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ISb Annual Survey Ultrasound Interpretation Form.....	01-19-06	
ISb Annual Survey Ultrasound Interpretation Form Short Version pages 1-3.....	01-19-06	
IDb Integration Interpretation (Ultrasound and Mammogram) Form.....	09-07-04	
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F6b Short Interval Follow-up Mammogram/Targeted US Form.....	07-26-07	
BX Diagnostic Non Surgical Breast Biopsy and Pathology Form.....	06-19-07	
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**See next page for Cost Effectiveness Forms**



		<u>Version Date</u>	<u>*Submission Date</u>
<b>Cost Effectiveness</b>			
CC	Cost Effectiveness Coversheet.....	10-20-03	
Q1	Willingness to Pay Mammography.....	10-20-03	
Q2	Willingness to Pay Mammography.....	10-20-03	
Q3	Willingness to Pay Mammography.....	10-20-03	
Q4	Willingness to Pay Mammography.....	10-20-03	
Q5	Willingness to Pay Mammography.....	10-20-03	
TL	Waiting-Time Trade Off Ultrasound Test (Telephone).....	10-15-03	
TM	Waiting-Time Trade Off Mammography (Telephone).....	10-15-03	
TS	Willingness to Pay Ultrasound and Mammography.....	10-17-03	
T1	Waiting-Time Trade Off Diagnostic Mammography (Telephone).....	10-15-03	
T2	Waiting-Time Trade Off Diagnostic Ultrasound (Telephone).....	10-15-03	
T3	Waiting-Time Trade Off Ultrasound Guided Core Biopsy (Telephone).....	10-15-03	
T4	Waiting-Time Trade Off Stereotactic Core Biopsy (Telephone).....	10-15-03	
T5	Waiting-Time Trade Off Surgical Biopsy (Telephone).....	10-16-03	
V1	Willingness to Pay Ultrasound.....	10-20-03	
V2	Willingness to Pay Ultrasound.....	10-20-03	
V3	Willingness to Pay Ultrasound.....	10-20-03	
V4	Willingness to Pay Ultrasound.....	10-20-03	
V5	Willingness to Pay Ultrasound.....	10-20-03	

<sup>1</sup>The "person responsible for the data" refers to the individual who has collated the data on this specific data form

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

<sup>3</sup>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

ACRIN Study 6666 Case #  
**PLACE LABEL HERE**

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant's Name \_\_\_\_\_ Participant's I.D. No. \_\_\_\_\_

**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  
mm dd yyyy (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  $\geq$  25 years old)  
mm dd yyyy
- \_\_\_\_\_ 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

# ACRIN 6666

## Registration

ACRIN Study 6666 Case #  
**PLACE LABEL HERE**

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant's Name \_\_\_\_\_ Participant's I.D. No. \_\_\_\_\_

\_\_\_\_\_ 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

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant's Name \_\_\_\_\_ Participant's I.D. No. \_\_\_\_\_

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



Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

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")

	Right Breast	Left Breast
Reduction	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (yyyy)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (yyyy)
Lift	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (yyyy)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (yyyy)
Implant placed	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (yyyy)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (yyyy)
Implant removed	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (yyyy)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (yyyy)

CONTINUED ON NEXT PAGE...

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_  
Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**11. Prior Diagnosis of Breast Cancer**

- No (proceed to Q12)
- Yes
  - Pathology report is available
  - Pathology report is not available
- Unknown (proceed to Q12)

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

Year	Breast	Pathology	Lymph nodes involved?
		(see code table Q11a)	
<input type="text"/>	<input type="radio"/> R <input type="radio"/> L	<input type="text"/>	<input type="radio"/> N <input type="radio"/> Y <input type="radio"/> Unknown
<input type="text"/>	<input type="radio"/> R <input type="radio"/> L	<input type="text"/>	<input type="radio"/> N <input type="radio"/> Y <input type="radio"/> Unknown
<input type="text"/>	<input type="radio"/> R <input type="radio"/> L	<input type="text"/>	<input type="radio"/> N <input type="radio"/> Y <input type="radio"/> Unknown
<input type="text"/>	<input type="radio"/> R <input type="radio"/> L	<input type="text"/>	<input type="radio"/> N <input type="radio"/> Y <input type="radio"/> Unknown

**Pathology Code Table (Q11a)**

- 1 Malignant, NOS
  - 2 Invasive ductal carcinoma\*
  - 3 DCIS
  - 4 Invasive ductal carcinoma and DCIS
  - 5 Invasive lobular carcinoma
  - 6 Invasive ductal and lobular carcinoma
  - 7 Lymphoma
  - 8 Metastatic from outside breast
  - 9 Other
  - 99 Unknown
- \* Invasive ductal carcinoma includes: medullary, colloid, mucinous, tubular
- NOTE:** LCIS (lobular carcinoma in situ) is not cancer, but a high-risk lesion to be listed in Q12.

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

Year	Breast	Treatment
<input type="text"/>	<input type="radio"/> R <input type="radio"/> L	<input type="text"/>
<input type="text"/>	<input type="radio"/> R <input type="radio"/> L	<input type="text"/>
<input type="text"/>	<input type="radio"/> R <input type="radio"/> L	<input type="text"/>
<input type="text"/>	<input type="radio"/> R <input type="radio"/> L	<input type="text"/>

**Treatment Code Table (Q11b)**

- 1 Lumpectomy and radiation
- 2 Lumpectomy alone (no radiation)
- 3 Mastectomy and radiation
- 4 Mastectomy alone

**11c. Was chemotherapy given?**

- No
- Yes (If yes, code time point)
  - Prior to surgery
  - After surgery
  - Both before and after surgery

**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

**12. Prior cyst excision and/or cyst aspiration**

Right breast	Left breast
<input type="radio"/> Not on study	<input type="radio"/> Not on study
<input type="radio"/> Never	<input type="radio"/> Never
<input type="radio"/> 1	<input type="radio"/> 1
<input type="radio"/> 2 or 3	<input type="radio"/> 2 or 3
<input type="radio"/> 4 or more	<input type="radio"/> 4 or more

**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")

Year	Breast	Biopsy result	Type of Biopsy
		(see code table A)	(see code table B)
<input type="text"/>	<input type="radio"/> R <input type="radio"/> L	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="radio"/> R <input type="radio"/> L	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="radio"/> R <input type="radio"/> L	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="radio"/> R <input type="radio"/> L	<input type="text"/>	<input type="text"/>

**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:****Code table for Relatives**

1 Mother	6 Maternal Aunt
2 Sister	7 Paternal Aunt
3 Daughter	8 Father
4 Maternal Grandmother	9 Other
5 Paternal Grandmother	

**Breast code table C (Q13b)**

1 Unilateral
2 Bilateral
99 Unknown

**Age at Diagnosis\***  
("99" if unknown)**Breast**  
(see code table C)

<input type="text"/>	Relative 1 w/breast cancer	<input type="text"/>	<input type="text"/>
<input type="text"/>	Relative 2 w/breast cancer	<input type="text"/>	<input type="text"/>
<input type="text"/>	Relative 3 w/breast cancer	<input type="text"/>	<input type="text"/>
<input type="text"/>	Relative 4 w/breast cancer	<input type="text"/>	<input type="text"/>

\* (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:****Code table for Relatives**

1 Mother	6 Maternal Aunt
2 Sister	7 Paternal Aunt
3 Daughter	8 Self
4 Maternal Grandmother	9 Other
5 Paternal Grandmother	

**Age at Diagnosis\***  
("99" if unknown)

<input type="text"/>	Relative 1 w/ovarian cancer	<input type="text"/>
<input type="text"/>	Relative 2 w/ovarian cancer	<input type="text"/>
<input type="text"/>	Relative 3 w/ovarian cancer	<input type="text"/>
<input type="text"/>	Relative 4 w/ovarian cancer	<input type="text"/>

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

15. Are you willing to answer questions about familial genetic tests?

- No (proceed to Q18)
- Yes (complete Q15a)

15a. Genetic testing has been performed to evaluate possible familial risk of breast cancer?

- No (proceed to Q18)
- Yes
  - Self only (proceed to Q16)
  - Family member(s) only (proceed to Q17)
  - Both self and family member(s) (proceed to Q16)

16. Genetic changes for self found by test?

- No (proceed to Q17)
- Yes (complete Q16a-Q16c)
- Unknown (proceed to Q17)

16a. Changes in BRCA-1 gene

- No
- Yes
- Unknown

16b. Changes in BRCA-2 gene

- No
- Yes
- Unknown

16c. Changes in other gene

- No (proceed to Q17)
- Yes
- 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?

- No family members tested (proceed to Q18)
- No family members had changes (proceed to Q18)
- Yes (complete table 17 a & 17b)
- Unknown (proceed to Q18)

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

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

17b. List 4 (closest) relatives:

Code table for Relatives	
1 Mother	6 Maternal Aunt
2 Sister	7 Paternal Aunt
3 Daughter	8 Father
4 Maternal Grandmother	9 Other
5 Paternal Grandmother	

Gene code table (Q17b)	
1	BRCA-1
2	BRCA-2
99	Unknown or not sure

Gene

- Family member A with change
- Family member B with change
- Family member C with change
- Family member D with change

18. Prior radiation treatment to the chest, axilla, and/or mediastinum **not** for breast cancer.

- No (proceed to Q19)
- Yes (complete Q18a, 18b and 18c)
- Unknown (proceed to Q19)

18a.    Age at radiation treatment (if age is unknown, code "99")

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

18c. Hodgkin's disease

- No
- Yes
- Other, specify \_\_\_\_\_

19. Lifetime risk for breast cancer by Gail Model:

% (attach printout)  
Code 98 if not applicable (e.g. participant is younger than 35 and /or has personal history of cancer or LCIS)

20. Lifetime risk for breast cancer by Claus Model:

% (attach printout)  
Code 98 if not applicable (e.g. no family history of breast cancer and/or participant has personal history of cancer or LCIS)

Sign, date and proceed to I2 form

Comments: \_\_\_\_\_

Signature of person responsible for data<sup>1</sup>

\_\_\_\_\_-\_\_\_\_\_-\_\_\_\_\_  
Date form completed (mm-dd-yyyy)

Signature of person entering data onto the web<sup>2</sup>

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



**ACRIN 6666  
Initial Evaluation Form Supplement**

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

**ACRIN Study 6666  
PLACE LABEL HERE**

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_  
 Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**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 <sup>1</sup>

\_\_\_\_\_-\_\_\_\_\_-\_\_\_\_\_  
 Date Form Completed (mm-dd-yyyy)

\_\_\_\_\_  
 Signature of person entering data onto web <sup>2</sup>

\_\_\_\_\_  
 Participant signature

<sup>1</sup>The "person responsible for the data" refers to the individual who has collated the data on this specific data form

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



**IA**

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

ACRIN Study 6666  
**PLACE LABEL HERE**

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**10f. Lesion type (check all that apply)**

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

**10g. Is this lesion at the site of prior biopsy?**

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

**11. Assessment/Recommendations for this lesion**

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

**11b. Assessment for this lesion**

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

**11c. Recommendation for this lesion**

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

**11d. Is this lesion assessed as probably benign AND recommended for intervention?**

- No (proceed to Q12)
- Yes (specify dominant reason)
  - Participant preference
  - Cancer present now
    - In this breast
    - In opposite breast
  - Patient risk factors
  - Vaguely palpable
  - Follow-up not reasonable
  - Interval increase (>20% in volume for masses)
  - Interval suspicious change
  - Investigator uncertainty

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

- No (proceed to Q13)
- Yes (proceed to Q15)

**IA**If this is a revised or corrected form, please check (✓)   
box and fax to 215-717-0936.**ACRIN Study 6666**  
**PLACE LABEL HERE**

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**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 <sup>1</sup>\_\_\_\_\_  
Date Form Completed (mm-dd-yyyy)\_\_\_\_\_  
Signature of person entering data onto web <sup>2</sup>

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Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**15. Additional Lesion Description****15a. Lesion #**  (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  upper
- Left  lower
- Bilateral, multiple  inner
- Axillary tail  outer
- 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)
  - 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

**15g. 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

**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)

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Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**18. Additional Lesion Description****18a. Lesion #**  (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  upper
- Left  lower
- Bilateral, multiple  inner
- Axillary tail  outer
- Retroareolar  Central

