifications (> 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
  - (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

### 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
  - 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? If yes, describe location and measurement of largest mass.
- No
- Yes

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

- R
- L

o o'clock cm cm

26c. Lesion Size

 Largest Horizontal Meas (mm) D1
 Measured Plane Vertical A-P meas (mm) D2 Horizontal Perpendicular Meas (mm) D3

- Trv
- Sag
- Rad
- Arad
- Oblique

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: ____________________________
### 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
  - Aspiration w/core biopsy if solid
  - US-guided core biopsy
  - Vacuum-assisted biopsy, guidance by US
  - Vacuum-assisted biopsy, guidance by Mammo
  - Excisional biopsy
- Comparison to current mammogram is required
- 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 #\[U\] (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).

32b. Was this "lesion" seen on a previous sonogram including any sonograms performed prior to study enrollment?
- No
- Yes

32c. 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>
<th>Second Measured Plane</th>
</tr>
</thead>
<tbody>
<tr>
<td>mm</td>
<td>Trv</td>
<td>mm</td>
<td>X</td>
<td>mm</td>
</tr>
<tr>
<td>mm</td>
<td>Sag</td>
<td>mm</td>
<td>Oblique</td>
<td>mm</td>
</tr>
<tr>
<td>mm</td>
<td>Rad</td>
<td>mm</td>
<td>Arad</td>
<td>mm</td>
</tr>
<tr>
<td>mm</td>
<td>Arad</td>
<td>mm</td>
<td>Oblique</td>
<td>mm</td>
</tr>
<tr>
<td>mm</td>
<td>Oblique</td>
<td>mm</td>
<td>Oblique</td>
<td>mm</td>
</tr>
</tbody>
</table>

32d. 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

32e. Special Case (see choices below)
- No
- 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)
  - Macrocalcifications (> 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
- 1 Negative
- 2 Benign (complete Q33b)
- 3 Probably Benign
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion
- 5 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)
  - 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

### 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 # \[U\] (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

38c. 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 (to nearest 0.5 cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>O R L</td>
<td></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?
- 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?
- No
- Yes

44c. Lesion Size

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

44d. 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

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)
  - Microcalcifications in mass
  - Microcalcifications 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?
(only complete if Q45a = Benign)
- 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
  (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
    - 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
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 **

(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

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

**50c. Lesion Size**

<table>
<thead>
<tr>
<th>Largest Horizontal Mea (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 D1X2X3 + 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>mm</td>
<td>o Trv</td>
<td>X</td>
<td>mm</td>
<td>o Trv</td>
<td>mm³</td>
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<tr>
<td>mm</td>
<td>o Sag</td>
<td>X</td>
<td>mm</td>
<td>o Sag</td>
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<td>mm</td>
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<td>o Arad</td>
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<tr>
<td>mm</td>
<td>o Oblique</td>
<td></td>
<td>mm</td>
<td>o Perpendicular Oblique</td>
<td></td>
</tr>
</tbody>
</table>

**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 microcyts
  - Intraductal mass
  - Lymph node
  - Calcifications without a mass
  - Foreign body
  - Post-Surgical scar
  - Other, specify: ________________________
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
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?
- Not applicable, no prior breast sonograms
- 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?
- Not applicable, multiple bilateral circumscribed masses
- Yes

**Breast**

<table>
<thead>
<tr>
<th>Clockface (report on the hour)</th>
<th>Distance from the nipple (to nearest 0.5 cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>O R O L o'clock</td>
<td>cm</td>
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</table>

56c. 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>
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<tr>
<td>o Oblique</td>
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</tbody>
</table>

56d. Is this lesion at the site of prior biopsy?
- Not applicable, multiple bilateral circumscribed masses
- 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

56e. Special Case (see choices below)
- Not applicable, multiple bilateral circumscribed masses
- Yes (if yes, detail below then proceed to Q56n)

**Special Case Features**
- 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.)
  - 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: ________________________________
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 # [ ] (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?
- 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? If yes, describe location and measurement of largest mass.
- No
- Yes

Breast

Clockface (report on the hour) Distance from Depth from skin to
(report on hour and 1/2 hour 
report on hour and 1/2 hour center of lesion 
e.g. 7:00 = 0700, 12:30 = 1230) (to nearest 0.5 cm)

- R
- O
- L

O'clock cm cm

62c. Lesion Size

Largest

Horizontal Measured Plane Vertical A-P Meas (mm) D2 Horizontal Perpendicular Meas (mm) D3 Second Measured Plane

Vertical A-P Meas (mm) D2

X

Horizontal Measured Plane Second Measured Plane

D1 X X

Volume D1XD2XD3 \(\div 2\)

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

62d. 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

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 high-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:__________________________
### 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

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### 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 (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?
- 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
  - 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

### 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
Instructions: Please complete an ID form for each case where either the mammogram or ultrasound had a final assessment other than negative or benign, or recommendation other than for annual follow-up. It is strongly recommended that the same Radiologist who performed the survey ultrasound completes the ID form. Comparison to prior breast imaging is recommended at the time of integration reading. Short interval follow-up should be reported on F6 form and additional evaluation on IM form.

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)
     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.)
     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)
     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.)
     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
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
  - 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)
### 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

### 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

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

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10. Additional Lesion Description

10a. Lesion Description (dominant feature)
- Mass
- Multiple bilateral circumscribed masses
- Asymmetry
- 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)

- Yes, cyst, not detailed on form IS (check all that apply)

- 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

10c. Is this lesion seen on ultrasound?
- No (proceed to Q10d)
- Yes and detailed on IS (complete)

- Yes, cyst, not detailed on form IS (check all that apply)

- 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

10d. 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)

10e. Combined reading likelihood of malignancy for this lesion [_____]% (best guess from 0-100)

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 □ upper
      - Left breast □ lower
      - Bilateral □ upper, □ lower, □ central
      - Axillary □ upper, □ lower, □ retroareolar, □ central
    - **Distance from the nipple [ ] cm**

11c. Is this lesion seen on ultrasound?
- No (proceed to Q11d)
- Yes and detailed on form 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 □ upper, □ lower
    - **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.)
   - In retrospect (only after reviewing ultrasound)
     - Quadrant - Location (check all that apply)
       - Right breast
       - Left breast
       - Bilateral multiple
       - Axillary tail
       - Retroareolar
       - Central
     - Distance from the nipple [ ] cm

12c. Is this lesion seen on ultrasound?
   - No (proceed to Q12d)
   - 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
     - 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

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

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.)
  
  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

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
14. Additional Lesion Description

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

14b. Is this lesion seen on mammography?
- No (proceed to Q14c)
- Yes, and detailed on form IA (complete)

14c. Is this lesion seen on ultrasound?
- No (proceed to Q14d)
- Yes and detailed on form IS (complete)

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
- 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.)

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.)
   - In retrospect (only after reviewing mammogram)
     - New Lesion # [U_____] (number sequentially where IS left off, e.g. UR2, UB2, UR3, etc.)

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
   - Primarily 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
     - (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

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)
  - New 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)
  - New 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

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

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
  - 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)
  - 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
**ACRIN Study 6666**

**SPACE LABEL HERE**

**ACRIN 6666**

**Additional Evaluation:**

**Additional Views/Targeted US**

For revised or corrected form check box and fax to 215-717-0936.

Instructions: The IM form is completed based on recommendations (from ID or MX form) for additional imaging after an abnormal screening. The IM form is also completed when a study participant returns for additional evaluation “off study”, i.e. not prompted by the annual screening US or mammography examinations. Examples of “off study events” (Q4b) would include: a) participant presents to the study site with a new clinical abnormality between annual screenings and requires additional evaluation; b) participant has an off-study MRI performed and presents to the study site with abnormalities requiring additional evaluation. For additional evaluation performed at another facility, not at a study site, information will be collected on the F1 form at the time of each annual screening. The IM form should be completed by the study radiologist who performs the targeted US if possible. If no targeted US was performed or if additional evaluation was performed by a non-study radiologist, then any study radiologist may complete the form. The lesion ID form should remain consistent from the ID or M3 form. For short interval follow-up, complete an F6 form instead of IM form or an M4 for a short interval follow-up MRI. Section I may be completed by the RA. Sections II through V should be completed by the Radiologist. Note: if additional evaluation is not able to be completed at first return visit, complete a second continuation form IM when the participant returns to complete additional evaluation. Description is only required for those lesions requiring additional evaluation based on ID form(s), M3 findings requiring additional evaluation based on the MX form, and for lesions found only on additional evaluation. Complete Section II for each lesion that requires description based on the ID form, each M3 finding that requires description based on the MX form recommendation, and/or clinical findings event if the additional imaging revealed no abnormalities. Complete form M3 if the MRI study is repeated as part of additional evaluation.

---

**I. GENERAL INFORMATION**

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

2. Did participant return for additional evaluation?
   - No (specify reason, STOP and sign form)
   - Second opinion felt not mandated
   - Participant refusal
   - Participant did not return
   - Unable to be performed and rescheduled
   - Yes
     - Completed
     - 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
   - Initial screening
   - 12 month screening
   - 24 month screening
   - 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?
   - Right Breast
   - Left Breast

7. How many lesions were recommended for additional evaluation for this breast based on ID form(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]
   - No (proceed to Q7b)
   - Yes (detail how many)
   - Not applicable, not done

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

---

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'clock or specify location:
         - Axilla
         - Retroareolar
         - Unknown
     - Nipple discharge (detail):
       - Bloody
       - Clear spontaneous
       - 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'clock or specify location:
         - Axilla
         - Retroareolar
         - Unknown
     - Nipple discharge (detail):
       - Bloody
       - Clear spontaneous
       - Other
     - Other, specify: __________
       - 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)?
   - No (proceed to Q10)
   - 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?
    - No available (proceed to Section IIA)
    - Available (complete, check all that apply)
      - Prior mammography
      - Prior targeted US
      - Right
      - Left
      - Prior survey US

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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)
     Lesson # from prior mammogram: [M] (if not applicable code 998)
     Lesson # 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 #)
   New lesion # [M] (e.g. MR1, MB1, ML1, MR2, etc.)
   o Yes
     Lesson # from prior mammogram: [M] (e.g. MR1, MB1, ML1, MR2, etc.)

11d. Was lesion enumerated on any prior study ultrasound?
   o No
     □ Simple cyst
     □ Not a simple cyst
   o Yes (complete)
     Lesson # 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.

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

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)
     □ 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

   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)
   o Simple cyst
   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 # [U] (e.g. UR1, UB1, UL1, UR2, etc.)
   o Yes

12c. Was lesion enumerated on any prior study ultrasound?
   o No (complete)
     □ Simple cyst (proceed to Q13)
     □ 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 # [U] (e.g. UR1, UB1, UL1, UR2, etc.)
   o Yes (complete)

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

   o No
   o Yes (complete)
     Lesson # 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 (report on 1/2 hour) (report on hour and 1/2 hour e.g. 7:00 = 0700, 12:30 = 1230)

Clockface

Distance from
the nipple

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

R L o’ clock cm cm

12e. Lesion Size

Largest Horizontal Meas (mm) D1

Measured Plane Vertical A-P meas (mm) D2

Horizontal Meas (mm) D3

Second Measured Plane Volume D1XD2XD3 ÷ 2

Trv Sag Rad Arad Oblique

mm mm mm

mm mm mm

mm

12f. Special Case (see choices below)

Yes (detail below then proceed to Q12o)

No

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 microcysts
Intraductal mass
Lymph node
Calcifications without a mass
Foreign body
Post-surgical scar
Other, specify

12g. Shape

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

12h. Orientation

O Parallel to skin
O Not parallel (includes round)

12i. Margin

O Circumscribed
O Not circumscribed (If not circumscribed, choose dominant feature)

Indistinct
Angular
Microlobulated
Spiculated

12j. 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.
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)
  - Macrocalcifications (> 0.5 mm)
  - Microcalcifications in mass
  - Microcalcifications 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

Section III.

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
   - 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
   - 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 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
   - 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
     - Vacuum-assisted biopsy, guided by MRI

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

17c. Recommendation for this 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
   - 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
     - Vacuum-assisted biopsy, guided by MRI

17d. 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.

Comments: ____________________________

______________________________

Signature of Radiologist responsible for the data 1

______________________________

Date Form Completed (mm-dd-yyyy)

Signature of person entering data onto web 2
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: (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)
- Participant refused
- Not needed after targeted US
- Scheduling constraints; participant rescheduled
- Other
- Yes (check all that apply)
  - R
  - L
  - True lateral
  - Magnification views
  - Rolled views
  - Repeat CC or MLO or both

18b. Lesion # from prior MRI: (e.g. GR1, GL1, GL2, etc.) if not applicable code 998

18c. 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
  - Lesion # from prior ultrasound: U
- Yes
  - Lesion # from prior mammogram: M
  - (e.g. MR1, MB1, ML1, MR2, etc.)

18d. 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 #
- Yes
  - Lesion # from prior mammogram: M
  - (e.g. MR1, MB1, ML1, MR2, 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
  - Upper
  - Lower
  - Left breast
  - Upper
  - Lower
  - Bilateral, multiple
  - Inner
  - Outer
  - Axillary tail
  - Central
  - 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)
- 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)
- Participant refused
- Not needed after additional mammographic views
- Scheduling constraints; participant rescheduled
- Other
- Yes (check all that apply)
  - Targeted only
  - Whole breast

19b. Lesion # from prior ultrasound: (e.g. UR1, UB1, UL1, UR2, etc.) if not applicable code 998

19c. Was lesion enumerated on any prior study ultrasound?
- No (complete then proceed to Q20)
  - Lesion # from prior ultrasound: U
  - (e.g. UR1, UB1, UL1, UR2, etc.)
- Yes
  - Lesion # from prior ultrasound: U
  - (e.g. UR1, UB1, UL1, UR2, etc.)

19d. Was lesion enumerated on any prior 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.

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

  - □ R □ L  □ o’ clock □ □ cm □ □ . □ cm

19e. **Lesion Size**

- **Largest Horizontal Meas (mm) D1**
  - □ □ □ mm
- **Vertical A-P meas (mm) D2**
  - X □ □ □ mm X
- **Horizontal Perpendicular Meas (mm) D3**
  - □ □ □ mm

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

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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

Section III.

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 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

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)
   - 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)
   - Yes
     - Lesion # from prior mammogram: [M]
     - Lesion # from prior ultrasound: [U]

23c. Was lesion enumerated on any prior study mammogram?
   - No and not visible in retrospect
   - No but now visible in retrospect
   - New lesion #
     - Lesion # from prior mammogram: [M]
     - Lesion # from prior ultrasound: [U]

23d. Was lesion enumerated on any prior study ultrasound?
   - No
     - Simple cyst
     - Not a simple cyst
   - Yes (complete)
     - Lesion # from ultrasound: [U]

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

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)
   - 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)
   - Yes
     - Lesion # from prior ultrasound: [U]

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
   - Not a simple cyst and now visible in retrospect
     - New lesion #
     - Lesion # from prior ultrasound: [U]

24d. Was lesion enumerated on any study mammogram (including additional views obtained today)?
   - No
   - Yes (complete)
     - Lesion # from mammogram or additional view number: [M]

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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)

Distance from 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

24e. Lesion Size

Largest

Horizontal Meas (mm) \( D_1 \)

Measured Plane

- o Trv
- o Sag
- o Rad
- o Arad
- o Oblique

Vertical A-P Meas (mm) \( D_2 \)

- X

Horizontal Perpendicular Meas (mm) \( D_3 \)

- X

24f. Special Case (see choices below)

- O No
- O Yes (detail below then proceed to Q24g)
  - o 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
  - 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 __________________________

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 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

**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.

IID. 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)
     ◦ Mammogram # (if not applicable code 998)
     ◦ Ultrasound # (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 #
   ◦ Yes
     ◦ Mammogram # (if not applicable code 998)
     ◦ Ultrasound # (if not applicable code 998)

28d. Was lesion enumerated on any prior study ultrasound?
   ◦ No
     ◦ Simple cyst
     ◦ Not a simple cyst
   ◦ Yes (complete)
     ◦ Ultrasound # (e.g. MR1, MB1, ML1, MR2, etc.)

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

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

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
     ◦ Microlaceluloculated
     ◦ 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)
     ◦ Ultrasound # (if not applicable code 998)
     ◦ Mammogram # (if not applicable code 998)
   ◦ Yes

29c. Was lesion enumerated on any prior study ultrasound?
   ◦ No (complete)
   ◦ Simple cyst
   ◦ Not a simple cyst
   ◦ New lesion #
   ◦ Yes (complete)
     ◦ Ultrasound # (e.g. UR1, UB1, UL1, UR2, etc.)

Was lesion enumerated on any study mammogram (including additional views obtained today)?
   ◦ No
   ◦ Yes (complete)
     ◦ Mammogram # (if not applicable code 998)
     ◦ Ultrasound # (if not applicable code 998)

"Copyright 2007"
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)

Volume D1XD2XD3 \( \approx \frac{2}{3} \) 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.

29e. Lesion Size

Largest Horizontal Meas (mm) D1

Measured Plane

Vertical A-P meas (mm) D2

Horizontal Perpendicular Meas (mm) D3

Second Measured Plane

Horizontal Meas (mm) D1

Second Measured Plane

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

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
### Section III. (by lesion)

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

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>31a. Percentage likelihood of malignancy for this lesion</td>
<td>1 No, 2 Negative, 3 Benign, 4A Low Suspicion of Malignancy, 4B Intermediate Suspicion, 4C Moderately High Suspicion, 5 Highly Suggestive of Malignancy</td>
</tr>
<tr>
<td>31b. Assessment for this lesion</td>
<td>1 Negative, 2 Benign, 3 Probably Benign, 4A Low Suspicion of Malignancy, 4B Intermediate Suspicion, 4C Moderately High Suspicion, 5 Highly Suggestive of Malignancy</td>
</tr>
<tr>
<td>31c. Recommendation(s) for this lesion</td>
<td>1 Routine screening in 1 year, 2 Diagnostic follow-up in 1 year, 3 Short-interval follow-up in 6 months with US, 4 Short-interval follow-up in 6 months with mammo, 5 Short-interval follow-up in 6 months with MRI, 6 Intervention and/or Additional Imaging (detail intervention and/or additional imaging), 7 Additional Imaging (detail intervention, see below)</td>
</tr>
<tr>
<td>Intervention</td>
<td>1 Aspiration with core biopsy if solid, 2 US-guided core biopsy, 3 Vacuum-assisted biopsy, guidance by US, 4 Vacuum-assisted biopsy, guidance by mammo, 5 Excisional biopsy, 6 Vacuum-assisted biopsy, guided by MRI</td>
</tr>
<tr>
<td>Additional Imaging</td>
<td>1 Targeted ultrasound (lesion seen on mammography), 2 Comparison to prior mammogram is required, 3 Additional mammographic projections</td>
</tr>
<tr>
<td>31d. Is this lesion assessed as probably benign AND recommended for intervention?</td>
<td>1 No, 2 Yes (specify dominant reason), 3 Participant preference, 4 Cancer present now, 5 In this breast, 6 In opposite breast, 7 Patient risks factors, 8 Vaguely palpable, 9 Follow-up not reasonable, 10 Interval increase (&gt;20% in volume for masses), 11 Interval suspicious change, 12 Investigator uncertainty</td>
</tr>
</tbody>
</table>

#### 32. Are there additional lesion(s) you wish to describe?

- No (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.

II E. 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)

R L
- Spot compression
- True lateral
- Laterally exaggerated CC
- Magnification views
- Rolled views
- Repeat CC or MLO or both

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

Lesion # from prior mammogram: [M]
(if not applicable code 998)

Lesion # from prior ultrasound: [U]
(if not applicable code 998)

- Yes

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

33d. 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.)