**18e. Distance from the nipple**    cm**18f. Lesion type** (check all that apply)

- Mass (select worst margin feature present)
  - Circumscribed (select one)
    - Fat-containing
    - Not fat-containing
  - Microlobulated
  - Obscured
  - Indistinct
  - Spiculated
- Associated features
  - No
  - Yes (check all that apply)
    - Calcifications (detail below)
    - Architectural distortion
    - 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

**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 (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

**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
- Left  lower
- Bilateral, multiple  inner
- Axillary tail  outer
- Retroareolar  Central

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 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

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

## 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)

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**24. Additional Lesion Description**

**24a. Lesion #**  (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  upper
- Left  lower
- Bilateral, multiple  inner
- Axillary tail  outer
- 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)
    - 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

**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
  - FNAB
- 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
- 4A Low Suspicion of Malignancy
- 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 Q13)
- Yes (proceed to Q27)

## 27. Additional Lesion Description

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

## 27b. Change in this lesion from prior mammogram?

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

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

## 27d. Location (check all that apply)

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

- Right  upper
- Left  lower
- Bilateral, multiple  inner
- Axillary tail  outer
- 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)
    - 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

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

## 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  upper
- Left  lower
- Bilateral, multiple  inner
- Axillary tail  outer
- Retroareolar  Central

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

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

## 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
  - FNAB
- 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)

**IA**If this is a revised or corrected form, please check (✓)   
box and fax to 215-717-0936.ACRIN Study 6666  
**PLACE LABEL HERE****33. Additional Lesion Description****33a. Lesion #**  (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.**    mm X    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  upper
- Left  lower
- Bilateral, multiple  inner
- Axillary tail  outer
- Retroareolar  Central

**33e. Distance from the nipple**    cm**33f. Lesion type** (check all that apply)

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

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**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**



Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**10. Greatest depth (thickness) of Breast by ultrasound**Right < 2 cm 2.0-2.9 cm 3.0-3.9 cm 4.0-4.9 cm 5.0-5.9 cm 6.0-6.9 cm >7 cm not applicableLeft < 2 cm 2.0-2.9 cm 3.0-3.9 cm 4.0-4.9 cm 5.0-5.9 cm 6.0-6.9 cm >7 cm not applicable**11. Background Echotexture****R L** 

Homogeneous

Diffusely Heterogeneous

 Focally Heterogeneous (If focally heterogenous, code all applicable quadrants)**Right Left** UOQ  UOQ UIQ  UIQ LOQ  LOQ LIQ  LIQ**12. Were any simple cysts identified?** No (proceed to Q12c) Yes (If yes, proceed to Q12a)12a.  Right  Solitary  2-3  numerous ( $\geq 4$ ) Left  Solitary  2-3  numerous ( $\geq 4$ )**12b. Detail Largest Cyst****Breast** R  L**Clockface**(report on hour and 1/2 hour  
e.g. 7:00=0700, 12:30=1230) o' clock**Distance from  
the nipple** cm**Depth from  
skin to center  
of cyst  
(to nearest 0.5 cm)** .  cm**Largest Dimension** mm**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.**

Lesion # \_\_\_\_\_

Lesion # \_\_\_\_\_

Lesion # \_\_\_\_\_

Lesion # \_\_\_\_\_

Lesion # \_\_\_\_\_

Lesion # \_\_\_\_\_

Lesion # \_\_\_\_\_

Lesion # \_\_\_\_\_

**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



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

ACRIN Study 6666  
**PLACE LABEL HERE**

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**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 <sup>1</sup>

\_\_\_\_\_  
Date Form Completed (mm-dd-yyyy)

\_\_\_\_\_  
Signature of person entering data onto web <sup>2</sup>



Institution \_\_\_\_\_ Institution No. \_\_\_\_\_  
Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

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

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

20a. Number of solid findings/lesions other than simple cysts: **Right Breast**  **Left Breast**   
(Note: If there are multiple bilateral similar-appearing circumscribed masses, code this as one bilateral lesion).

20b. Lesion # U (e.g. UR1, UB1, UL1 etc.)  
(Retain lesion numbering from initial study survey sonogram. If this is the first examination, begin with R1 for the first lesion in the right breast, R2 for the second lesion in the right breast etc. If the finding is new since a prior study sonogram, use next sequential #. Describe any new or suspicious findings first. Location, distance from nipple, depth to lesion center and measurements are completed for all reportable findings).

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

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

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

- No
- Yes

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

20c. Lesion Size

<b><u>Largest</u></b> <b><u>Horizontal</u></b> <b><u>Meas (mm) D1</u></b>	<b><u>Measured Plane</u></b>	<b><u>Vertical A-P</u></b> <b><u>meas (mm) D2</u></b>	<b><u>Horizontal</u></b> <b><u>Perpendicular Meas</u></b> <b><u>(mm) D3</u></b>	<b><u>Second</u></b> <b><u>Measured Plane</u></b>	<b><u>Volume D1XD2XD3 ÷ 2</u></b>
_____ mm	<input type="radio"/> Trv <input type="radio"/> Sag <input type="radio"/> Rad <input type="radio"/> Arad <input type="radio"/> Oblique	X _____ mm X	_____ mm	<input type="radio"/> Trv <input type="radio"/> Sag <input type="radio"/> Rad <input type="radio"/> Arad <input type="radio"/> Perpendicular Oblique	_____ mm <sup>3</sup>

**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.

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: \_\_\_\_\_

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**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 (lesion seen on US)
    - Comparison to prior mammograms is required
    - Additional mammographic projections

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

- No (proceed to Q24)
- Yes (specify dominant reason)
  - Participant preference
  - Cancer present now
    - In this breast
    - In opposite breast
  - Patient risk factors
  - Vaguely palpable
  - Follow-up not reasonable
  - Increased (> 20% in volume for masses)
  - Interval suspicious change
  - Investigator uncertainty

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**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)

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

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

<u>Breast</u>	<u>Clockface</u> (report on the hour)	<u>Distance from</u> <u>the nipple</u>	<u>Depth from skin to</u> <u>center of lesion</u> (to nearest 0.5 cm)
	(report on hour and 1/2 hour e.g. 7:00=0700, 12:30=1230)		
<input type="radio"/> R <input type="radio"/> L	[ ] o' clock	[ ] [ ] cm	[ ] [ ] [ ] [ ] cm

## 26c. Lesion Size

<u>Largest</u> <u>Horizontal</u> <u>Meas (mm) D1</u>	<u>Measured Plane</u>	<u>Vertical A-P</u> <u>meas (mm) D2</u>	<u>Horizontal</u> <u>Perpendicular Meas</u> <u>(mm) D3</u>	<u>Second</u> <u>Measured Plane</u>	<u>Volume D1XD2XD3 ÷ 2</u>
[ ] [ ] [ ] mm	<ul style="list-style-type: none"> <li><input type="radio"/> Trv</li> <li><input type="radio"/> Sag</li> <li><input type="radio"/> Rad</li> <li><input type="radio"/> Arad</li> <li><input type="radio"/> Oblique</li> </ul>	X [ ] [ ] [ ] mm X	[ ] [ ] mm	<ul style="list-style-type: none"> <li><input type="radio"/> Trv</li> <li><input type="radio"/> Sag</li> <li><input type="radio"/> Rad</li> <li><input type="radio"/> Arad</li> <li><input type="radio"/> Perpendicular Oblique</li> </ul>	[ ] [ ] [ ] mm <sup>3</sup>

**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.

## 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: \_\_\_\_\_

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**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?**

- (only complete if Q27a = Benign)
- No (proceed to Q28)
  - Yes (complete)
    - < 1 year ago
    - 1-2 years ago
    - > 2 years ago

**28. Recommendation for this lesion**

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

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

- No (proceed to Q30)
- Yes (specify dominant reason)
  - Participant preference
  - Cancer present now
    - In this breast
    - In opposite breast
  - Patient risk factors
  - Vaguely palpable
  - Follow-up not reasonable
  - Increased (> 20% in volume for masses)
  - Interval suspicious change
  - Investigator uncertainty

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**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)

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

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?

- 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

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

## 32c. Lesion Size

<u>Largest</u> <u>Horizontal</u> <u>Meas (mm) D1</u>	<u>Measured Plane</u>	<u>Vertical A-P</u> <u>meas (mm) D2</u>	<u>Horizontal</u> <u>Perpendicular Meas</u> <u>(mm) D3</u>	<u>Second</u> <u>Measured Plane</u>	<u>Volume D1XD2XD3 ÷ 2</u>
_____ mm	o Trv o Sag o Rad o Arad o Oblique	X _____ mm X	_____ mm	o Trv o Sag o Rad o Arad o Perpendicular Oblique	_____ mm <sup>3</sup>

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

## 32d. Is this lesion at the site of prior biopsy?

- 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: \_\_\_\_\_

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**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



Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**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)

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_  
Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

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
  - 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

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

38c. Lesion Size

<u>Largest</u> <u>Horizontal</u> <u>Meas (mm) D1</u>	<u>Measured Plane</u>	<u>Vertical A-P</u> <u>meas (mm) D2</u>	<u>Horizontal</u> <u>Perpendicular Meas</u> <u>(mm) D3</u>	<u>Second</u> <u>Measured Plane</u>	<u>Volume D1XD2XD3 ÷ 2</u>
[ ] [ ] [ ] mm	<ul style="list-style-type: none"> <li><input type="radio"/> Trv</li> <li><input type="radio"/> Sag</li> <li><input type="radio"/> Rad</li> <li><input type="radio"/> Arad</li> <li><input type="radio"/> Oblique</li> </ul>	X [ ] [ ] [ ] mm X	[ ] [ ] mm	<ul style="list-style-type: none"> <li><input type="radio"/> Trv</li> <li><input type="radio"/> Sag</li> <li><input type="radio"/> Rad</li> <li><input type="radio"/> Arad</li> <li><input type="radio"/> Perpendicular Oblique</li> </ul>	[ ] [ ] [ ] mm <sup>3</sup>

**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.

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: \_\_\_\_\_

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**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?**

- (only complete if Q39a = Benign)
- 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 (lesion seen on US)
    - 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

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**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)

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

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
  - 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

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

## 44c. Lesion Size

<u>Largest</u> <u>Horizontal</u> <u>Meas (mm) D1</u>	<u>Measured Plane</u>	<u>Vertical A-P</u> <u>meas (mm) D2</u>	<u>Horizontal</u> <u>Perpendicular Meas</u> (mm) D3	<u>Second</u> <u>Measured Plane</u>	<u>Volume D1XD2XD3 ÷ 2</u>
____ mm	<input type="radio"/> Trv <input type="radio"/> Sag <input type="radio"/> Rad <input type="radio"/> Arad <input type="radio"/> Oblique	X _____ mm X	_____ mm	<input type="radio"/> Trv <input type="radio"/> Sag <input type="radio"/> Rad <input type="radio"/> Arad <input type="radio"/> Perpendicular Oblique	_____ mm <sup>3</sup>

**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.

## 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: \_\_\_\_\_

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**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** (check all that apply)
    - 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

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**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)

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_  
Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**50. Additional lesions other than simple cysts** (maximum of 4 per breast)

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

**50b. Was this "lesion" seen on a previous sonogram including any sonograms performed prior to study enrollment?**

- Not applicable, no prior breast sonograms
- No
- Yes
  - 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

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

**50c. Lesion Size**

<u>Largest</u> <u>Horizontal</u> <u>Meas (mm) D1</u>	<u>Measured Plane</u>	<u>Vertical A-P</u> <u>meas (mm) D2</u>	<u>Horizontal</u> <u>Perpendicular Meas</u> <u>(mm) D3</u>	<u>Second</u> <u>Measured Plane</u>	<u>Volume D1XD2XD3 ÷ 2</u>
mm	<input type="radio"/> Trv <input type="radio"/> Sag <input type="radio"/> Rad <input type="radio"/> Arad <input type="radio"/> Oblique	X       mm X	mm	<input type="radio"/> Trv <input type="radio"/> Sag <input type="radio"/> Rad <input type="radio"/> Arad <input type="radio"/> Perpendicular Oblique	mm <sup>3</sup>

**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.

**50d. Is this lesion at the site of prior biopsy?**

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

**50e. Special Case** (see choices below)

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



Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**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?**

- (only complete if Q51a = Benign)
- 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

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**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)

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_  
Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

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
- 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

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

56c. Lesion Size

<u>Largest</u> <u>Horizontal</u> <u>Meas (mm) D1</u>	<u>Measured Plane</u>	<u>Vertical A-P</u> <u>meas (mm) D2</u>	<u>Horizontal</u> <u>Perpendicular Meas</u> <u>(mm) D3</u>	<u>Second</u> <u>Measured Plane</u>	<u>Volume D1XD2XD3 ÷ 2</u>
____ mm	<input type="radio"/> Trv <input type="radio"/> Sag <input type="radio"/> Rad <input type="radio"/> Arad <input type="radio"/> Oblique	_____ mm	_____ mm	<input type="radio"/> Trv <input type="radio"/> Sag <input type="radio"/> Rad <input type="radio"/> Arad <input type="radio"/> Perpendicular Oblique	_____ mm <sup>3</sup>

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

56d. Is this lesion at the site of prior biopsy?