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
- Upper
- Lower
- Inner
- Outer
- Central

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)

☐ Circumscribed
☐ Fat-containing
☐ Not fat-containing
☐ Microlobulated
☐ Obscured
☐ Indistinct
☐ Spiculated

☐ Focal
Connell
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)

- Targeted only
- Whole breast

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

Lesion # from prior mammogram: [M]
(if not applicable code 998)

Lesion # from prior ultrasound: [U]
(if not applicable code 998)

- Yes

34c. Was lesion enumerated on any prior study ultrasound?
- No (complete)
  - Simple cyst (proceed to Q35)
  - 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.)
Check if this "lesion" is multiple bilateral circumscribed masses. Describe largest mass in Q34d and Q34e then proceed to Q34f.

<table>
<thead>
<tr>
<th>Clockface (report on 1/2 hour)</th>
<th>Distance from the nipple (to nearest 0.5 cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast</td>
<td></td>
</tr>
<tr>
<td>R</td>
<td>cm</td>
</tr>
<tr>
<td>L</td>
<td>cm</td>
</tr>
</tbody>
</table>

34e. 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>
<th>Second Measured Plane</th>
</tr>
</thead>
<tbody>
<tr>
<td>mm</td>
<td>Trv</td>
<td>Sag</td>
<td>Rad</td>
<td>Oblique</td>
</tr>
</tbody>
</table>

34f. Special Case (see choices below)

- No
- Yes (detail below then proceed to Q34o)
  - 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).
  - 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

34g. Shape

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

34h. Orientation

- Parallel to skin
- Not parallel (includes round)

34i. Margin

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

34j. 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.
34k. Echo Pattern
- Anechoic
- Hyperechoic
- Complex cystic
- Hypoechoic with few tiny cystic areas
- Isoechoic to fat
- Mixed hypoechoic and hypoechoic
- Hypoechoic to fat

34l. 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

Section III.

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?
   - No (specify reason and proceed to Q39)
   - 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

38b. Was lesion seen on additional mammographic view(s)?
   - No e.g. resolved on additional views (complete then proceed to Q39)

   - Yes (check all that apply)
     - Lesion # from prior mammogram: [M] (if not applicable code 998)
     - Lesion # from prior ultrasound: [U] (if not applicable code 998)

38c. 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] (e.g. MR1, MB1, ML1, MR2, etc.)
   - Yes
     - Lesion # from prior mammogram: [M] (e.g. MR1, MB1, ML1, MR2, etc.)

38d. 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.)

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
   (largest diameter) (largest perpendicular dimension)

38h. 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

39. Sonographic Lesion Description

39a. Was ultrasound performed again directed to this lesion?
   - No (specify reason and proceed to Q40)

   - Yes (check all that apply)
     - Targeted only
     - Whole breast

39b. Was lesion seen on this Ultrasound?
   - No (complete then proceed to Q40)

   - Yes

39c. Was lesion enumerated on any prior study ultrasound?
   - No (complete)

   - Yes (complete)
     - Lesion # from prior ultrasound: [U] (if not applicable code 998)

39d. Was lesion enumerated on any prior 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.)
39d. □ Check if this "lesion" is multiple bilateral circumscribed masses. Describe largest mass in Q39d and Q39e then proceed to Q39f.

<table>
<thead>
<tr>
<th>Breast</th>
<th>(report on 1/2 hour)</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>
</tr>
</tbody>
</table>

- OR L 
- o'clock
- cm
- . cm

39e. 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>
</tr>
</thead>
<tbody>
<tr>
<td>Horiz</td>
<td>Trv</td>
<td>Sag</td>
<td>Arad</td>
<td>Oblique</td>
</tr>
<tr>
<td>mm</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

39f. Special Case (see choices below)

- O No
- O Yes (detail below then proceed to Q39o)
  - o 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).
  - 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 ____________________________

39g. Shape

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

39h. Orientation

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

39i. Margin

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

39j. 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.

41. Assessment/Recommendations (by lesion)

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
  - 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
- 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 IIIG)
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.

43. Mammographic Lesion Description

43a. Were additional mammographic views obtained directed to this finding?
- No (specify reason and proceed to Q44)
- Not recommended
- Participant refused
- Not needed after targeted US
- Scheduling constraints; participant rescheduled
- Other
- Yes (check all that apply)

43b. Was lesion seen on additional mammographic view(s)?
- No e.g. resolved on additional views (complete then proceed to Q44)
- Yes

43c. 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 #
- Yes

43d. Was lesion enumerated on any prior study ultrasound?
- No
- Simple cyst
- Not a simple cyst
- Yes (complete)

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

44. Sonographic Lesion Description

44a. Was ultrasound performed again directed to this lesion?
- No (specify reason and proceed to Q45)
- Not recommended
- Participant refused
- Not needed after additional mammographic views
- Scheduling constraints; participant rescheduled
- Other
- Yes (check all that apply)

44b. Was lesion seen on this Ultrasound?
- No (complete then proceed to Q45)
- Yes

44c. Was lesion enumerated on any prior study ultrasound?
- No
- 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 #)
- New lesion #
- Yes

44d. 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

44e. Distance from nipple cm by Sonography

44f. Size of lesion by Sonography:

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

44h. Lesion Description Sonography
(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

45. Image Summaries

45a. Digital breast image(s) viewed by radiologist?
- Yes
- No

45b. Digital mammogram(s) reviewed by radiologist?
- Yes
- No

45c. Digital mammogram(s) reviewed by radiologist?
- Yes
- No

45d. Digital mammogram(s) reviewed by radiologist?
- Yes
- No

45e. Digital mammogram(s) reviewed by radiologist?
- Yes
- No

45f. Digital mammogram(s) reviewed by radiologist?
- Yes
- No

45g. Digital mammogram(s) reviewed by radiologist?
- Yes
- No

45h. Digital mammogram(s) reviewed by radiologist?
- Yes
- No

45i. Digital mammogram(s) reviewed by radiologist?
- Yes
- No

45j. Digital mammogram(s) reviewed by radiologist?
- Yes
- No

45k. Digital mammogram(s) reviewed by radiologist?
- Yes
- No

45l. Digital mammogram(s) reviewed by radiologist?
- Yes
- No

45m. Digital mammogram(s) reviewed by radiologist?
- Yes
- No

45n. Digital mammogram(s) reviewed by radiologist?
- Yes
- No

45o. Digital mammogram(s) reviewed by radiologist?
- Yes
- No

45p. Digital mammogram(s) reviewed by radiologist?
- Yes
- No

45q. Digital mammogram(s) reviewed by radiologist?
- Yes
- No

45r. Digital mammogram(s) reviewed by radiologist?
- Yes
- No

45s. Digital mammogram(s) reviewed by radiologist?
- Yes
- No

45t. Digital mammogram(s) reviewed by radiologist?
- Yes
- No

45u. Digital mammogram(s) reviewed by radiologist?
- Yes
- No

45v. Digital mammogram(s) reviewed by radiologist?
- Yes
- No

45w. Digital mammogram(s) reviewed by radiologist?
- Yes
- No

45x. Digital mammogram(s) reviewed by radiologist?
- Yes
- No

45y. Digital mammogram(s) reviewed by radiologist?
- Yes
- No

45z. Digital mammogram(s) reviewed by radiologist?
- Yes
- No

46. Findings on Biopsy

46a. Biopsy performed?
- Yes
- No

46b. Biopsy performed?
- Yes
- No

46c. Biopsy performed?
- Yes
- No

46d. Biopsy performed?
- Yes
- No

46e. Biopsy performed?
- Yes
- No

46f. Biopsy performed?
- Yes
- No

46g. Biopsy performed?
- Yes
- No

46h. Biopsy performed?
- Yes
- No

46i. Biopsy performed?
- Yes
- No

46j. Biopsy performed?
- Yes
- No

46k. Biopsy performed?
- Yes
- No

46l. Biopsy performed?
- Yes
- No

46m. Biopsy performed?
- Yes
- No

46n. Biopsy performed?
- Yes
- No

46o. Biopsy performed?
- Yes
- No

46p. Biopsy performed?
- Yes
- No

46q. Biopsy performed?
- Yes
- No

46r. Biopsy performed?
- Yes
- No

46s. Biopsy performed?
- Yes
- No

46t. Biopsy performed?
- Yes
- No

46u. Biopsy performed?
- Yes
- No

46v. Biopsy performed?
- Yes
- No

46w. Biopsy performed?
- Yes
- No

46x. Biopsy performed?
- Yes
- No

46y. Biopsy performed?
- Yes
- No

46z. Biopsy performed?
- Yes
- No
44d. □ Check if this "lesion" is multiple bilateral circumscribed masses. 
Describe largest mass in Q44d and Q44e then proceed to Q44f.

Breast (report on 1/2 hour)

Clockface

Distance from the nipple

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

44e. Lesion Size

Largest Meas (mm) D1

Height

Width

Depth

Measured Plane

Vertical A-P meas (mm) D2

Horizontal Meas (mm) D3

Second Measured Plane

Volume D1XD2XD3 ÷ 2

44f. Special Case (see choices below)

□ No

□ Yes (detail below then proceed to Q44g)

- 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

□ Oval

□ Two or three gentle lobulations

□ Round

□ Irregular

44h. Orientation

□ Parallel to skin

□ Not parallel (includes round)

44i. Margin

□ Circumscribed

□ Not circumscribed (If not circumscribed, choose dominant feature)

□ Indistinct

□ Angular

□ Microlobulated

□ Spiculated

44j. Boundary Zone

□ Abrupt Interface

□ Echogenic Halo

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ACRIN 6666

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
  - Vacuum-assisted biopsy, guided by MRI
  - Vacuum-assisted biopsy, guided by US
  - Additional mammographic projections
  - Excisional biopsy
  - Additional imaging and/or additional intervention

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.

III. Lesion # from prior MRI: (e.g. GR1, GL1, GL2, etc.)

48. Mammographic Lesion Description

48a. Were additional mammographic views obtained directed to this finding?
   o No (specify reason and proceed to Q49)
   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)

48b. Was lesion seen on additional mammographic view(s)?
   o No e.g. resolved on additional views (complete then proceed to Q49)
   o Yes (check all that apply)

48c. 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
     (assign next sequential mammogram lesion #)

48d. Was lesion enumerated on any prior study ultrasound?
   o No
   o Simple cyst
     (assign next sequential sonogram lesion #)
   o Not a simple cyst
     (assign next sequential sonogram lesion #)
   o Yes (complete)

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.

48f. Distance from nipple cm by Mammography

48g. Size of lesion by Mammography:

   mm X mm

48h. Lesion Description Mammography

(2007)
49d. □ Check if this "lesion" is multiple bilateral circumscribed masses. Describe largest mass in Q49d and Q49e then proceed to Q49f.

<table>
<thead>
<tr>
<th>Clockface</th>
<th>Distance from the nipple</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast (report on 1/2 hour)</td>
<td>(report on hour and 1/2 hour e.g. 7:00 = 7, 12:30 = 12:5)</td>
</tr>
<tr>
<td>O R O L</td>
<td>o' clock cm cm</td>
</tr>
</tbody>
</table>

49e. 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 ÷ 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>o Trv</td>
<td>o Sag</td>
<td>o Rad</td>
<td>o Arad</td>
<td>o Oblique</td>
<td>mm</td>
</tr>
</tbody>
</table>

49f. Special Case (see choices below)
- O No
- O Yes (detail below then proceed to Q49o)
  - O 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).
  - 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 _____________

49g. Shape
- O Oval
- O Two or three gentle lobulations
- O Round
- O Irregular

49h. Orientation
- O Parallel to skin
- O Not parallel (includes round)

49i. Margin
- O Circumscribed
- O Not circumscribed (If not circumscribed, choose dominant feature)
  - □ Indistinct
  - □ Angular
  - □ Microlobulated
  - □ Spiculated

49j. 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.
49k. Echo Pattern
- Anechoic
- Hyperechoic
- Complex cystic
- Hypoechoic with few tiny cystic areas
- Isoechoic to fat
- Mixed hyperechoic and hypoechoic
- Hypoechoic to fat

49l. Posterior Features
- None
- Enhancement
- Combined shadowing/enhancement
- Shadowing

49m. Surrounding Tissue
- No effect
- Effect (check all that apply)
  - Duct changes
  - Edema
  - Cooper's ligament distortion
  - Architectural distortion
  - Skin thickening
  - Skin retraction

49n. Vascularity (flow)
- None
- Yes (check all that apply)
  - Present in lesion
  - Present immediately adjacent to lesion
  - Increased in surrounding tissue
- Not performed

49o. Calcifications on ultrasound
- None
- Present (check all that apply)
  - Macrocalcifications (> 0.5 mm)
  - Microcalcifications in mass
  - Microcalcifications outside mass

49p. 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 (by lesion)

51a. [ ] % likelihood of malignancy for this lesion

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 mammom
- 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 mammom
    - 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)
   - Second opinion, felt not warranted
   - Participant refusal
   - Participant unable to be contacted
   - Unable to be performed and rescheduled
   - Yes
   - 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?
   (check all that apply)
   - 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'clock or specify location:
       - Axilla
       - Retroareolar
       - Unknown
     - Nipple discharge (detail):
       - Bloody
       - Clear spontaneous
       - 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'clock or specify location:
       - Axilla
       - Retroareolar
       - Unknown
     - Nipple discharge (detail):
       - Bloody
       - Clear spontaneous
       - 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
       - Right
       - Left
       - Bilateral
     - Outside US
     - Outside mammogram

10. Comparison studies other than most recent annual mammogram and study US?
    - Not available (proceed to Q11)
    - Available (complete, check all that apply)
      - Prior mammography
      - Prior US
      - Prior targeted US
      - Right
      - Left
      - Prior survey US
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?
- No (specify reason and proceed to Q12)
  - Not recommended
  - Participant refused
  - Not needed after targeted US
  - Scheduling constraints; participant rescheduled
  - Other
  - Yes

11b. Change in this lesion from prior mammogram(s)?
- New
- 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)
- Decreasing
- Stable
- Fluctuating bilateral circumscribed masses
- Increasing
- Other suspicious change(s)
- Increasing and other suspicious change(s)

11c. 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.)

11d. 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.)

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

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)
  - 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

12. Sonographic Lesion Description

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

12b. Change in this lesion from prior ultrasound?
- New
- 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)
- Decreasing
- Stable
- Fluctuating bilateral circumscribed masses
- Increasing
- Other suspicious change(s)
- Increasing and other suspicious change(s)

12c. Was lesion enumerated on any prior study ultrasound?
- No (complete)
- Simple cyst (proceed to Q13)
  - 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 #)
- 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)?
- No
- 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: □ Check if this "lesion" is multiple bilateral circumscribed masses. Describe largest mass in Q12e and Q12f then proceed to Q12g.

<table>
<thead>
<tr>
<th>Clockface</th>
<th>Distance from</th>
<th>Depth from skin to</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast</td>
<td>(report on 1/2 hour)</td>
<td>center of lesion</td>
</tr>
<tr>
<td>(report on hour and 1/2 hour)</td>
<td>(to nearest 0.5 cm)</td>
<td></td>
</tr>
<tr>
<td>O R O L</td>
<td>O' clock</td>
<td>cm</td>
</tr>
</tbody>
</table>

12f. 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>
<th>Measured Plane</th>
<th>Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>D1</td>
<td>Trv</td>
<td>X</td>
<td>Trv</td>
<td>Sag</td>
<td>D1XD2XD3/2</td>
</tr>
<tr>
<td>mm</td>
<td>Sag</td>
<td>mm</td>
<td>Sag</td>
<td>Trv</td>
<td>mm³</td>
</tr>
<tr>
<td>mm</td>
<td>Arad</td>
<td>mm</td>
<td>Arad</td>
<td>Sag</td>
<td></td>
</tr>
<tr>
<td>mm</td>
<td>Oblique</td>
<td>mm</td>
<td>Oblique</td>
<td>Trv</td>
<td></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
  ○ Calculations 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.
Section III.

14. Assessment/Recommendations

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

14b. 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

14c. Known benign by prior biopsy?
   o No (proceed to Q14d)
   o Yes (complete)
     o < 1 year ago
     o 1-2 years ago
     o > 2 years ago

14d. Recommendation(s) for this lesion
   o Return to routine screening
   o Diagnostic follow-up to coincide with next annual exam
   o Short-interval follow-up in 6 months with US
   o Short-interval follow-up in 6 months with mammography
   o Short-interval follow-up in 6 months with MRI
   o Intervention and/or Additional Imaging
     (detail intervention and/or additional imaging)
     o 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 mammogram
       o Excisional biopsy
       o US-guided biopsy, if US negative, MRI guided biopsy
     o Additional Imaging
       o Targeted ultrasound (lesion seen on mammography)
       o Comparison to prior mammogram is required
       o Additional mammographic projections

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

15. Are there additional lesion(s) you wish to describe?
   o No (proceed to Q16)
   o 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
   - 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 breast
   - 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
   - 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
   - 1 Negative
   - 2 Benign
   - 3 Probably Benign
   - 4A Low Suspicion of Malignancy
   - 4B Intermediate Suspicion
   - 4C Moderately High Suspicion
   - 5 Highly Suggestive of Malignancy

   17c. Recommendation for this breast
   - 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
   - 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.

Comments:

__________________________________________________________________________
__________________________________________________________________________
__________________________________________________________________________

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

Signature of person entering data onto web 2 ____________________________
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?
   o No (specify reason and proceed to Q19)
     o Not recommended
     o Participant refused
     o Not needed after targeted US
     o Scheduling constraints; participant rescheduled
     o Other
     o Yes

18b. Change in this lesion from prior mammogram(s)?
   o New
   o Gone (complete then proceed to Q19)
     [M]
   (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)

18c. 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
     [M]
     (e.g. MR1, MB1, ML1, MR2, etc.)

18d. Was lesion enumerated on any prior study ultrasound?
   o No
     o Simple cyst
     o Not a simple cyst
     o Yes (complete)
     [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.

   o Right breast  o Upper
   o Left breast o Lower
   o Bilateral, multiple  o Inner
   o Axillary tail  o outer
   o Retroareolar  o 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)
   o Mass (select worst 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
   o 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 Clustered
     o Multiple clusters (same morphology)
     o Regional
     o Linear
     o Segmental
     o Diffuse scattered
     o In mass or asymmetry
   o Architectural Distortion

19. Sonographic Lesion Description

19a. Was ultrasound performed of this lesion on this follow-up evaluation?
   o No (specify reason and proceed to Q20)
     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

19b. Change in this lesion from prior ultrasound?
   o New
     o Gone (complete then proceed to Q20)
     [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)

19c. Was lesion enumerated on any prior study ultrasound?
   o No (complete)
     o Simple cyst (proceed to Q20)
     o Not a simple cyst
     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)
     [U]
     (e.g. UR1, UB1, UL1, UR2, etc.)

19d. Was lesion enumerated on any study mammogram (including views obtained today)?
   o No
   o Yes (complete)
     [M]
     (e.g. MR1, MB1, ML1, MR2, etc.)
19e. □ Check if this "lesion" is multiple bilateral circumscribed masses. Describe largest mass in Q19e and Q19f then proceed to Q19g.

<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 1/2 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>O R O L</td>
<td>o'clock</td>
<td>cm</td>
<td>cm</td>
</tr>
</tbody>
</table>

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 Meas (mm) D3</th>
<th>Second Measured Plane</th>
<th>Volume D1XD2XD3 ÷ 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>mm</td>
<td>Trv</td>
<td>X</td>
<td>mm</td>
<td>Trv</td>
<td>mm³</td>
</tr>
<tr>
<td>o Trv</td>
<td>o Sag</td>
<td></td>
<td>o Arad</td>
<td>o Arad</td>
<td></td>
</tr>
<tr>
<td>o Rad</td>
<td>o Oblique</td>
<td></td>
<td></td>
<td>o Perpendicular Oblique</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 19i).
    - 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
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)
     - Micocalcifications in mass
     - Micocalcifications 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
   - 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
     - 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: [space] (e.g. GR1, GL1, GL2, etc.)
(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)
  - 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 #)
- Yes
  - New lesion # [M]
  - 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

23f. Distance from nipple [ ] cm by Mammography

23g. Size of lesion by Mammography:

[ ] mm (largest diameter) x [ ] mm (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 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)
  - 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
  - Not visible in retrospect
  - Other
  - Yes (complete)
  - New lesion # [U]
  - 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)
- New lesion # [U]
  - Lesion # from mammogram (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.