- 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

56e. Special Case (see choices below)

- No
- 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: \_\_\_\_\_

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**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

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**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)

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_  
Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

62. Additional lesions other than simple cysts (maximum of 4 per breast)

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

62b. Was this "lesion" seen on a previous sonogram including any sonograms performed prior to study enrollment?

- 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

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

62c. Lesion Size

<u>Largest</u> <u>Horizontal</u> <u>Meas (mm) D1</u>	<u>Measured Plane</u>	<u>Vertical A-P</u> <u>meas (mm) D2</u>	<u>Horizontal</u> <u>Perpendicular Meas</u> <u>(mm) D3</u>	<u>Second</u> <u>Measured Plane</u>	<u>Volume D1XD2XD3 ÷ 2</u>
_____ mm	<input type="radio"/> Trv <input type="radio"/> Sag <input type="radio"/> Rad <input type="radio"/> Arad <input type="radio"/> Oblique	X _____ mm X	_____ mm	<input type="radio"/> Trv <input type="radio"/> Sag <input type="radio"/> Rad <input type="radio"/> Arad <input type="radio"/> Perpendicular Oblique	_____ mm <sup>3</sup>

**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.

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 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: \_\_\_\_\_

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**62f. Shape**

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

**62g. Orientation**

- Parallel to skin
- Not parallel (includes round)

**62h. Margin**

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

**62i. Boundary Zone**

- Abrupt Interface
- Echogenic Halo

**62j. Echo Pattern**

- Anechoic
- Hyperechoic
- Complex cystic
- Hypoechoic with few tiny cystic areas
- Isoechoic to fat
- Mixed hyperechoic and hypoechoic
- Hypoechoic to fat

**62k. Posterior Features**

- None
- Enhancement
- Combined shadowing/enhancement
- Shadowing

**62l. Surrounding Tissue**

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

**62m. Vascularity (flow)**

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

**62n. Calcifications**

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

**62o. Lesion palpable in retrospect during sonography?**

- No
- Yes

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

- 1 Negative
- 2 Benign (complete Q63b)
- 3 Probably Benign
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion
- 5 Highly Suggestive of Malignancy

**63b. Known benign by prior biopsy?**

- (only complete if Q63a = Benign)
- No (proceed to Q64)
  - Yes (complete)
    - < 1 year ago
    - 1-2 years ago
    - > 2 years ago

**64. Recommendation for this lesion**

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

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

- No (proceed to Q66)
- Yes (specify dominant reason)
  - Participant preference
  - Cancer present now
    - In this breast
    - In opposite breast
  - Patient risk factors
  - Vaguely palpable
  - Follow-up not reasonable
  - Increased (> 20% in volume for masses)
  - Interval suspicious change
  - Investigator uncertainty

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**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





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Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**7g. Assessment for this lesion**

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

**7h. Recommendation for this lesion**

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

**7i. Is this lesion assessed as probably benign AND recommended for intervention?**

- No (proceed to Q7j)
- Yes (check dominant reason)
  - Participant preference
  - Cancer present now
    - In this breast
    - In opposite breast
  - Patient risk factors
  - Vaguely palpable
  - Follow-up not reasonable
  - Interval increase (>20% in volume for masses)
  - Interval suspicious change
  - Investigator uncertainty

**7j. Are there additional lesion(s) you wish to describe?**

- No (proceed to Q8)
- Yes (proceed to Q10)

**Continue onto next page**

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Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**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 (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

**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 (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

**Stop: Form complete, sign and date below.**

Comments: \_\_\_\_\_

\_\_\_\_\_  
Signature of Radiologist responsible for the data <sup>1</sup>\_\_\_\_\_  
Date Form Completed (mm-dd-yyyy)\_\_\_\_\_  
Signature of person entering data onto web <sup>2</sup>

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Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**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)
  - 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 multiple  inner
    - Axillary tail  outer
    - Retroareolar  Central
  - Distance from the nipple \_\_\_\_\_ cm

**10c. Is this lesion seen on ultrasound?**

- No (proceed to Q10d)
- 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  Left breast
  - Clockface location:** \_\_\_\_\_ o'clock (hour and half hour e.g. 7:00 = 0700, 12:30 = 1230)
  - 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)

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Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**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)

- |   |                                  |
|---|----------------------------------|
| <input type="radio"/> Right breast          | <input type="checkbox"/> upper   |
| <input type="radio"/> Left breast           | <input type="checkbox"/> lower   |
| <input type="checkbox"/> Bilateral multiple | <input type="checkbox"/> inner   |
| <input type="checkbox"/> Axillary tail      | <input type="checkbox"/> outer   |
| <input type="checkbox"/> Retroareolar       | <input type="checkbox"/> Central |

Distance from the nipple \_\_\_\_\_ cm

**11c. Is this lesion seen on ultrasound?**

- No (proceed to Q11d)
- Yes and detailed on form **IS** (complete)
- Yes, cyst, not detailed on form **IS**
- In retrospect (only after reviewing mammogram)

New Lesion # **U** \_\_\_\_\_ (number sequentially where **IS** left off, e.g. UR2, UB2, UR3, etc.)**Detail lesion location** Right breast     Left breast

Clockface location: \_\_\_\_\_ o'clock

(hour and half hour e.g. 7:00 = 0700, 12:30 = 1230)

Distance from the nipple \_\_\_\_\_ cm

**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)

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**12. Additional Lesion Description****12a. Lesion Description (dominant feature)**

- Mass
- Multiple bilateral circumscribed masses
- Asymmetry
- Calcifications
- Architectural distortion
- Mixed calcifications and mass/density

**12b. Is this lesion seen on mammography?**

- No (proceed to Q12c)
- Yes, and detailed on form IA (complete)
  - Lesion ID **M** \_\_\_\_\_ on form IA (e.g. MR1, MB1, ML1 etc.)
- In retrospect (only after reviewing ultrasound)
  - New Lesion # **M** \_\_\_\_\_ (number sequentially where IA left off, e.g. MR2, MB2, MR3, etc.)
  - Detail lesion location**
  - Quadrant - Location** (check all that apply)
    - Right breast  upper
    - Left breast  lower
    - Bilateral multiple  inner
    - Axillary tail  outer
    - 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**
  - 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)

**ID**If this is a revised or corrected form, please check box **ACRIN Study 6666  
PLACE LABEL HERE****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  upper
    - Left breast  lower
    - Bilateral multiple  inner
    - Axillary tail  outer
    - Retroareolar  Central
- 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.)
- Yes, cyst, not detailed on form **IS**
- In retrospect (only after reviewing mammogram)  
**New Lesion #** **U**  (number sequentially where IS left off, e.g. UR2, UB2, UR3, etc.)  
**Detail lesion location**  
 Right breast  Left breast  
**Clockface location:**  o'clock  
(hour and half hour e.g. 7:00 = 0700, 12:30 = 1230)  
**Distance from the nipple**   cm

**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

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**13g. Assessment for this lesion**

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

**13h. Recommendation for this lesion**

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

**13i. Is this lesion assessed as probably benign AND recommended for intervention?**

- No (proceed to Q13j)
- Yes (check dominant reason)
  - Participant preference
  - Cancer present now
    - In this breast
    - In opposite breast
  - Patient risk factors
  - Vaguely palpable
  - Follow-up not reasonable
  - Interval increase (>20% in volume for masses)
  - Interval suspicious change
  - Investigator uncertainty

**13j. Are there additional lesions you wish to describe?**

- No (proceed to Q8)
- Yes (proceed to Q14)

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**14. Additional Lesion Description****14a. Lesion Description (dominant feature)**

- Mass
- Multiple bilateral circumscribed masses
- Asymmetry
- Calcifications
- Architectural distortion
- Mixed calcifications and mass/density

**14b. Is this lesion seen on mammography?**

- No (proceed to Q14c)
- Yes, and detailed on form IA (complete)
  - Lesion ID **M** \_\_\_\_\_ on form IA (e.g. MR1, MB1, ML1 etc.)
- In retrospect (only after reviewing ultrasound)
  - New Lesion # **M** \_\_\_\_\_ (number sequentially where IA left off, e.g. MR2, MB2, MR3, etc.)
  - 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

**14c. Is this lesion seen on ultrasound?**

- No (proceed to Q14d)
- Yes and detailed on IS (complete)
  - Lesion ID **U** \_\_\_\_\_ on form IS (e.g. UR1, UB1, UL1 etc.)
- Yes, cyst, not detailed on form IS
- In retrospect (only after reviewing mammogram)
  - New Lesion # **U** \_\_\_\_\_ (number sequentially where IS left off, e.g. UR2, UB2, UR3, etc.)
  - 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

**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)



**ID**If this is a revised or corrected form, please check box **ACRIN Study 6666  
PLACE LABEL HERE**

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**15. Additional Lesion Description****15a. Lesion Description (dominant feature)**

- Mass
- Multiple bilateral circumscribed masses
- Asymmetry
- Calcifications
- Architectural distortion
- Mixed calcifications and mass/density

**15b. Is this lesion seen on mammography?**

- No (proceed to Q15c)
- Yes, and detailed on form **IA** (complete)  
Lesion ID **M** \_\_\_\_\_ on form IA  
(e.g. MR1, MB1, ML1 etc.)
- In retrospect (only after reviewing ultrasound)  
New Lesion # **M** \_\_\_\_\_ (number sequentially where IA left off, e.g. MR2, MB2, MR3, etc.)  
Detail lesion location  
Quadrant - Location (check all that apply)
  - Right breast  upper
  - Left breast  lower
  - Bilateral multiple  inner
  - Axillary tail  outer
  - Retroareolar  Central

Distance from the nipple \_\_\_\_\_ cm

**15c. Is this lesion seen on ultrasound?**

- No (proceed to Q15d)
- 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  Left breast  
Clockface location: \_\_\_\_\_ o'clock  
(hour and half hour e.g. 7:00 = 0700, 12:30 = 1230)  
Distance from the nipple \_\_\_\_\_ cm

**15d. How certain are you that there is correspondence of the lesion on both mammography and ultrasound?**

\_\_\_\_\_ % (best guess from 0-100; code 998 if not seen on both modalities)

**15e. Combined reading likelihood of malignancy for this lesion \_\_\_\_\_ % (best guess from 0-100)****15f. Final assessment/recommendation for this lesion is based:**

- Primarily on mammogram
- Primarily on ultrasound
- On both mammography and ultrasound
- 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)

**ID**If this is a revised or corrected form, please check box **ACRIN Study 6666  
PLACE LABEL HERE**

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**16. Additional Lesion Description****16a. Lesion Description (dominant feature)**

- Mass
- Multiple bilateral circumscribed masses
- Asymmetry
- Calcifications
- Architectural distortion
- Mixed calcifications and mass/density

**16b. Is this lesion seen on mammography?**

- No (proceed to Q16c)
- Yes, and detailed on form **IA** (complete)  
Lesion ID **M** \_\_\_\_\_ on form IA  
(e.g. MR1, MB1, ML1 etc.)
- In retrospect (only after reviewing ultrasound)  
New Lesion # **M** \_\_\_\_\_ (number sequentially where IA left off, e.g. MR2, MB2, MR3, etc.)  
Detail lesion location  
Quadrant - Location (check all that apply)
  - Right breast  upper
  - Left breast  lower
  - Bilateral multiple  inner
  - Axillary tail  outer
  - Retroareolar  Central