<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>0 R</td>
<td>o'clock cm</td>
<td></td>
<td>cm</td>
</tr>
<tr>
<td>0 L</td>
<td>cm</td>
<td></td>
<td>cm</td>
</tr>
</tbody>
</table>

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>
<th>Volume D1XD2XD3 ÷ 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>o Trv</td>
<td>X mm</td>
<td>X mm</td>
<td>X mm</td>
<td>o Trv</td>
<td>mm³</td>
</tr>
<tr>
<td>o Sag</td>
<td></td>
<td></td>
<td></td>
<td>o Sag</td>
<td></td>
</tr>
<tr>
<td>o Rad</td>
<td></td>
<td></td>
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<td>o Rad</td>
<td></td>
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<tr>
<td>o Arad</td>
<td></td>
<td></td>
<td></td>
<td>o Perpendicular Oblique</td>
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</tr>
<tr>
<td>o Oblique</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

24g. Special Case (see choices below)

- No
- Yes, detail below then proceed to Q24p (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
  - Microclobulated
  - Spiculated

24k. Boundary Zone

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

### 24m. Posterior Features
- None
- Enhancement
- Combined shadowing/enhancement
- Shadowing

### 24n. Surrounding Tissue
- No effect
- Effect (check all that apply)
  - Duct changes
  - Edema
  - Cooper's ligament distortion
  - Architectural distortion
  - Skin thickening
  - Skin retraction

### 24o. Vascularity (flow)
- None
- Yes (check all that apply)
  - Present in lesion
  - Present immediately adjacent to lesion
  - Increased in surrounding tissue
- Not performed

### 24p. Calcifications on ultrasound
- None
- Present (check all that apply)
  - Macrocalcifications (> 0.5 mm)
  - Microcalcifications in mass
  - Microcalcifications outside mass

### 24q. Was lesion palpable in retrospect during sonography?
- No
- Yes, in retrospect
- Yes, participant presented with lump

### 25. Is this lesion at the site of prior biopsy?
- No (proceed to Q26)
- 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.**

### 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
  - (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

#### 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: [ ] (e.g. GR1, GL1, GL2, etc.) (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]
   - No but now visible in retrospect
     - New lesion # [M]

28d. Was lesion enumerated on any prior study ultrasound?
   - No
   - Simple cyst
   - Not a simple cyst
     - Yes (complete)

28e. Location on Mammography: (check all that apply)
   - Right breast
   - Left breast
   - Bilateral, multiple
   - Axillary tail
   - Retroareolar
   - Upper
   - Lower
   - Inner
   - Outer
   - Central

28f. Distance from nipple [ ] cm by Mammography

28g. Size of lesion by Mammography:
   - [ ] mm (largest diameter)
   - [ ] mm (largest perpendicular dimension)
   - [ ] mm (other size)

29. Sonographic Lesion Description

29a. Was ultrasound performed of this lesion on this follow-up evaluation?
   - 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. Change in this lesion from prior ultrasound?
   - New
   - Gone (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)
     - Decreasing
     - Stable
     - Fluctuating bilateral circumscribed masses
     - Increasing
     - Other suspicious change(s)
     - Increasing and other suspicious change(s)

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
     - Not a simple cyst and now 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)

29d. 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.)
29e. Check if this "lesion" is multiple bilateral circumscribed masses. Describe largest mass in Q29e and Q29f then proceed to Q29g.

Breast Clockface

(report on 1/2 hour)

Distance from
depth

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

O R O L

O’clock

cm

29f. Lesion Size

Largest

Horizontal

Meas (mm) D1

Trv

Sag

Rad

Oblique

Second

Horizontal

Meas (mm) D3

Trv

Sag

Rad

Oblique

Volume

D1XD2XD3  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.

29g. Special Case (see choices below)

O No

O Yes (detail below then proceed to Q29p)

O 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 29j).

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

29h. Shape

O Oval

O Two or three gentle lobulations

O Round

O Irregular

29i. Orientation

O Parallel to skin

O Not parallel (includes round)

29j. Margin

O Circumscribed

O Not circumscribed (If not circumscribed, choose dominant feature)

O Indistinct

O Angular

O Microlobulated

O Spiculated

29k. Boundary Zone

O Abrupt Interface

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

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

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

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

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

29q. 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

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
- 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

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: [ ] (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?
   o No (specify reason and proceed to Q34)
   o Not recommended
   o Participant refused
   o Not needed after targeted US
   o Scheduling constraints; participant rescheduled
   o Other
   o Yes

33b. Change in this lesion from prior mammogram(s)?
   o New
   o Gone (complete then proceed to Q34)

   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)

33c. 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]
   o Yes
   Lesion # from prior mammogram: [M]
   (e.g., MR1, MB1, ML1, MR2, etc.)

33d. 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.)

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.

   o Right breast
   o Left breast
   o Bilateral, multiple
   o Axillary tail
   o 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)
   o Circumscribed
   o Fat-containing
   o Not fat-containing
   o Microlobulated
   o Obliterated
   o Indistinct
   o Spiculated

   □ 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

34. Sonographic Lesion Description

34a. Was ultrasound performed of this lesion on this follow-up evaluation?
   o No (specify reason and proceed to Q35)
   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

34b. Change in this lesion from prior ultrasound?
   o New
   o Gone (complete then proceed to Q35)

   Lesion # from prior ultrasound: [U]
   (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)

34c. Was lesion enumerated on any prior study ultrasound?
   o No (complete)
   o Simple cyst (proceed to Q35)
   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 #: [U]
   o Yes (complete)
   Lesion # from prior ultrasound: [U]
   (e.g., UR1, UB1, UL1, UR2, etc.)

34d. 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.)
34e. □ Check if this "lesion" is multiple bilateral circumscribed masses. Describe largest mass in Q34e and Q34f then proceed to Q34g.

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

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>
<th>Volume D1XD2XD3 ÷ 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>O Trv</td>
<td>O Sag</td>
<td>X</td>
<td>X</td>
<td>O Trv</td>
<td></td>
</tr>
<tr>
<td>O Sag</td>
<td>O Rad</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>
</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
34. Echo Pattern
- Anechoic
- Hyperechoic
- Complex cystic
- Hypoechoic with few tiny cystic areas
- Isoechoic to fat
- Mixed hyperechoic and hypoechoic
- Hypoechoic to fat

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

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

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

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

34q. 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

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. Known benign by prior biopsy?
- No (proceed to Q36d)
- Yes (complete)
  - < 1 year ago
  - 1-2 years ago
  - > 2 years ago

36d. 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

36e. 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 Q38)
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.)
(if not applicable code 998)

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
     - Lease # from prior mammogram: [ ]
     (if not applicable code 998)
   - Gone (complete then proceed to Q39)
     - Lease # from prior ultrasound: [ ]
     (if not applicable code 998)
   - Decreasing
   - Stable
   - Fluctuating bilateral circumscribed masses
   - Increasing
   - Other suspicious change(s)
   - Increasing and other suspicious change(s)

38c. 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 #)
   - Yes
     - Lease # from prior mammogram: [ ]
     (e.g. MR1, MB1, ML1, MR2, etc.)

38d. Was lesion enumerated on any prior study ultrasound?
   - No
     - Simple cyst
   - Yes (complete)
     - Lease # from ultrasound: [ ]
     (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.

   - 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
   (largest diameter) (largest perpendicular dimension)

38h. Lesion Description Mammography

   - 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

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)
     - Targeted only
     - Whole breast

39b. Change in this lesion from prior ultrasound?
   - New
   - Gone (complete then proceed to Q40)
     - Lease # from prior mammogram: [ ]
     (if not applicable code 998)
   - Decreasing
   - Stable
   - Fluctuating bilateral circumscribed masses
   - Increasing
   - Other suspicious change(s)
   - Increasing and other suspicious change(s)

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
     (assign next sequential sonogram lesion #)
   - Not a simple cyst and now visible in retrospect
     (assign next sequential sonogram lesion #)
   - Yes (complete)
     - Lease # from prior ultrasound: [ ]
     (e.g. UR1, UB1, UL1, UR2, etc.)

39d. Was lesion enumerated on any study mammogram (including views obtained today)?
   - No
   - Yes (complete)
     - Lease # from mammogram: [ ]
     (e.g. MR1, MB1, ML1, MR2, etc.)
39e. □ Check if this "lesion" is multiple bilateral circumscribed masses. Describe largest mass in Q39e and Q39f then proceed to Q39g.

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

Clockface
O R O L

Distance from
the nipple

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

O cm

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>
<th>Volume D1XD2XD3 ÷ 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trv</td>
<td>Sag</td>
<td>Rad</td>
<td>Oblique</td>
<td></td>
<td>mm³</td>
</tr>
<tr>
<td>mm</td>
<td>mm</td>
<td>mm</td>
<td>mm</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

39g. Special Case (see choices below)

O No
O Yes (detail below then proceed to Q39p)

O 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 39l).

☐ 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 _______________________

39h. Shape

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

39i. Orientation

O Parallel to skin
O Not parallel (includes round)

39j. Margin

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

39k. 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.

#### 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
  - **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?
   - Yes
   - No (specify reason and proceed to Q44)
   - Not recommended
   - Participant refused
   - Not needed after targeted US
   - Scheduling constraints; participant rescheduled
   - Other

43b. Change in this lesion from prior mammogram(s)?
   - New
   - Gone (complete then proceed to Q44)
   - Decreasing
   - Stable
   - Fluctuating bilateral circumscribed masses
   - Increasing
   - Other suspicious change(s)
   - Increasing and other suspicious change(s)

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

43d. Was lesion enumerated on any prior study ultrasound?
   - Yes
   - No
   - Simple cyst
   - Not a simple cyst
   - Other suspicious change(s)

43e. Location on Mammography: (check all that apply)
   - Right breast
   - Left breast
   - Bilateral, multiple
   - Axillary tail
   - Retroareolar
   - Central
   - Upper
   - Lower
   - Inner
   - Outer

43f. Distance from nipple [_____] cm by Mammography

43g. Size of lesion by Mammography:
   [_____] mm x [_____] mm
   (largest diameter) (largest perpendicular dimension)

44. Sonographic Lesion Description

44a. Was ultrasound performed of this lesion on this follow-up evaluation?
   - Yes (check all that apply)
   - Targeted only
   - Whole breast

44b. Change in this lesion from prior ultrasound?
   - New
   - Gone (complete then proceed to Q45)
   - Decreasing
   - Stable
   - Fluctuating bilateral circumscribed masses
   - Increasing
   - Other suspicious change(s)
   - Increasing and other suspicious change(s)

44c. Was lesion enumerated on any prior study ultrasound?
   - Yes (complete)
   - 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 #)

44d. Was lesion enumerated on any study mammogram (including views obtained today)?
   - Yes (complete)
   - No

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44e. □ Check if this “lesion” is multiple bilateral circumscribed masses. Describe largest mass in Q44e and Q44f then proceed to Q44g.

<table>
<thead>
<tr>
<th>Clockface</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>Breast (report on 1/2 hour) i.e. 7:00 = 0700, 12:30 = 1230)</td>
<td>o R o L</td>
<td>cm</td>
</tr>
</tbody>
</table>

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>Volume D1XD2XD3 ÷ 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meas</td>
<td>Trv</td>
<td>Sag</td>
<td>Rad</td>
<td>Oblique</td>
<td>X</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).
  - 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 ____________________________

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)
  - o Indistinct
  - o Angular
  - o Microlobulated
  - o Spiculated

44k. Boundary Zone

- o Abrupt Interface
- o Echogenic Halo
44l. 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  
  - Intervention  
    - Aspiration with core biopsy if solid  
    - US-guided core biopsy  
    - Vacuum-assisted biopsy, guidance by US  
    - Vacuum-assisted biopsy, guidance by mammog  
    - 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.)
   (If not applicable code 998)

48. Mammographic Lesion Description

48a. Were mammographic views obtained of this finding on this follow-up evaluation?
   o No (specify reason and proceed to Q49)
   o Not recommended
   o Participant refused
   o Not needed after targeted US
   o Scheduling constraints; participant rescheduled
   o Other
   o Yes

48b. Change in this lesion from prior mammogram(s)?
   o New
   o Gone (complete then proceed to Q49)
   Lesion # from prior mammogram: ________
   (If not applicable code 998)
   Lesion # from prior ultrasound: ________
   (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)

48c. 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 #: ________
   (e.g., MR1, MB1, ML1, MR2, etc.)
   o Yes
   Lesion # from prior mammogram: ________

48d. Was lesion enumerated on any prior study ultrasound?
   o No
   o Simple cyst
   o Not a simple cyst
   o Yes (complete)
   Lesion # from ultrasound: ________
   (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.
   o Right breast
   o Left breast
   o Bilateral, multiple
   o Axillary tail
   o 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?
   o No (specify reason and proceed to Q50)
   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

49b. Change in this lesion from prior ultrasound?
   o New
   o Gone (complete then proceed to Q50)
   Lesion # from prior mammogram: ________
   (If not applicable code 998)
   Lesion # from prior ultrasound: ________
   (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)

49c. Was lesion enumerated on any prior study ultrasound?
   o No (complete)
   o Simple cyst (proceed to Q50)
   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 #: ________
   (e.g., UR1, UB1, UL1, UR2, etc.)
   o Yes (complete)
   Lesion # from prior ultrasound: ________

49d. Was lesion enumerated on any study mammogram (including views obtained today)?
   o No
   o Yes (complete)
   Lesion # from mammogram: ________
   (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.

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

Clockface

Distance from
the nipple

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

O R O L

0' clock

0.0 cm

0.0 cm

49f. Lesion Size

Largest
Horizontal Meas (mm) D1

--- mm

Measured Plane

Trv

Sag

Rad

Arad

Oblique

Vertical A-P meas (mm) D2

--- mm

--- mm

Horizontal Perpendicular Meas (mm) D3

--- mm

--- mm

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.

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?
   o No; If no, specify reason from code table (STOP and sign form)
   o Yes (continue)

2. Date of Procedure _______—_______—_______ (mm-dd-yyyy)
   2a. Time point in study prompting this biopsy
       o Initial screening
       o 6 month follow-up
       o 12 month screening
       o 18 month follow-up
       o 24 month screening
       o 30 month follow-up
       o 36 month follow-up
       o 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?
       o No (proceed to Q6)
       o Yes (complete Q5b)
       o Pending (proceed to Q6)
   5b. Did central review change management?
       o No (proceed to Q6) Local result Central result (reference code table)
       o Yes (complete) Upgrade from to Downgrade from to

6a. Guidance method:
   o US
   o Stereotactic prone
   o Stereotactic upright
   o Mammographic
   o MRI
   o No image guidance (e.g. palpable or duct excision)
   o 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
   - Clockface or specify Location
     (report on hour and 1/2 hour, e.g. 7:00 = 0700, 12:30 = 1230)
     o axilla
     o retroareolar
     o central
   - Distance from Nipple cm
   - Size (largest dimension) mm

8. Lesion type (check all that apply)
   - Mass
   - Asymmetry
   - Calcifications
   - Architectural distortion

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)
       - Within 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 ____________________________

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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 ________________________________
ACRIN 6666 Diagnostic Needle Localization Surgical Biopsy Form

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 ___________ to Central result ___________ (reference code table)
     - Downgrade from Local result ___________ to Central result ___________

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
   Clockface or specify Location OR
   (report on hour and 1/2 hour e.g. 7:00 = 0700, 12:30 = 1230)
   - o R o L [__________ o’ clock]
   - o axilla
   - o retroareolar
   - o central

   Distance from Nipple ______ cm

   Size (largest dimension) ______ mm

*Copyright 2007*
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 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: __________________________

III. HISTOPATHOLOGY

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.

12. Benign
    - No (proceed to Q13)
    - Yes (If 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 __________________________

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 ductal extension
      - Lobular carcinoma in situ
        - Check if ductal extension
      - Atypical papilloma
      - Columnar alteration with atypia
      - Other __________________________
### ACRIN Study 6666

**PLACEMENT LABEL HERE**

<table>
<thead>
<tr>
<th>Institution No.</th>
<th>Institution No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participant Initials</td>
<td>Case No.</td>
</tr>
</tbody>
</table>

#### 16. Microcalcifications
- Not present
- Not detailed
- In cancer
- In benign areas only
- In benign and malignant areas

#### IV. MANAGEMENT

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
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

3c. Axillary dissection
   - Not done (proceed to Q4)
   - Performed (complete)

   Number of nodes retrieved [ ]
   Number malignant [ ]
   - Check if extracapsular invasion
4. Pathology Specimen ID# __________________________

4a. Were slides sent for central review and results obtained?
   o No (proceed to Q5)
   o Yes (complete Q4b)
   o Pending (proceed to Q5)

4b. Did central review change management?
   o No (proceed to Q5)
   o Yes (complete)
     o Upgrade from _____ to _____
     o Downgrade from _____ to _____

Code Table for Q4b (upgrade/downgrade)
1. Benign (other than below)
2. Papilloma
3. Possible phyllodes
4. Radial scar/complex sclerosing lesion
5. ADH
6. ALH or LCIS
7. Atypical papillary lesion
8. DCIS
9. Invasive Cancer

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 Distance from Nipple Size (largest dimension) Lesion number
(report on hour and 1/2 hour e.g. 7:00 = 0700, 12:30 = 1230)

o R o L o’ clock  OR  o axilla o retroareolar o central cm mm

Provide pathology at this surgery for the lesion described above
   o Cancer
   o Atypical/high-risk
   o Benign
   o Unsure of correlation with final surgical specimen

5b. Was there another previously enumerated lesion removed from this breast during this surgery?
   o No (proceed to Q6)
   o Yes (proceed to Q13)

6. Final Margin Status (check all that apply)
   □ Margins clear
     o 10 mm or more
     o 4-9 mm
     o 1-3 mm
     o < 1 mm
     o 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)?
   o No
   o Yes (please complete another S1 when performed)
   o Unknown
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 there lymphovascular invasion?
- 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

What is the PR status?
- Positive
- Negative
- Not assessed
- Unknown

What is the Her-2/neu (c-erb2) status?
- Negative
- 1+
- 2+
- 3+
- Not assessed
- 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?
  (Note: A cancer found only on second look mammography or US after MRI would be classified as not identified on mammography or US.)
- No (detail)
  - Number of additional malignant foci: [ ] [ ] (code 999 if unknown)
  - 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 T1 mic Microinvasive tumor, \( \leq 0.1 \text{ cm in greatest diameter} \)
     o T1a Invasive tumor, \( 0.1 < x \leq 0.5 \text{ cm in greatest diameter} \)
     o T1b Invasive tumor, \( 0.5 < x \leq 1.0 \text{ cm in greatest diameter} \)
     o T1c Invasive tumor, \( 1.0 < x \leq 2.0 \text{ cm in greatest diameter} \)
   o T2 Invasive tumor, \( 2.0 < x \leq 5.0 \text{ cm in greatest diameter} \)
   o T3 Invasive tumor, \( > 5 \text{ cm in greatest diameter} \)
   o T4 Tumor of any size with:
     o Direct extension to chest wall, T4a
     o Direct extension to skin with edema (including peau d’ orange) or ulceration of skin of the breast or satellite skin nodules confined to the same breast, T4b
     o Both skin and chest wall extension, T4c
     o Dermal lymphatics involved, inflammatory cancer, T4d