Distance from the nipple \_\_\_\_\_ cm

**16c. Is this lesion seen on ultrasound?**

- No (proceed to Q16d)
- Yes and detailed on **IS** (complete)  
Lesion ID **U** \_\_\_\_\_ on form **IS**  
(e.g. UR1, UB1, UL1 etc.)
- Yes, cyst, not detailed on form **IS**
- In retrospect (only after reviewing mammogram)  
New Lesion # **U** \_\_\_\_\_ (number sequentially where IS left off, e.g. UR2, UB2, UR3, etc.)  
Detail lesion location  
 Right breast  Left breast  
Clockface location: \_\_\_\_\_ o'clock  
(hour and half hour e.g. 7:00 = 0700, 12:30 = 1230)  
Distance from the nipple \_\_\_\_\_ cm

**16d. How certain are you that there is correspondence of the lesion on both mammography and ultrasound?**

\_\_\_\_\_ % (best guess from 0-100; code 998 if not seen on both modalities)

**16e. Combined reading likelihood of malignancy for this lesion \_\_\_\_\_ % (best guess from 0-100)****16f. Final assessment/recommendation for this lesion is based:**

- Primarily on mammogram
- Primarily on ultrasound
- On both mammography and ultrasound
- Primarily on risk factors or clinical history

**16g. Assessment for this lesion**

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

**16h. Recommendation for this lesion**

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

**16i. Is this lesion assessed as probably benign AND recommended for intervention?**

- No (proceed to Final Assessment(s) Q8, Q9)
- Yes (specify dominant reason)
  - Participant preference
  - Cancer present now
    - In this breast
    - In opposite breast
  - Patient risk factors
  - Vaguely palpable
  - Follow-up not reasonable
  - Interval increase (>20% in volume for masses)
  - Interval suspicious change
  - Investigator uncertainty

**Proceed to Final Assessment(s), Q8, Q9**



**ACRIN 6666**  
**Additional Evaluation:**  
**Additional Views/Targeted US**

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

**ACRIN Study 6666**  
**PLACE LABEL HERE**

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**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# 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 even 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? (check all that apply)**
  - 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 IA]
    - 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 Q9)

**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?**

- Not available (proceed to Section IIA)
- Available (complete, check all that apply)
  - Prior mammography
  - Prior targeted US
    - Right  Left
  - Prior survey US



# ACRIN 6666

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# ACRIN Study 6666 PLACE LABEL HERE

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

## 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?

- No (specify reason and proceed to Q12)
  - Not recommended
  - Participant refused
  - Not needed after targeted US
  - Scheduling constraints; participant rescheduled
  - Other
- Yes (check all that apply)

- |                          |                          |                          |
|--------------------------|--------------------------|--------------------------|
| <b>R</b>                 | <b>L</b>                 |                          |
| <input type="checkbox"/> | <input type="checkbox"/> | Spot compression         |
| <input type="checkbox"/> | <input type="checkbox"/> | True lateral             |
| <input type="checkbox"/> | <input type="checkbox"/> | Laterally exaggerated CC |
| <input type="checkbox"/> | <input type="checkbox"/> | Magnification views      |
| <input type="checkbox"/> | <input type="checkbox"/> | Rolled views             |
| <input type="checkbox"/> | <input type="checkbox"/> | Repeat CC or MLO or both |

#### 11b. Was lesion seen on additional mammographic view(s)?

- No e.g. resolved on additional views (complete then proceed to Q12)
  - Lesion # from prior mammogram **M**  
(if not applicable code 998)
  - Lesion # from prior ultrasound **U**  
(if not applicable code 998)
- Yes

#### 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.

- |  |                                  |
|--|----------------------------------|
| <input type="radio"/> Right breast           | <input type="checkbox"/> Upper   |
| <input type="radio"/> Left breast            | <input type="checkbox"/> Lower   |
| <input type="checkbox"/> Bilateral, multiple | <input type="checkbox"/> Inner   |
| <input type="checkbox"/> Axillary tail       | <input type="checkbox"/> Outer   |
| <input type="checkbox"/> Retroareolar        | <input type="checkbox"/> 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 worst margin feature present)
  - Circumscribed
    - Fat-containing
    - Not fat-containing
  - Microlobulated
  - Obscured
  - Indistinct
  - Spiculated
- Asymmetry (code type of asymmetry)
  - Focal
    - Asymmetry seen on
      - One view
      - Both views
    - Global
- Calcifications (code morphology and distribution)
  - Morphology of calcifications (check all that apply)
    - Coarse typically benign
    - Milk of calcium
    - Coarse heterogeneous
    - Punctate (<0.5 mm, uniformly round)
    - Amorphous/Indistinct
    - Pleomorphic
    - Branching/Fine linear
  - Distribution of calcifications (check all that apply)
    - Clustered
    - Multiple clusters (same morphology)
    - Regional
    - Linear
    - Segmental
    - Diffuse scattered
    - In mass or asymmetry
- Architectural Distortion

## 12. Sonographic Lesion Description

#### 12a. Was ultrasound performed again directed to this lesion?

- 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. Was lesion seen on this Ultrasound?

- No (complete then proceed to Q13)
  - Lesion # from prior mammogram **M**  
(if not applicable code 998)
  - Lesion # from prior ultrasound **U**  
(if not applicable code 998)
- Yes

#### 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 #)
    - 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.)



# ACRIN 6666

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## ACRIN Study 6666 PLACE LABEL HERE

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

12d.  Check if this "lesion" is multiple bilateral circumscribed masses. Describe largest mass in Q12d and Q12e then proceed to Q12f.

<b>Breast</b>	<b>Clockface</b> (report on 1/2 hour) <small>(report on hour and 1/2 hour e.g. 7:00=0700, 12:30=1230)</small>	<b>Distance from the nipple</b>	<b>Depth from skin to center of lesion (to nearest 0.5 cm)</b>
<input type="radio"/> R <input type="radio"/> L	<input type="text"/> o' clock	<input type="text"/> cm	<input type="text"/> . <input type="text"/> cm

### 12e. Lesion Size

<b>Largest Horizontal Meas (mm) D1</b>	<b>Measured Plane</b>	<b>Vertical A-P meas (mm) D2</b>	<b>Horizontal Perpendicular Meas (mm) D3</b>	<b>Second Measured Plane</b>	<b>Volume D1XD2XD3 ÷ 2</b>
<input type="text"/> mm	<input type="radio"/> Trv <input type="radio"/> Sag <input type="radio"/> Rad <input type="radio"/> Arad <input type="radio"/> Oblique	<input checked="" type="checkbox"/> <input type="text"/> mm <input checked="" type="checkbox"/>	<input type="text"/> mm	<input type="radio"/> Trv <input type="radio"/> Sag <input type="radio"/> Rad <input type="radio"/> Arad <input type="radio"/> Perpendicular Oblique	<input type="text"/> mm <sup>3</sup>

**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.

### 12f. Special Case (see choices below)

- No
- Yes (detail below then proceed to Q12o)
  - 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

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

### 12h. Orientation

- Parallel to skin
- Not parallel (includes round)

### 12i. Margin

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

### 12j. Boundary Zone

- Abrupt Interface
- Echogenic Halo



Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

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 (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

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)



Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

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 (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
    - Vacuum-assisted biopsy, guided by MRI
  - 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

- 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 (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
    - Vacuum-assisted biopsy, guided by MRI
  - 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 <sup>1</sup>

Date Form Completed (mm-dd-yyyy)

Signature of person entering data onto web <sup>2</sup>



Institution \_\_\_\_\_

Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_

Case No. \_\_\_\_\_

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.

IIB. 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)
o Not recommended
o Participant refused
o Not needed after targeted US
o Scheduling constraints; participant rescheduled
o Other
Yes (check all that apply)
R L
o Spot compression
o True lateral
o Laterally exaggerated CC
o Magnification views
o Rolled views
o Repeat CC or MLO or both

18b. Was lesion seen on additional mammographic view(s)?

- No e.g. resolved on additional views (complete then proceed to Q19)
Lesion # from prior mammogram 
(if not applicable code 998)
Lesion # from prior ultrasound 
(if not applicable code 998)
Yes

18c. Was lesion enumerated on any prior study mammogram?

- No and not visible in retrospect (assign next sequential mammogram lesion #)
No but now visible in retrospect (assign next sequential mammogram lesion #)
New lesion # 
Yes
Lesion # from prior mammogram: 
(e.g. MR1, MB1, ML1, MR2, etc.)

18d. Was lesion enumerated on any prior study ultrasound?

- No
o Simple cyst
o Not a simple cyst
Yes (complete)
Lesion # from ultrasound: 
(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 Left breast
o Bilateral, multiple
o Axillary tail
o Retroareolar
o Upper
o Lower
o Inner
o Outer
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)

- Mass (select worse margin feature present)
o Circumscribed
o Fat-containing
o Not fat-containing
o Microlobulated
o Obscured
o Indistinct
o Spiculated
Asymmetry (code type of asymmetry)
o Focal
Asymmetry seen on
o One view
o Both views
o Global
Calcifications (code morphology and distribution)
Morphology of calcifications (check all that apply)
o Coarse typically benign
o Milk of calcium
o Coarse heterogeneous
o Punctate (<0.5 mm, uniformly round)
o Amorphous/Indistinct
o Pleomorphic
o Branching/Fine linear
Distribution of calcifications (check all that apply)
o 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 again directed to this lesion?

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

19b. Was lesion seen on this Ultrasound?

- No (complete then proceed to Q20)
Lesion # from prior mammogram 
(if not applicable code 998)
Lesion # from prior ultrasound 
(if not applicable code 998)
Yes

19c. Was lesion enumerated on any prior study ultrasound?

- No (complete)
o Simple cyst (proceed to Q20)
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 # 
Yes (complete)
Lesion # from prior ultrasound: 
(e.g. UR1, UB1, UL1, UR2, etc.)

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

- No
Yes (complete)
Lesion # from mammogram or additional view number: 
(e.g. MR1, MB1, ML1, MR2, etc.)





# ACRIN 6666

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## ACRIN Study 6666 PLACE LABEL HERE

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

19d.  Check if this "lesion" is multiple bilateral circumscribed masses. Describe largest mass in Q19d and Q19e then proceed to Q19f.

<b>Breast</b>	<b>Clockface</b> <b>(report on 1/2 hour)</b>	<b>Distance from</b> <b>the nipple</b>	<b>Depth from skin to</b> <b>center of lesion</b> <b>(to nearest 0.5 cm)</b>
<input type="checkbox"/> R <input type="checkbox"/> L	(report on hour and 1/2 hour e.g. 7:00=0700, 12:30=1230)		
	<input type="text"/> o' clock	<input type="text"/> cm	<input type="text"/> . <input type="text"/> cm

### 19e. Lesion Size

<b>Largest Horizontal Meas (mm) D1</b>	<b>Measured Plane</b>	<b>Vertical A-P meas (mm) D2</b>	<b>Horizontal Perpendicular Meas (mm) D3</b>	<b>Second Measured Plane</b>	<b>Volume D1XD2XD3 ÷ 2</b>
<input type="text"/> mm	<input type="checkbox"/> Trv <input type="checkbox"/> Sag <input type="checkbox"/> Rad <input type="checkbox"/> Arad <input type="checkbox"/> Oblique	<b>X</b> <input type="text"/> mm <b>X</b>	<input type="text"/> mm	<input type="checkbox"/> Trv <input type="checkbox"/> Sag <input type="checkbox"/> Rad <input type="checkbox"/> Arad <input type="checkbox"/> Perpendicular Oblique	<input type="text"/> mm <sup>3</sup>

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

### 19f. Special Case (see choices below)

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

### 19g. Shape

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

### 19h. Orientation

- Parallel to skin
- Not parallel (includes round)

### 19i. Margin

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

### 19j. Boundary Zone

- Abrupt Interface
- Echogenic Halo



Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

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)



# ACRIN 6666

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# ACRIN Study 6666 PLACE LABEL HERE

Institution \_\_\_\_\_

Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_

Case No. \_\_\_\_\_

## 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.

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

### 23. Mammographic Lesion Description

#### 23a. Were additional mammographic views obtained directed to this finding?

- No (specify reason and proceed to Q24)
  - Not recommended
  - Participant refused
  - Not needed after targeted US
  - Scheduling constraints; participant rescheduled
  - Other
- Yes (check all that apply)
 

<b>R</b>	<b>L</b>	
<input type="checkbox"/>	<input type="checkbox"/>	Spot compression
<input type="checkbox"/>	<input type="checkbox"/>	True lateral
<input type="checkbox"/>	<input type="checkbox"/>	Laterally exaggerated CC
<input type="checkbox"/>	<input type="checkbox"/>	Magnification views
<input type="checkbox"/>	<input type="checkbox"/>	Rolled views
<input type="checkbox"/>	<input type="checkbox"/>	Repeat CC or MLO or both

#### 23b. Was lesion seen on additional mammographic view(s)?

- No e.g. resolved on additional views (complete then proceed to Q24)
 

Lesion # from prior mammogram **M**  
(if not applicable code 998)

Lesion # from prior ultrasound **U**  
(if not applicable code 998)
- Yes

#### 23c. Was lesion enumerated on any prior study mammogram?

- No and not visible in retrospect (assign next sequential mammogram lesion #)
- No but now visible in retrospect (assign next sequential mammogram lesion #)
 

New lesion # **M**
- Yes
 

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

#### 23d. Was lesion enumerated on any prior study ultrasound?

- No
  - Simple cyst
  - Not a simple cyst
- Yes (complete)
 

Lesion # from ultrasound: **U**  
(e.g. UR1, UB1, UL1, UR2, etc.)