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)\(^3\)
     o pN0(i-) No regional lymph node metastasis histologically, negative IHC
   o N1 Metastasis in moveable ipsilateral lymph node(s)
     o pN1mi 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\(^5\)
     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\(^6\)
   o N2 Metastases in ipsilateral axillary lymph nodes fixed or matted, or in clinically apparent\(^6\) ipsilateral internal mammary 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 N2b Metastasis only in clinically apparent\(^5\) ipsilateral internal mammary nodes and in the absence of clinically evident axillary lymph node metastasis
     o pN2 Metastasis in 4-9 axillary lymph nodes, or in clinically apparent\(^5\) 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\(^5\) 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\(^5\) 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\(^5\) 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 supraclavicular lymph nodes
     o pN3b Metastasis in clinically apparent\(^5\) 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\(^5\)
     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
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 (report on hour and 1/2 hour e.g. 7:00 = 0700, 12:30 = 1230)</th>
<th>OR</th>
<th>Distance from Nipple</th>
<th>Size (largest dimension)</th>
<th>Lesion number (e.g. MR1, UL2, GR1, etc)</th>
</tr>
</thead>
<tbody>
<tr>
<td>o R o L</td>
<td>o clock</td>
<td></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 (report on hour and 1/2 hour e.g. 7:00 = 0700, 12:30 = 1230)</th>
<th>OR</th>
<th>Distance from Nipple</th>
<th>Size (largest dimension)</th>
<th>Lesion number (e.g. MR1, UL2, GR1, etc)</th>
</tr>
</thead>
<tbody>
<tr>
<td>o R o L</td>
<td>o clock</td>
<td></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 (report on hour and 1/2 hour e.g. 7:00 = 0700, 12:30 = 1230)</th>
<th>OR</th>
<th>Distance from Nipple</th>
<th>Size (largest dimension)</th>
<th>Lesion number (e.g. MR1, UL2, GR1, etc)</th>
</tr>
</thead>
<tbody>
<tr>
<td>o R o L</td>
<td>o clock</td>
<td></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
   o Right Breast
   o Left Breast

1b. Is this form M3 a continuation of another M3 for this breast?
   o No, proceed to Q2
   o Yes, proceed to Q5

2. Was an MRI done?
   o No; If no, specify reason from code table
     (stop and sign form)
   o 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?
   o No
   o 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
   o None/minimal
   o Moderate, patchy
   o Moderate, uniform
   o Marked

3e. Significant artifacts for this breast?
   o No (proceed to Q4)
   o 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
   o Purely cystic/fluid
   o Moderately hyperintense (at least partially solid)
   o Slightly hyperintense
   o Hypointense or not seen

6b. Finding type (study breast)
   o Focus/foci < 5 mm (proceed to Q6c)
   o Mass (answer Q7 then skip to Q9)
   o Non mass enhancement (skip to Q8)
   o Scar (skip to Q10)

6c. If focus/foci (detail then proceed to Q10)
   o Solitary
   If Solitary, largest diameter in mm
   o 2-3
   o ≥ 4

7. Mass size encompassed by Gd enhancement
   (record three dimensions)
   med-lat x mm sup-inf y mm ant-post z mm

7a. Mass Shape
   o Round
   o Oval
   o Lobulated
   o Irregular

7b. Mass Margin
   o Smooth
   o Irregular
   o Spiculated

7c. Mass Internal Enhancement
   o Homogeneous
   o Heterogeneous
   o Rim enhancement
   o Dark internal septation(s)
   o Enhanced internal septation(s)
   o Central internal enhancement

7d. Fat containing
   o No
   o Yes

7e. Mass Degree of Enhancement
   o Minimal
   o Moderate
   o Marked

   ** proceed to question 9 **

6666 M3 06-08-06 1 of 3
8. Type of non-mass enhancement
   o Focal area
   o Linear
   o Ductal
   o Segmental
   o Regional
   o Multiple regions
   o Diffuse

8a. Largest diameter ______ mm

8b. Non-Mass enhancement symmetry
   o Not applicable
   o Symmetric
   o Asymmetric

8c. Non-Mass enhancement internal characteristics
   o Homogeneous
   o Heterogeneous
   o Stippled/punctate
   o Clumped
   o Reticular/dendritic

III. ASSOCIATED FINDINGS

9. Associated findings (finding noted in Q5)
   o No (skip to Q10)
   o 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
    o Nipple
    o Central Region
    o UIQ
    o LIQ
    o UOQ
    o LOQ
    o Axillary Tail
    o Breast, NOS
    o Subareolar
    o Multiple scattered areas
    o Other, Specify __________________________

10a. Maximum distance of Finding From the Nipple
     ______ mm

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

V. KINETIC CURVE ASSESSMENT

11. CAD used for this lesion
    o No
    o Yes, for kinetics only
    o Lesion only detected after CAD

11a. Initial enhancement phase
    o Not applicable
    o Slow
    o Medium
    o Rapid

11b. Delayed enhancement phase
    (after 2 minutes or after curve begins to change)
    o Not applicable
    o Persistent
    o Plateau
    o 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 completed: _____-____-____ (mm-dd-yyyy)

Signature of person responsible for the data  

Signature of person entering data onto the web  

6666   M3  06-08-06   3 of 3
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. __________ 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 __________ mm __________ 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 ____________________________

10a. Maximum distance of Finding From the Nipple
     __________ mm

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

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
   o 1 Negative, no abnormal enhancement
   o 2 Benign
   o 3 Probably Benign finding
   o 4A Low Suspicion of Malignancy
   o 4B Intermediate Suspicion of Malignancy
   o 4C Moderately High Suspicion of Malignancy
   o 5 Highly Suggestive of Malignancy

12a. Recommendation for this lesion
   o Routine follow-up
   o Short-interval follow-up with MRI in _____ months
   o Biopsy (detail)
     o US-guided biopsy; if US negative, MRI-guided biopsy
     o MRI guided biopsy directly
     o Other, specify; ____________________________
   o Additional Imaging
     □ Additional mammographic views
     □ Ultrasound targeted to finding
       o If US negative, routine follow-up
       o If US negative, short-interval follow-up with MRI in _____ months
     □ Repeat MRI due to
       o Technical problem or motion (detail in comments)
       o Incomplete
       o Abnormalities likely due to phase in cycle
       o Other, specify; ____________________________

13. Likelihood of malignancy for this finding, 0-100%

COMMENTS:_____________________________________________________
______________________________________________________________
______________________________________________________________

Signature of person responsible for the data ¹

Date form completed² _____-____-____ (mm-dd-yyyy)

Signature of person entering data onto the web ²
Instructions: After completing an M3 form for each breast (or M4 if this is a short interval follow-up MRI), please review current mammogram, US and MRI together.

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**

   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

6d. **Recommendation for right breast**

   Follow-up
   o Routine screening in 1 year
   o Diagnostic follow-up in 1 year
   o Short-interval follow-up in 6 months with US
   o Short-interval follow-up in 6 months with mammography
   o Short-interval follow-up MRI in 6 months
   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 mammography
     o Excisional biopsy
     o MRI-guided vacuum assisted biopsy if not US biopsy
     [ ] Additional Imaging (check all that apply)
     [ ] Additional evaluation
     o Comparison to prior mammogram is required
     o Targeted ultrasound (lesion seen on mammography)
     o Ultrasound targeted to MRI abnormality
     o Additional mammographic projections
     [ ] Repeat ultrasound
     o Technique/interpretation in question
     o Possibly abnormal
     [ ] Repeat mammogram
     o Incomplete
     o Motion artifact/other technical problem
     [ ] Repeat MRI
     o Motion artifact or other technical problem
     o Incomplete
     o 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**

   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

7d. **Recommendation for left breast**

   Follow-up
   o Routine screening in 1 year
   o Diagnostic follow-up in 1 year
   o Short-interval follow-up in 6 months with US
   o Short-interval follow-up in 6 months with mammography
   o Short-interval follow-up MRI in 6 months
   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 mammography
     o Excisional biopsy
     o MRI-guided vacuum assisted biopsy if not US biopsy
     [ ] Additional Imaging (check all that apply)
     [ ] Additional evaluation
     o Comparison to prior mammogram is required
     o Targeted ultrasound (lesion seen on mammography)
     o Ultrasound targeted to MRI abnormality
     o Additional mammographic projections
     [ ] Repeat ultrasound
     o Technique/interpretation in question
     o Possibly abnormal
     [ ] Repeat mammogram
     o Incomplete
     o Motion artifact/other technical problem
     [ ] Repeat MRI
     o Motion artifact or other technical problem
     o Incomplete
     o Abnormalities likely due to phase in cycle

**COMMENTS:**

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

Signature of person responsible for the data

________________________________________________________________________

Signature of person entering data onto the web

"Copyright 2007"
1. Time point of this follow-up
   o 12 months
   o 24 months
   o 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
   o At appointment
   o By telephone
   o Other, specify __________________________

4. Participant Status
   o Alive (proceed to Q5)
   o Dead (complete Q4a)
   o 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?
   o No (provide reason in Q5a)
   o Yes (complete then proceed to Q5b and Q5c)
     o Right (complete Qs 5b and 5c)
     o Left (complete Qs 5b and 5d)
     o Both (complete Qs 5b-5d)
     o Unknown (proceed to Q6)

5a. Provide reason CBE not done (then proceed to Q6):
   o Patient missed appointment
   o Patient unable to be located
   o Patient pregnant or lactating
   o Patient refused
   o Referring physician's choice
   o Expired
   o Other, specify __________________________

5b. Date of follow-up CBE ____________ mm dd yyyy

5c. Have there been any clinically significant changes in the right breast since the last annual examination?
   o No or breast not on study
   o Yes (check all clinical changes that apply)
     o Palpable mass (complete location)
       Location of abnormality ______ o'clock or specify location:
         o Axilla
         o Retroareolar
         o Unknown
     o Nipple discharge (detail):
       o Bloody
       o Clear spontaneous
       o Other
     o Other, specify: __________________________

5d. Have there been any clinically significant changes in the left breast since the last annual examination?
   o No or breast not on study
   o Yes (check all clinical changes that apply)
     o Palpable mass (complete location)
       Location of abnormality ______ o'clock or specify location:
         o Axilla
         o Retroareolar
         o Unknown
     o Nipple discharge (detail):
       o Bloody
       o Clear spontaneous
       o Other
     o Other, specify: __________________________

6. Current use of hormones?
   o No (proceed to Q7)
   o 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.)
   o No (proceed to Section III)
   o Yes (complete Q7a)

7a. Check all breast imaging performed since last visit:
   o Mammogram (complete Q8)
   o Ultrasound (complete Q11)
   o MRI (complete Q14)
   o Other (complete Q17)
   o 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 ___-______-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 ___-______-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
- Other 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, BIRADS 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, BIRADS 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
- Other 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, BIRADS 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, BIRADS 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?

   o No (Proceed to Q21)
   o Yes, not previously reported (Complete Q20a)
   o Yes, previously reported (Proceed to Q21)
   o 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.