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

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

- |  |                                  |
|--|----------------------------------|
| <input type="checkbox"/> Right breast        | <input type="checkbox"/> Upper   |
| <input type="checkbox"/> Left breast         | <input type="checkbox"/> Lower   |
| <input type="checkbox"/> Bilateral, multiple | <input type="checkbox"/> Inner   |
| <input type="checkbox"/> Axillary tail       | <input type="checkbox"/> Outer   |
| <input type="checkbox"/> Retroareolar        | <input type="checkbox"/> Central |

**23f. Distance from nipple** \_\_\_\_\_ cm **by Mammography**

**23g. Size of lesion by Mammography:**

\_\_\_\_\_ mm **X** \_\_\_\_\_ mm  
(largest diameter) (largest perpendicular dimension)

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

- Mass (select worse margin feature present)
  - Circumscribed
    - Fat-containing
    - Not fat-containing
  - Microlobulated
  - Obscured
  - Indistinct
  - Spiculated
- Asymmetry (code type of asymmetry)
  - Focal
 

Asymmetry seen on

    - One view
    - Both views
  - Global
- Calcifications (code morphology and distribution)
 

Morphology of calcifications (check all that apply)

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

Distribution of calcifications (check all that apply)

  - Clustered
  - Multiple clusters (same morphology)
  - Regional
  - Linear
  - Segmental
  - Diffuse scattered
  - In mass or asymmetry
- Architectural Distortion

## 24. Sonographic Lesion Description

#### 24a. Was ultrasound performed again directed to this lesion?

- No (specify reason and proceed to Q25)
  - Not recommended
  - Participant refused
  - Not needed after additional mammographic views
  - Scheduling constraints; participant rescheduled
  - Other
- Yes (check all that apply)
  - Targeted only
  - Whole breast

#### 24b. Was lesion seen on this Ultrasound?

- No (complete then proceed to Q25)
 

Lesion # from prior mammogram **M**  
(if not applicable code 998)

Lesion # from prior ultrasound **U**  
(if not applicable code 998)
- Yes

#### 24c. Was lesion enumerated on any prior study ultrasound?

- No (complete)
  - Simple cyst (proceed to Q25)
  - Not a simple cyst and not visible in retrospect (assign next sequential sonogram lesion #)
  - Not a simple cyst and now visible in retrospect (assign next sequential sonogram lesion #)
 

New lesion # **U**
- Yes (complete)
 

Lesion # from prior ultrasound: **U**  
(e.g. UR1, UB1, UL1, UR2, etc.)

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

- No
- Yes (complete)
 

Lesion # from mammogram or additional view number: **M**  
(e.g. MR1, MB1, ML1, MR2, etc.)



# ACRIN 6666

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Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

24d.  Check if this "lesion" is multiple bilateral circumscribed masses. Describe largest mass in Q24d and Q24e then proceed to Q24f.

<b>Breast</b>	<b>Clockface</b> (report on 1/2 hour e.g. 7:00=0700, 12:30=1230)	<b>Distance from the nipple</b>	<b>Depth from skin to center of lesion (to nearest 0.5 cm)</b>
<input type="checkbox"/> R <input type="checkbox"/> L	<input type="text"/> o' clock	<input type="text"/> cm	<input type="text"/> . <input type="text"/> cm

### 24e. Lesion Size

<b>Largest Horizontal Meas (mm) D1</b>	<b>Measured Plane</b>	<b>Vertical A-P meas (mm) D2</b>	<b>Horizontal Perpendicular Meas (mm) D3</b>	<b>Second Measured Plane</b>	<b>Volume D1XD2XD3 ÷ 2</b>
<input type="text"/> mm	<input type="checkbox"/> Trv <input type="checkbox"/> Sag <input type="checkbox"/> Rad <input type="checkbox"/> Arad <input type="checkbox"/> Oblique	<input type="text"/> mm <b>X</b>	<input type="text"/> mm <b>X</b>	<input type="checkbox"/> Trv <input type="checkbox"/> Sag <input type="checkbox"/> Rad <input type="checkbox"/> Arad <input type="checkbox"/> Perpendicular Oblique	<input type="text"/> mm <sup>3</sup>

**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.

### 24f. Special Case (see choices below)

- No
- Yes (detail below then proceed to Q24o)
  - Complicated Cyst (**Note:** Do not use this term for "complex cystic masses". For complex cystic masses code "no" for Q24f, proceed to Q24g and indicate "complex cystic" at 24k).
    - Homogenous low-level echoes
    - Fluid debris level
    - Mobile internal echoes
    - Multiple bilateral complicated cysts in company of simple cysts
  - Multiple bilateral solid oval, circumscribed masses
  - Mass in or on skin
  - Clustered microcysts
  - Intraductal mass
  - Lymph node
  - Calcifications without a mass
  - Foreign body
  - Post-surgical scar
  - Other, specify \_\_\_\_\_

### 24g. Shape

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

### 24h. Orientation

- Parallel to skin
- Not parallel (includes round)

### 24i. Margin

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

### 24j. Boundary Zone

- Abrupt Interface
- Echogenic Halo



Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**24k. Echo Pattern**

- Anechoic
- Hyperechoic
- Complex cystic
- Hypoechoic with few tiny cystic areas
- Isoechoic to fat
- Mixed hyperechoic and hypoechoic
- Hypoechoic to fat

**24l. Posterior Features**

- None
- Enhancement
- Combined shadowing/enhancement
- Shadowing

**24m. Surrounding Tissue**

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

**24n. Vascularity (flow)**

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

**24o. Calcifications on ultrasound**

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

**24p. 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 (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 (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

**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)



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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.

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)

- |                          |                          |                          |
|--------------------------|--------------------------|--------------------------|
| <b>R</b>                 | <b>L</b>                 |                          |
| <input type="checkbox"/> | <input type="checkbox"/> | Spot compression         |
| <input type="checkbox"/> | <input type="checkbox"/> | True lateral             |
| <input type="checkbox"/> | <input type="checkbox"/> | Laterally exaggerated CC |
| <input type="checkbox"/> | <input type="checkbox"/> | Magnification views      |
| <input type="checkbox"/> | <input type="checkbox"/> | Rolled views             |
| <input type="checkbox"/> | <input type="checkbox"/> | Repeat CC or MLO or both |

#### 28b. Was lesion seen on additional mammographic view(s)?

- No e.g. resolved on additional views (complete then proceed to Q29)
  - Lesion # from prior mammogram **M**  
(if not applicable code 998)
  - Lesion # from prior ultrasound **U**  
(if not applicable code 998)
- Yes

#### 28c. Was lesion enumerated on any prior study mammogram?

- No and not visible in retrospect (assign next sequential mammogram lesion #)
- No but now visible in retrospect (assign next sequential mammogram lesion #)
  - New lesion # **M**
- Yes
  - Lesion # from prior ultrasound: **M**  
(e.g. MR1, MB1, ML1, MR2, etc.)

#### 28d. Was lesion enumerated on any prior study ultrasound?

- No
  - Simple cyst
  - Not a simple cyst
- Yes (complete)
  - Lesion # from ultrasound: **U**  
(e.g. UR1, UB1, UL1, UR2, etc.)

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

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

- |  |                                  |
|--|----------------------------------|
| <input type="checkbox"/> Right breast        | <input type="checkbox"/> Upper   |
| <input type="checkbox"/> Left breast         | <input type="checkbox"/> Lower   |
| <input type="checkbox"/> Bilateral, multiple | <input type="checkbox"/> Inner   |
| <input type="checkbox"/> Axillary tail       | <input type="checkbox"/> Outer   |
| <input type="checkbox"/> Retroareolar        | <input type="checkbox"/> 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
  - Microlobulated
  - Obscured
  - Indistinct
  - Spiculated
- Asymmetry (code type of asymmetry)
  - Focal
    - Asymmetry seen on
      - One view
      - Both views
  - Global
- Calcifications (code morphology and distribution)
  - Morphology of calcifications (check all that apply)
    - Coarse typically benign
    - Milk of calcium
    - Coarse heterogeneous
    - Punctate (<0.5 mm, uniformly round)
    - Amorphous/Indistinct
    - Pleomorphic
    - Branching/Fine linear
  - Distribution of calcifications (check all that apply)
    - Clustered
    - Multiple clusters (same morphology)
    - Regional
    - Linear
    - Segmental
    - Diffuse scattered
    - In mass or asymmetry
- Architectural Distortion

## 29. Sonographic Lesion Description

### 29a. Was ultrasound performed again directed to this lesion?

- No (specify reason and proceed to Q30)
  - Not recommended
  - Participant refused
  - Not needed after additional mammographic views
  - Scheduling constraints; participant rescheduled
  - Other
- Yes (check all that apply)
  - Targeted only
  - Whole breast

### 29b. Was lesion seen on this Ultrasound?

- No (complete then proceed to Q30)
  - Lesion # from prior mammogram **M**  
(if not applicable code 998)
  - Lesion # from prior ultrasound **U**  
(if not applicable code 998)
- Yes

### 29c. Was lesion enumerated on any prior study ultrasound?

- No (complete)
  - Simple cyst (proceed to Q30)
  - Not a simple cyst and not visible in retrospect (assign next sequential sonogram lesion #)
  - Not a simple cyst and now visible in retrospect (assign next sequential sonogram lesion #)
    - New lesion # **U**
- Yes (complete)
  - Lesion # from prior ultrasound: **U**  
(e.g. UR1, UB1, UL1, UR2, etc.)

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

- No
- Yes (complete)
  - Lesion # from mammogram or additional view number: **M**  
(e.g. MR1, MB1, ML1, MR2, etc.)



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Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

29d.  Check if this "lesion" is multiple bilateral circumscribed masses. Describe largest mass in Q29d and Q29e then proceed to Q29f.

<b>Breast</b>	<b>Clockface</b> (report on 1/2 hour) <small>(report on hour and 1/2 hour e.g. 7:00=0700, 12:30=1230)</small>	<b>Distance from the nipple</b>	<b>Depth from skin to center of lesion (to nearest 0.5 cm)</b>
<input type="radio"/> R <input type="radio"/> L	<input type="text"/> o' clock	<input type="text"/> cm	<input type="text"/> cm

### 29e. Lesion Size

<b>Largest Horizontal Meas (mm) D1</b>	<b>Measured Plane</b>	<b>Vertical A-P meas (mm) D2</b>	<b>Horizontal Perpendicular Meas (mm) D3</b>	<b>Second Measured Plane</b>	<b>Volume D1XD2XD3 ÷ 2</b>
<input type="text"/> mm	<input type="radio"/> Trv <input type="radio"/> Sag <input type="radio"/> Rad <input type="radio"/> Arad <input type="radio"/> Oblique	<input checked="" type="checkbox"/> <input type="text"/> mm	<input type="text"/> mm	<input type="radio"/> Trv <input type="radio"/> Sag <input type="radio"/> Rad <input type="radio"/> Arad <input type="radio"/> Perpendicular Oblique	<input type="text"/> mm <sup>3</sup>

**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.

### 29f. Special Case (see choices below)

- No
- Yes (detail below then proceed to Q29o)
  - 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



Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**29k. Echo Pattern**

- Anechoic
- Hyperechoic
- Complex cystic
- Hypoechoic with few tiny cystic areas
- Isoechoic to fat
- Mixed hyperechoic and hypoechoic
- Hypoechoic to fat

**29l. Posterior Features**

- None
- Enhancement
- Combined shadowing/enhancement
- Shadowing

**29m. Surrounding Tissue**

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

**29n. Vascularity (flow)**

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

**29o. Calcifications on ultrasound**

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

**29p. Was lesion palpable in retrospect during sonography?**

- No
- Yes, in retrospect
- Yes, participant presented with lump

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

- No (proceed to Q31)
- Yes (If yes, select procedure)
  - Core/vacuum biopsy site with clip
  - Core/vacuum biopsy site without marker
  - Surgical biopsy site (select diagnosis)
    - Benign
    - Atypical/high-risk lesion
    - Cancer site
    - Unknown
  - Biopsy details unknown
  - FNAB
- Not applicable, multiple bilateral circumscribed masses

**Section III. (by lesion)**

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

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

**31b. Assessment for this lesion**

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

**31c. Recommendation(s) for this lesion**

- Routine screening in 1 year
- Diagnostic follow-up in 1 year
- Short-interval follow-up in 6 months with US
- Short-interval follow-up in 6 months with 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

**31d. Is this lesion assessed as probably benign AND recommended for intervention?**

- No (proceed to Q32)
- Yes (specify dominant reason)
  - Participant preference
  - Cancer present now
    - In this breast
    - In opposite breast
  - Patient risks factors
  - Vaguely palpable
  - Follow-up not reasonable
  - Interval increase (>20% in volume for masses)
  - Interval suspicious change
  - Investigator uncertainty

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

- No (proceed to Q16)
- Yes (proceed to Section IIE)





Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

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.) (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)
o Not recommended
o Participant refused
o Not needed after targeted US
o Scheduling constraints; participant rescheduled
o Other

Yes (check all that apply)

- R L
o Spot compression
o True lateral
o Laterally exaggerated CC
o Magnification views
o Rolled views
o 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

(if not applicable code 998)

Lesion # from prior ultrasound

(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 #)
o No but now visible in retrospect (assign next sequential mammogram lesion #)

New lesion #

Yes

Lesion # from prior mammogram:

(e.g. MR1, MB1, ML1, MR2, etc.)

33d. Was lesion enumerated on any prior study ultrasound?

- No
o Simple cyst
o Not a simple cyst

Yes (complete)

Lesion # from ultrasound:

(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
o Upper
o Lower
o Inner
o Outer
o 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)

Mass (select worse margin feature present)

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

Asymmetry (code type of asymmetry)

- 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 again directed to this lesion?

- 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

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

(if not applicable code 998)

Lesion # from prior ultrasound

(if not applicable code 998)

Yes

34c. Was lesion enumerated on any prior study ultrasound?

- 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 #

Yes (complete)

Lesion # from prior ultrasound:

(e.g. UR1, UB1, UL1, UR2, etc.)

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

No

Yes (complete)

Lesion # from mammogram or additional view

number:

(e.g. MR1, MB1, ML1, MR2, etc.)



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Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

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

<b>Breast</b>	<b>Clockface</b> (report on 1/2 hour)	<b>Distance from the nipple</b>	<b>Depth from skin to center of lesion</b> (to nearest 0.5 cm)
<input type="checkbox"/> R <input type="checkbox"/> L	<input type="text"/> o' clock e.g. 7:00=0700, 12:30=1230	<input type="text"/> cm	<input type="text"/> . <input type="text"/> cm

### 34e. Lesion Size

<b>Largest Horizontal Meas (mm) D1</b>	<b>Measured Plane</b>	<b>Vertical A-P meas (mm) D2</b>	<b>Horizontal Perpendicular Meas (mm) D3</b>	<b>Second Measured Plane</b>	<b>Volume D1XD2XD3 ÷ 2</b>
<input type="text"/> mm	<input type="checkbox"/> Trv <input type="checkbox"/> Sag <input type="checkbox"/> Rad <input type="checkbox"/> Arad <input type="checkbox"/> Oblique	<input checked="" type="checkbox"/> <input type="text"/> mm	<input checked="" type="checkbox"/> <input type="text"/> mm	<input type="checkbox"/> Trv <input type="checkbox"/> Sag <input type="checkbox"/> Rad <input type="checkbox"/> Arad <input type="checkbox"/> Perpendicular Oblique	<input type="text"/> mm <sup>3</sup>

**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.

### 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



Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**34k. Echo Pattern**

- Anechoic
- Hyperechoic
- Complex cystic
- Hypoechoic with few tiny cystic areas
- Isoechoic to fat
- Mixed hyperechoic 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 (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

**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)



# ACRIN 6666

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Institution \_\_\_\_\_

Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_

Case No. \_\_\_\_\_

## 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.)  
(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)

- |                          |                          |                          |
|--------------------------|--------------------------|--------------------------|
| <b>R</b>                 | <b>L</b>                 |                          |
| <input type="checkbox"/> | <input type="checkbox"/> | Spot compression         |
| <input type="checkbox"/> | <input type="checkbox"/> | True lateral             |
| <input type="checkbox"/> | <input type="checkbox"/> | Laterally exaggerated CC |
| <input type="checkbox"/> | <input type="checkbox"/> | Magnification views      |
| <input type="checkbox"/> | <input type="checkbox"/> | Rolled views             |
| <input type="checkbox"/> | <input type="checkbox"/> | 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)
  - Lesion # from prior mammogram
  - (if not applicable code 998)
  - Lesion # from prior ultrasound
  - (if not applicable code 998)
- Yes

#### 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 #
- Yes
  - Lesion # from prior mammogram:
  - (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:
  - (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.

- |  |                                  |
|--|----------------------------------|
| <input type="radio"/> Right breast           | <input type="checkbox"/> Upper   |
| <input type="radio"/> Left breast            | <input type="checkbox"/> Lower   |
| <input type="checkbox"/> Bilateral, multiple | <input type="checkbox"/> Inner   |
| <input type="checkbox"/> Axillary tail       | <input type="checkbox"/> Outer   |
| <input type="checkbox"/> Retroareolar        | <input type="checkbox"/> Central |

38f. Distance from nipple  cm by Mammography

38g. Size of lesion by Mammography:

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

#### 38h. Lesion Description Mammography

(check all that apply)

- Mass (select worse margin feature present)
  - 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)
  - 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. Was lesion seen on this Ultrasound?

- No (complete then proceed to Q40)
  - Lesion # from prior mammogram
  - (if not applicable code 998)
  - Lesion # from prior ultrasound
  - (if not applicable code 998)
- Yes

#### 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 #)
    - New lesion #
- Yes (complete)
  - Lesion # from prior ultrasound:
  - (e.g. UR1, UB1, UL1, UR2, etc.)

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

- No
- Yes (complete)
  - Lesion # from mammogram or additional view number:
  - (e.g. MR1, MB1, ML1, MR2, etc.)



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Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

39d.  Check if this "lesion" is multiple bilateral circumscribed masses. Describe largest mass in Q39d and Q39e then proceed to Q39f.

<b>Breast</b>	<b>Clockface</b> (report on 1/2 hour) <small>(report on hour and 1/2 hour e.g. 7:00=0700, 12:30=1230)</small>	<b>Distance from the nipple</b>	<b>Depth from skin to center of lesion (to nearest 0.5 cm)</b>
<input type="radio"/> R <input type="radio"/> L	_____ o' clock	____ cm	____.____ cm

### 39e. Lesion Size

<b>Largest Horizontal Meas (mm) D1</b>	<b>Measured Plane</b>	<b>Vertical A-P meas (mm) D2</b>	<b>Horizontal Perpendicular Meas (mm) D3</b>	<b>Second Measured Plane</b>	<b>Volume D1XD2XD3 ÷ 2</b>
____ mm	<input type="radio"/> Trv <input type="radio"/> Sag <input type="radio"/> Rad <input type="radio"/> Arad <input type="radio"/> Oblique	<b>X</b> ____ mm <b>X</b>	____ mm	<input type="radio"/> Trv <input type="radio"/> Sag <input type="radio"/> Rad <input type="radio"/> Arad <input type="radio"/> Perpendicular Oblique	____ mm <sup>3</sup>

**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.

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

- No
- Yes (detail below then proceed to Q39o)
  - Complicated Cyst (**Note:** Do not use this term for "complex cystic masses". For complex cystic masses code "no" for Q39f, proceed to Q39g and indicate "complex cystic" at 39k).
    - Homogenous low-level echoes
    - Fluid debris level
    - Mobile internal echoes
    - Multiple bilateral complicated cysts in company of simple cysts
  - Multiple bilateral solid oval, circumscribed masses
  - Mass in or on skin
  - Clustered microcysts
  - Intraductal mass
  - Lymph node
  - Calcifications without a mass
  - Foreign body
  - Post-surgical scar
  - Other, specify \_\_\_\_\_

### 39g. Shape

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

### 39h. Orientation

- Parallel to skin
- Not parallel (includes round)

### 39i. Margin

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

### 39j. Boundary Zone

- Abrupt Interface
- Echogenic Halo



Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**39k. Echo Pattern**

- Anechoic
- Hyperechoic
- Complex cystic
- Hypoechoic with few tiny cystic areas
- Isoechoic to fat
- Mixed hyperechoic and hypoechoic
- Hypoechoic to fat

**39l. Posterior Features**

- None
- Enhancement
- Combined shadowing/enhancement
- Shadowing

**39m. Surrounding Tissue**

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

**39n. Vascularity (flow)**

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

**39o. Calcifications on ultrasound**

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

**39p. Was lesion palpable in retrospect during sonography?**

- No
- Yes, in retrospect
- Yes, participant presented with lump

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

- No (proceed to Q41)
- Yes (If yes, select procedure)
  - Core/vacuum biopsy site with clip
  - 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.**

**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 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

**41d. Is this lesion assessed as probably benign AND recommended for intervention?**

- No (proceed to Q42)
- Yes (specify dominant reason)
  - Participant preference
  - Cancer present now
    - In this breast
    - In opposite breast
  - Patient risks factors
  - Vaguely palpable
  - Follow-up not reasonable
  - Interval increase (>20% in volume for masses)
  - Interval suspicious change
  - Investigator uncertainty

**42. Are there additional lesion(s) you wish to describe?**

- No (proceed to Q16)
- Yes (proceed to Section IIG)



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Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

## 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.)  
(if not applicable code 998)

### 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)

- |                          |                          |                          |
|--------------------------|--------------------------|--------------------------|
| <b>R</b>                 | <b>L</b>                 |                          |
| <input type="checkbox"/> | <input type="checkbox"/> | Spot compression         |
| <input type="checkbox"/> | <input type="checkbox"/> | True lateral             |
| <input type="checkbox"/> | <input type="checkbox"/> | Laterally exaggerated CC |
| <input type="checkbox"/> | <input type="checkbox"/> | Magnification views      |
| <input type="checkbox"/> | <input type="checkbox"/> | Rolled views             |
| <input type="checkbox"/> | <input type="checkbox"/> | Repeat CC or MLO or both |

#### 43b. Was lesion seen on additional mammographic view(s)?

- No e.g. resolved on additional views (complete then proceed to Q44)
  - Lesion # from prior mammogram
  - (if not applicable code 998)
  - Lesion # from prior ultrasound
  - (if not applicable code 998)
- 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
  - Lesion # from prior mammogram:
  - (e.g. MR1, MB1, ML1, MR2, etc.)

#### 43d. Was lesion enumerated on any prior study ultrasound?

- No
  - Simple cyst
  - Not a simple cyst
- Yes (complete)
  - Lesion # from ultrasound:
  - (e.g. UR1, UB1, UL1, UR2, etc.)