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<tr>
<th>Intervention Code Table (Q20a)</th>
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<tbody>
<tr>
<td>1  Cyst Aspiration</td>
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<tr>
<td>2  FNAB (complete BX)</td>
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<tr>
<td>3  Core Needle Biopsy (complete BX)</td>
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<td>4  Excisional Biopsy (complete NL)</td>
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<td>5  Lumpectomy (complete S1)</td>
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<td>6  Sentinel Lymph Node (complete S1)</td>
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<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>
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<tr>
<td>99  Specimens Unknown</td>
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<tr>
<th>Intervention</th>
<th>Date (mm-yyyy)</th>
<th>Details</th>
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<th>L</th>
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Section IV. Summary/Treatment

21. Was a breast cancer diagnosed in the past 11 months?

   o No (Complete Q21a)
   o Yes, not already reported (Proceed to Q21b and complete BX and S1 forms)
   o Yes, already reported on BX and/or, NL and S1 (Proceed to Q22)
   o Unknown (Proceed to Q22)

21a. Most reliable source regarding Negative breast cancer status for this participant. (Complete then proceed to Q22)

   o Participant herself says she has not been diagnosed with breast cancer
   o No findings reported in participant's medical chart
   o Participant's Primary Care Physician (PCP) (no abnormality found at last clinical exam)
   o Report of clinical exam
   o Other Physician (no abnormality found at last clinical exam)
   o Relative or friend stated that participant has not been diagnosed with breast cancer
   o Participant is not listed on the cancer registry for the area in which she lives
   o Hospital billing department reports no charges for breast cancer treatment
   o Other, specify ________

21b. Most reliable source regarding Positive breast cancer status for this participant.

   o Pathology report
   o Cancer diagnosis is reported in participant's medical chart
   o Participant's Primary Care Physician (PCP) reports breast cancer
   o Participant herself says she has been diagnosed with breast cancer
   o Death certificate in municipality of last known address that lists cause of death as breast cancer
   o Relative or friend states that participant has been diagnosed with breast cancer
   o Participant is listed on the cancer registry for the area in which she lives
   o Hospital billing department reports charges for breast cancer treatment
   o Other, specify ____________________

21c. Site of breast cancer

   o Right
   o Left
   o 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>
<td></td>
<td></td>
<td></td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
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<tr>
<td></td>
<td></td>
<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  

Date Form Completed (mm-dd-yyyy)

Signature of person entering data onto web  

# 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: [ ] (e.g. UR3, ML2, GR1, etc.)

4. Will any biopsies be performed on any study breast(s) at this time?
   - O No, detail reason: [ ] (STOP and sign form)
   - O Yes, detail which breast (check all that apply):
     - O Right (please complete a BX form for each biopsy)
     - O Left (please complete a BX form for each biopsy)
   - O Unknown (STOP and sign form)

Comments:

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
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________________________________________________________________________

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 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>1</td>
<td></td>
<td>1 = Mild</td>
<td>1 = Unrelated</td>
<td>1 = No</td>
<td>1 = None</td>
<td>1 = Recovered</td>
<td>(mm-dd-yyyy); check box &quot;on-going&quot; if the AE is on-going at the time of report</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>2 = Moderate</td>
<td>2 = Unlikely</td>
<td>2 = Yes</td>
<td>2 = Medication Therapy</td>
<td>2 = Improved</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
<td>3 = Severe</td>
<td>3 = Possible</td>
<td>3 = Procedure</td>
<td>3 = Ongoing</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>4 = Life</td>
<td>4 = Probable</td>
<td>4 = Hospitalization</td>
<td>4 = Death</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>threatening or disabling</td>
<td>5 = Definite</td>
<td>5 = Other</td>
<td>5 = Death</td>
<td></td>
<td></td>
</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*
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:  
     • Is now lesion # ____________ at time point: 
       - 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.
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

____________________________________________________________________________

____________________________________________________________________________

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Person responsible for data

____________________________________________________________________________

____________________________________________________________________________

Date form completed _____ - _____ - _______ (mm-dd-yyyy)

HQ Use Only

____________________________________________________________________________

____________________________________________________________________________

HQ Research Associate

Date form completed _____ - _____ - _______ (mm-dd-yyyy)
**Clinical Image Quality Form**

**ACRIN Study 6666**

**Case # ____________**

**Site # ____________**

**INSTRUCTIONS:** Upon completion of this form please fax to ACRIN at 215-717-0936. This form is to be completed by the study reference physicist and radiologist, within 30 days of receipt of images. If this is a revised or corrected form, indicate by checking box.

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
       ○ 1 No
       ○ 2 Yes

   4b. 2nd review date ______-____-____
       Acceptable
       ○ 1 No
       ○ 2 Yes

5. US SYSTEM UNDER REVIEW:
   ○ Philips/ATL Model ____________________________
   ○ Siemens/Acuson Model _________________________
   ○ GE Model ____________________________
   ○ Toshiba Model ____________________________
   ○ Other specify ____________________________

**IMAGE QUALITY**

6. DOES IMAGING MEET PROTOCOL SPECIFICATIONS?
   ○ 1 No, Detail ____________________________
   ○ 2 Yes

7. ARE THERE FINDINGS ON THIS STUDY?
   ○ 1 No (proceed to Q8)
   ○ 2 Yes

   7a. Simple cyst only:
       ○ 1 No
       ○ 2 Yes

   7b. Are lesions other than cyst(s) or scar(s) present?
       ○ 1 No
       ○ 2 Yes

   7c. Are lesion(s) imaged with spatial compounding
       ○ 1 No
       ○ 2 Yes

   7d. Are lesion(s) imaged without spatial compounding
       ○ 1 No
       ○ 2 Yes

   7e. Are lesion(s) imaged with power Doppler?
       ○ 1 No
       ○ 2 Yes

8. ARE IMAGES PROPERLY LABELED?
   ○ 1 No, Detail ____________________________
   ○ 2 Yes
   ○ 3 Yes except survey images only indicate quadrant

9. ARE IMAGES PRESENT FROM EACH QUADRANT?
   Right Breast
   ○ 1 No
   ○ 2 Yes
   ○ 3 Not on study

   Left Breast
   ○ 1 No
   ○ 2 Yes
   ○ 3 Not on study

10. OVERALL US IMAGE QUALITY
    ○ Unacceptable (proceed to Q10a)
    ○ Minor deficiences, but acceptable (proceed to Q10a)
    ○ Acceptable (proceed to Q11)
    ○ 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

ACTIONS
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 _____-____-____
# ACRIN 6666 Image Transmittal Form

**Instructions:** This form to be completed by ACRIN HQ imaging associate as needed.

1. **Site number** [1]
2. **Case number** [2]
3. **Breast**
   - Right [3]
   - Left [4]
4. **Image available** [5]
   - No, if no provide reason not available [6] STOP and sign form
   - Yes
5. **Type of images**
   - Additional mammographic views [7] Date: _____-____-____ mm-dd-yyyy [8]
   - Ultrasound [9] Date: _____-____-____ mm-dd-yyyy [10]
   - Images from biopsy (detail in Q6) [13] Date: _____-____-____ mm-dd-yyyy [14]
6. **Images from biopsy guidance**
   - US guided [15]
     - FNAB [16] Date: _____-____-____ mm-dd-yyyy [17]
     - Core biopsy [18] Date: _____-____-____ mm-dd-yyyy [19]
     - Needle localization [20] Date: _____-____-____ mm-dd-yyyy [21]
   - Stereotactically guided [22]
     - Core biopsy [23] Date: _____-____-____ mm-dd-yyyy [24]
     - Needle localization [25] Date: _____-____-____ mm-dd-yyyy [26]
   - MRI-guided [27]
     - Core biopsy [28] Date: _____-____-____ mm-dd-yyyy [29]
     - Needle localization [30] Date: _____-____-____ mm-dd-yyyy [31]
   - Mammographically-guided needle localization [32] Date: _____-____-____ mm-dd-yyyy [33]
   - Other, [34] specify _______________________________ [35] Date: _____-____-____ mm-dd-yyyy [36]

Initials of imaging Associate completing form [37] Date form completed (mm-dd-yyyy) [38]

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ACRIN 6666
Image Transmittal Form

Instructions: This form to be completed by ACRIN HQ imaging associate as needed.

1. Site number [ ]

2. Case number [ ]

3. Breast
   - Right [ ]
   - Left [ ]

4. Image available [ ]
   - No, if no provide reason not available
   - Yes

5. Type of images
   - Additional mammographic views [ ] Date: _____-____-_____ mm-dd-yyyy
   - Ultrasound [ ] Date: _____-____-_____ mm-dd-yyyy
   - MRI [ ] Date: _____-____-_____ mm-dd-yyyy
   - Images from biopsy (detail in Q6) [ ] Date: _____-____-_____ mm-dd-yyyy

6. Images from biopsy guidance
   - US guided [ ]
     - FNAB [ ] Date: _____-____-_____ mm-dd-yyyy
     - Core biopsy [ ] Date: _____-____-_____ mm-dd-yyyy
     - Needle localization [ ] Date: _____-____-_____ mm-dd-yyyy
   - Stereotactically guided [ ]
     - Core biopsy [ ] Date: _____-____-_____ mm-dd-yyyy
     - Needle localization [ ] Date: _____-____-_____ mm-dd-yyyy
   - MRI-guided [ ]
     - Core biopsy [ ] Date: _____-____-_____ mm-dd-yyyy
     - Needle localization [ ] Date: _____-____-_____ mm-dd-yyyy
   - Mammographically-guided needle localization [ ] Date: _____-____-_____ mm-dd-yyyy
   - Other, specify [ ] Date: _____-____-_____ mm-dd-yyyy

 initials of imaging Associate completing form [ ]

date form completed (mm-dd-yyyy) [ ]

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