#### 43e. Location on Mammography: (check all that apply)

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

- |  |                                  |
|--|----------------------------------|
| <input type="radio"/> Right breast           | <input type="checkbox"/> Upper   |
| <input type="radio"/> Left breast            | <input type="checkbox"/> Lower   |
| <input type="checkbox"/> Bilateral, multiple | <input type="checkbox"/> Inner   |
| <input type="checkbox"/> Axillary tail       | <input type="checkbox"/> Outer   |
| <input type="checkbox"/> Retroareolar        | <input type="checkbox"/> 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
- Architectural Distortion

## 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)
  - Targeted only
  - Whole breast

#### 44b. Was lesion seen on this Ultrasound?

- No (complete then proceed to Q45)
  - Lesion # from prior mammogram
  - (if not applicable code 998)
  - Lesion # from prior ultrasound
  - (if not applicable code 998)
- Yes

#### 44c. Was lesion enumerated on any prior study ultrasound?

- No (complete)
  - Simple cyst (proceed to Q45)
  - Not a simple cyst and not visible in retrospect (assign next sequential sonogram lesion #)
  - Not a simple cyst and now visible in retrospect (assign next sequential sonogram lesion #)
    - New lesion #
- Yes (complete)
  - Lesion # from prior ultrasound:
  - (e.g. UR1, UB1, UL1, UR2, etc.)

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

- No
- Yes (complete)
  - Lesion # from mammogram or additional view number:
  - (e.g. MR1, MB1, ML1, MR2, etc.)



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Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

44d.  Check if this "lesion" is multiple bilateral circumscribed masses. Describe largest mass in Q44d and Q44e then proceed to Q44f.

<b>Breast</b>	<b>Clockface</b> (report on 1/2 hour)	<b>Distance from the nipple</b>	<b>Depth from skin to center of lesion</b> (to nearest 0.5 cm)
<input type="radio"/> R <input type="radio"/> L	<input type="text"/> o' clock	<input type="text"/> cm	<input type="text"/> . <input type="text"/> cm

### 44e. Lesion Size

<b>Largest Horizontal Meas (mm) D1</b>	<b>Measured Plane</b>	<b>Vertical A-P meas (mm) D2</b>	<b>Horizontal Perpendicular Meas (mm) D3</b>	<b>Second Measured Plane</b>	<b>Volume D1XD2XD3 ÷ 2</b>
<input type="text"/> mm	<input type="radio"/> Trv <input type="radio"/> Sag <input type="radio"/> Rad <input type="radio"/> Arad <input type="radio"/> Oblique	<b>X</b> <input type="text"/> mm <b>X</b>	<input type="text"/> mm	<input type="radio"/> Trv <input type="radio"/> Sag <input type="radio"/> Rad <input type="radio"/> Arad <input type="radio"/> Perpendicular Oblique	<input type="text"/> mm <sup>3</sup>

**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.

### 44f. Special Case (see choices below)

- No
- Yes (detail below then proceed to Q44o)
  - Complicated Cyst (**Note:** Do not use this term for "complex cystic masses". For complex cystic masses code "no" for Q44f, proceed to Q44g and indicate "complex cystic" at 44k).
    - Homogenous low-level echoes
    - Fluid debris level
    - Mobile internal echoes
    - Multiple bilateral complicated cysts in company of simple cysts
  - Multiple bilateral solid oval, circumscribed masses
  - Mass in or on skin
  - Clustered microcysts
  - Intraductal mass
  - Lymph node
  - Calcifications without a mass
  - Foreign body
  - Post-surgical scar
  - Other, specify \_\_\_\_\_

### 44g. Shape

- 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





Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**44k. Echo Pattern**

- Anechoic
- Hyperechoic
- Complex cystic
- Hypoechoic with few tiny cystic areas
- Isoechoic to fat
- Mixed hyperechoic and hypoechoic
- Hypoechoic to fat

**44l. Posterior Features**

- None
- Enhancement
- Combined shadowing/enhancement
- Shadowing

**44m. Surrounding Tissue**

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

**44n. Vascularity (flow)**

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

**44o. Calcifications on ultrasound**

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

**44p. Was lesion palpable in retrospect during sonography?**

- No
- Yes, in retrospect
- Yes, participant presented with lump

**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

**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 (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

**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)



# ACRIN 6666

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

# ACRIN Study 6666 PLACE LABEL HERE

Institution \_\_\_\_\_

Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_

Case No. \_\_\_\_\_

## 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: **G** (e.g. GR1, GL1, GL2, etc.)  
(if not applicable code 998)

### 48. Mammographic Lesion Description

#### 48a. Were additional mammographic views obtained directed to this finding?

- No (specify reason and proceed to Q49)
  - Not recommended
  - Participant refused
  - Not needed after targeted US
  - Scheduling constraints; participant rescheduled
  - Other
- Yes (check all that apply)

- |                          |                          |                          |
|--------------------------|--------------------------|--------------------------|
| <b>R</b>                 | <b>L</b>                 |                          |
| <input type="checkbox"/> | <input type="checkbox"/> | Spot compression         |
| <input type="checkbox"/> | <input type="checkbox"/> | True lateral             |
| <input type="checkbox"/> | <input type="checkbox"/> | Laterally exaggerated CC |
| <input type="checkbox"/> | <input type="checkbox"/> | Magnification views      |
| <input type="checkbox"/> | <input type="checkbox"/> | Rolled views             |
| <input type="checkbox"/> | <input type="checkbox"/> | Repeat CC or MLO or both |

#### 48b. Was lesion seen on additional mammographic view(s)?

- No e.g. resolved on additional views (complete then proceed to Q49)
  - Lesion # from prior mammogram **M**  
(if not applicable code 998)
  - Lesion # from prior ultrasound **U**  
(if not applicable code 998)
- Yes

#### 48c. Was lesion enumerated on any prior study mammogram?

- No and not visible in retrospect (assign next sequential mammogram lesion #)
- No but now visible in retrospect (assign next sequential mammogram lesion #)
  - New lesion # **M**
- Yes
  - Lesion # from prior mammogram: **M**  
(e.g. MR1, MB1, ML1, MR2, etc.)

#### 48d. Was lesion enumerated on any prior study ultrasound?

- No
  - Simple cyst
  - Not a simple cyst
- Yes (complete)
  - Lesion # from ultrasound: **U**  
(e.g. UR1, UB1, UL1, UR2, etc.)

#### 48e. Location on Mammography: (check all that apply)

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

- |  |                                  |
|--|----------------------------------|
| <input type="checkbox"/> Right breast        | <input type="checkbox"/> Upper   |
| <input type="checkbox"/> Left breast         | <input type="checkbox"/> Lower   |
| <input type="checkbox"/> Bilateral, multiple | <input type="checkbox"/> Inner   |
| <input type="checkbox"/> Axillary tail       | <input type="checkbox"/> Outer   |
| <input type="checkbox"/> Retroareolar        | <input type="checkbox"/> Central |

48f. Distance from nipple \_\_\_\_\_ cm by Mammography

48g. Size of lesion by Mammography:

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

48h. Lesion Description Mammography  
(check all that apply)

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

## 49. Sonographic Lesion Description

#### 49a. Was ultrasound performed again directed to this lesion?

- No (specify reason and proceed to Q50)
  - Not recommended
  - Participant refused
  - Not needed after additional mammographic views
  - Scheduling constraints; participant rescheduled
  - Other
- Yes (check all that apply)
  - Targeted only
  - Whole breast

#### 49b. Was lesion seen on this Ultrasound?

- No (complete then proceed to Q50)
  - Lesion # from prior mammogram **M**  
(if not applicable code 998)
  - Lesion # from prior ultrasound **U**  
(if not applicable code 998)
- Yes

#### 49c. Was lesion enumerated on any prior study ultrasound?

- No (complete)
  - Simple cyst (proceed to Q50)
  - Not a simple cyst and not visible in retrospect (assign next sequential sonogram lesion #)
  - Not a simple cyst and now visible in retrospect (assign next sequential sonogram lesion #)
    - New lesion # **U**
- Yes (complete)
  - 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.)



# ACRIN 6666

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

## ACRIN Study 6666 PLACE LABEL HERE

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

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

<b>Breast</b>	<b>Clockface</b> (report on 1/2 hour)	<b>Distance from the nipple</b>	<b>Depth from skin to center of lesion</b> (to nearest 0.5 cm)
<input type="checkbox"/> R <input type="checkbox"/> L	(report on hour and 1/2 hour e.g. 7:00 = 7, 12:30 = 12.5)		
	<input type="text"/> o' clock	<input type="text"/> cm	<input type="text"/> . <input type="text"/> cm

### 49e. Lesion Size

<b>Largest Horizontal Meas (mm) D1</b>	<b>Measured Plane</b>	<b>Vertical A-P meas (mm) D2</b>	<b>Horizontal Perpendicular Meas (mm) D3</b>	<b>Second Measured Plane</b>	<b>Volume D1XD2XD3 ÷ 2</b>
<input type="text"/> mm	<input type="radio"/> Trv <input type="radio"/> Sag <input type="radio"/> Rad <input type="radio"/> Arad <input type="radio"/> Oblique	<b>X</b> <input type="text"/> mm <b>X</b>	<input type="text"/> mm	<input type="radio"/> Trv <input type="radio"/> Sag <input type="radio"/> Rad <input type="radio"/> Arad <input type="radio"/> Perpendicular Oblique	<input type="text"/> mm <sup>3</sup>

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

### 49f. Special Case (see choices below)

- No
- Yes (detail below then proceed to Q49o)
  - Complicated Cyst (**Note:** Do not use this term for "complex cystic masses". For complex cystic masses code "no" for Q49f, proceed to Q49g and indicate "complex cystic" at 49k).
    - Homogenous low-level echoes
    - 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 \_\_\_\_\_

### 49g. Shape

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

### 49h. Orientation

- Parallel to skin
- Not parallel (includes round)

### 49i. Margin

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

### 49j. Boundary Zone

- Abrupt Interface
- Echogenic Halo



Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**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 (best guess from 0-100)

**51b. Assessment for this lesion**

- 1 Negative
- 2 Benign
- 3 Probably Benign (Q51d required)
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion
- 5 Highly Suggestive of Malignancy

**51c. Recommendation(s) for this lesion**

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

**51d. Is this lesion assessed as probably benign AND recommended for intervention?**

- No (proceed to Final Assessment(s) Q16, Q17)
- Yes (specify dominant reason)
  - Participant preference
  - Cancer present now
    - In this breast
    - In opposite breast
  - Patient risks factors
  - Vaguely palpable
  - Follow-up not reasonable
  - Interval increase (>20% in volume for masses)
  - Interval suspicious change
  - Investigator uncertainty

**Proceed to Final Assessment(s) Q16, Q17.**



**ACRIN 6666**  
**Short Interval Follow-up**  
**Mammogram/Targeted US**

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

**ACRIN Study 6666**  
**PLACE LABEL HERE**

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**Instructions:** The **F6** form is completed based on recommendations for short-interval follow-up. The **F6** form is intended for use for short-interval follow-up in between annual examinations (e.g. 6 months, 18 months). If a second short-interval follow-up is needed which coincides with the annual examinations, please use forms **IA** and **IS** instead. The **F6** form should be completed by the radiologist who performs the targeted US. If no targeted US was performed then any study radiologist may complete the form. The lesion **Id#** should remain consistent from the **IA** or **IS** form on which the lesion was first reported. Section I may be completed by the RA. Sections II through IV should be completed by the Radiologist. If follow-up evaluation is not able to be completed at first return visit, complete a second "continuation" form **F6** when patient returns to complete follow-up. **Note:** Description is only required for those lesions requiring short interval follow-up and for lesions found only on this follow-up evaluation. Complete Section II for each lesion that requires description. Use **IM** form to report any additional evaluation prompted by new clinical abnormalities or MRI findings in between annual examinations. If a short interval follow-up MRI was performed, please complete an **M4**.

**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)
    - (Check box if date unknown)

**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
    - Note:** Complete BX form if core or FNA done, NL form for surgical biopsy and S1 if cancer found.
  - 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 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

 (if not applicable code 998)
 

Lesion # 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)

**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 #
- Yes
 

Lesion # from prior mammogram:

 (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:

 (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)

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**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

 (if not applicable code 998)
 

Lesion # 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)

**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 #)
 

New lesion #
- Yes (complete)
 

Lesion # from prior ultrasound:

 (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

 (e.g. MR1, MB1, ML1, MR2, etc.)

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

12e.  Check if this "lesion" is multiple bilateral circumscribed masses. Describe largest mass in Q12e and Q12f then proceed to Q12g.

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

**12f. Lesion Size**

<b>Largest</b> <b>Horizontal</b> <b>Meas (mm) D1</b>	<b>Measured Plane</b>	<b>Vertical A-P</b> <b>meas (mm) D2</b>	<b>Horizontal</b> <b>Perpendicular Meas</b> <b>(mm) D3</b>	<b>Second</b> <b>Measured Plane</b>	<b>Volume D1XD2XD3 ÷ 2</b>
____ mm	<input type="radio"/> Trv <input type="radio"/> Sag <input type="radio"/> Rad <input type="radio"/> Arad <input type="radio"/> Oblique	<b>X</b> ____ mm <b>X</b>	____ mm	<input type="radio"/> Trv <input type="radio"/> Sag <input type="radio"/> Rad <input type="radio"/> Arad <input type="radio"/> Perpendicular Oblique	____ mm <sup>3</sup>

**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.

**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 12l).
    - Homogenous low-level echoes
    - Fluid debris level
    - Mobile internal echoes
    - Multiple bilateral complicated cysts in company of simple cysts
  - Multiple bilateral solid oval, circumscribed masses
  - Mass in or on skin
  - Clustered microcysts
  - Intraductal mass
  - Lymph node
  - Calcifications without a mass
  - Foreign body
  - Post-surgical scar
  - Other, specify \_\_\_\_\_

**12h. Shape**

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

**12i. Orientation**

- Parallel to skin
- Not parallel (includes round)

**12j. Margin**

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

**12k. Boundary Zone**

- Abrupt Interface
- Echogenic Halo

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**12l. Echo Pattern**

- Anechoic
- Hyperechoic
- Complex cystic
- Hypoechoic with few tiny cystic areas
- Isoechoic to fat
- Mixed hyperechoic and hypoechoic
- Hypoechoic to fat

**12m. Posterior Features**

- None
- Enhancement
- Combined shadowing/enhancement
- Shadowing

**12n. Surrounding Tissue**

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

**12o. Vascularity (flow)**

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

**12p. Calcifications on ultrasound**

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

**12q. Was lesion palpable in retrospect during sonography?**

- No
- Yes, in retrospect
- Yes, participant presented with lump

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

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

**Section III.****14. Assessment/Recommendations****14a.**     % likelihood of malignancy for this lesion (best guess from 0-100)**14b. Assessment for this lesion**

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

**14c. Known benign by prior biopsy?**

- No (proceed to Q14d)
- Yes (complete)
  - < 1 year ago
  - 1-2 years ago
  - > 2 years ago

**14d. Recommendation(s) for this lesion**

- Return to routine screening
- Diagnostic follow-up to coincide with next annual exam
- Short-interval follow-up in 6 months with US
- Short-interval follow-up in 6 months with mammography
- Short-interval follow-up in 6 months with MRI
- Intervention and/or Additional Imaging (detail intervention and/or additional imaging)
  - Intervention**
    - Aspiration with core biopsy if solid
    - US-guided core biopsy
    - Vacuum-assisted biopsy, guidance by US
    - Vacuum-assisted biopsy, guidance by mammo
    - Excisional biopsy
    - US-guided biopsy, if US negative, MRI guided biopsy
  - Additional Imaging**
    - Targeted ultrasound (lesion seen on mammography)
    - Comparison to prior mammogram is required
    - Additional mammographic projections

**14e. Is this lesion assessed as probably benign AND recommended for intervention?**

- No (proceed to Q15)
- Yes (specify dominant reason)
  - Participant preference
  - Cancer present now
    - In this breast
    - In opposite breast
  - Patient risks factors
  - Vaguely palpable
  - Follow-up not reasonable
  - Interval increase (>20% in volume for masses)
  - Interval suspicious change
  - Investigator uncertainty

**15. Are there additional lesion(s) you wish to describe?**

- No (proceed to Q16)
- Yes (proceed to Q18)



Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**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 mammo
    - 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 mammo
    - 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 <sup>1</sup>

Date Form Completed (mm-dd-yyyy)

Signature of person entering data onto web <sup>2</sup>

**II. Results (by lesion)**

Please complete Mammographic Lesion Description and Sonographic Lesion Description for each lesion being followed and for any new findings on this follow-up examination.

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

**18. Mammographic Lesion Description**

**18a. Were mammographic views obtained of this finding on this follow-up evaluation?**

- No (specify reason and proceed to Q19)
  - Not recommended
  - Participant refused
  - Not needed after targeted US
  - Scheduling constraints; participant rescheduled
  - Other
- Yes

**18b. Change in this lesion from prior mammogram(s)?**

- New
- Gone (complete then proceed to Q19)  
Lesion # from prior mammogram   
(if not applicable code 998)  
Lesion # 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)

**18c. Was lesion enumerated on any prior study mammogram?**

- No and not visible in retrospect (assign next sequential mammogram lesion #)
- No but now visible in retrospect (assign next sequential mammogram lesion #)  
New lesion #
- Yes  
Lesion # from prior mammogram:   
(e.g. MR1, MB1, ML1, MR2, etc.)

**18d. Was lesion enumerated on any prior study ultrasound?**

- No
  - Simple cyst
  - Not a simple cyst
- Yes (complete)  
Lesion # from ultrasound:   
(e.g. UR1, UB1, UL1, UR2, etc.)

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

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

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

**18f. Distance from nipple  cm by Mammography**

**18g. Size of lesion by Mammography:**

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

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**18h. Lesion Description Mammography**

- (check all that apply)
- Mass (select worse margin feature present)
    - Circumscribed
    - Fat-containing
    - Not fat-containing
    - Microlobulated
    - Obscured
    - Indistinct
    - Spiculated
  - Asymmetry (code type of asymmetry)
    - Focal  
Asymmetry seen on
      - One view
      - Both views
    - Global
  - Calcifications (code morphology and distribution)
 

Morphology of calcifications (check all that apply)

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

Distribution of calcifications (check all that apply)

    - Clustered
    - Multiple clusters (same morphology)
    - Regional
    - Linear
    - Segmental
    - Diffuse scattered
    - In mass or asymmetry
  - Architectural Distortion

**19. Sonographic Lesion Description**

**19a. Was ultrasound performed of this lesion on this follow-up evaluation?**

- No (specify reason and proceed to Q20)
  - Not recommended
  - Participant refused
  - Not needed after additional mammographic views
  - Scheduling constraints; participant rescheduled
  - Other
- Yes (check all that apply)
  - Targeted only
  - Whole breast

**19b. Change in this lesion from prior ultrasound?**

- New
- Gone (complete then proceed to Q20)  
Lesion # from prior mammogram   
(if not applicable code 998)  
Lesion # 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)

**19c. Was lesion enumerated on any prior study ultrasound?**

- No (complete)
  - Simple cyst (proceed to Q20)
  - Not a simple cyst and not visible in retrospect (assign next sequential sonogram lesion #)
  - Not a simple cyst and now visible in retrospect (assign next sequential sonogram lesion #)  
New lesion #
- Yes (complete)  
Lesion # from prior ultrasound:   
(e.g. UR1, UB1, UL1, UR2, etc.)

**19d. Was lesion enumerated on any study mammogram (including views obtained today)?**

- No
- Yes (complete)  
Lesion # from mammogram   
(e.g. MR1, MB1, ML1, MR2, etc.)

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

19e.  Check if this "lesion" is multiple bilateral circumscribed masses. Describe largest mass in Q19e and Q19f then proceed to Q19g.

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

19f. **Lesion Size**

<u>Largest Horizontal Meas (mm) D1</u>	<u>Measured Plane</u>	<u>Vertical A-P meas (mm) D2</u>	<u>Horizontal Perpendicular Meas (mm) D3</u>	<u>Second Measured Plane</u>	<u>Volume D1XD2XD3 ÷ 2</u>
____ ____  mm	<input type="radio"/> Trv <input type="radio"/> Sag <input type="radio"/> Rad <input type="radio"/> Arad <input type="radio"/> Oblique	<b>X</b> ____ ____  mm <b>X</b>	____ ____  mm	<input type="radio"/> Trv <input type="radio"/> Sag <input type="radio"/> Rad <input type="radio"/> Arad <input type="radio"/> Perpendicular Oblique	____ ____  mm <sup>3</sup>

**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.

19g. **Special Case** (see choices below)

- No
- Yes (detail below then proceed to Q19p)
  - Complicated Cyst (**Note:** Do not use this term for "complex cystic masses". For complex cystic masses code "no" for Q19g, proceed to Q19h and indicate "complex cystic" at 19l).
    - Homogenous low-level echoes
    - Fluid debris level
    - Mobile internal echoes
    - Multiple bilateral complicated cysts in company of simple cysts
  - Multiple bilateral solid oval, circumscribed masses
  - Mass in or on skin
  - Clustered microcysts
  - Intraductal mass
  - Lymph node
  - Calcifications without a mass
  - Foreign body
  - Post-surgical scar
  - Other, specify \_\_\_\_\_

19h. **Shape**

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

19i. **Orientation**

- Parallel to skin
- Not parallel (includes round)

19j. **Margin**

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

19k. **Boundary Zone**

- Abrupt Interface
- Echogenic Halo

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**19l. Echo Pattern**

- Anechoic
- Hyperechoic
- Complex cystic
- Hypoechoic with few tiny cystic areas
- Isoechoic to fat
- Mixed hyperechoic and hypoechoic
- Hypoechoic to fat

**19m. Posterior Features**

- None
- Enhancement
- Combined shadowing/enhancement
- Shadowing

**19n. Surrounding Tissue**

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

**19o. Vascularity (flow)**

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

**19p. Calcifications on ultrasound**

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

**19q. Was lesion palpable in retrospect during sonography?**

- No
- Yes, in retrospect
- Yes, participant presented with lump

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

- No (proceed to Q21)
- Yes (If yes, select procedure)
  - Core/vacuum biopsy site with clip
  - Core/vacuum biopsy site without marker
  - Surgical biopsy site (select diagnosis)
    - Benign
    - Atypical/high-risk lesion
    - Cancer site
    - Unknown
  - Biopsy details unknown
  - FNAB
- Not applicable, multiple bilateral circumscribed masses

**Section III.****21. Assessment/Recommendations****21a.**     % likelihood of malignancy for this lesion (best guess from 0-100)**21b. Assessment for this lesion**

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

**21c. Known benign by prior biopsy?**

- No (proceed to Q21d)
- Yes (complete)
  - < 1 year ago
  - 1-2 years ago
  - > 2 years ago

**21d. Recommendation(s) for this lesion**

- Return to routine screening
- Diagnostic follow-up to coincide with next annual exam
- Short-interval follow-up in 6 months with US
- Short-interval follow-up in 6 months with mammography
- 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

**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)



Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

24e.  Check if this "lesion" is multiple bilateral circumscribed masses. Describe largest mass in Q24e and Q24f then proceed to Q24g.

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

24f. **Lesion Size**

<b>Largest Horizontal Meas (mm) D1</b>	<b>Measured Plane</b>	<b>Vertical A-P meas (mm) D2</b>	<b>Horizontal Perpendicular Meas (mm) D3</b>	<b>Second Measured Plane</b>	<b>Volume D1XD2XD3 ÷ 2</b>
____ mm	o Trv o Sag o Rad o Arad o Oblique	<b>X</b> ____ mm <b>X</b>	____ mm	o Trv o Sag o Rad o Arad o Perpendicular Oblique	____ mm <sup>3</sup>

**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.

24g. **Special Case** (see choices below)

- No
- Yes (detail below then proceed to Q24p)
  - Complicated Cyst (**Note:** Do not use this term for "complex cystic masses". For complex cystic masses code "no" for Q24g, proceed to Q24h and indicate "complex cystic" at 24i).
    - Homogenous low-level echoes
    - Fluid debris level
    - Mobile internal echoes
    - Multiple bilateral complicated cysts in company of simple cysts
  - Multiple bilateral solid oval, circumscribed masses
  - Mass in or on skin
  - Clustered microcysts
  - Intraductal mass
  - Lymph node
  - Calcifications without a mass
  - Foreign body
  - Post-surgical scar
  - Other, specify \_\_\_\_\_

24h. **Shape**

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

24i. **Orientation**

- Parallel to skin
- Not parallel (includes round)

24j. **Margin**

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

24k. **Boundary Zone**

- Abrupt Interface
- Echogenic Halo

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**24l. 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 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

**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  (if not applicable code 998)
- Lesion # 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)

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

**28d. Was lesion enumerated on any prior study ultrasound?**

- No
  - Simple cyst
  - Not a simple cyst
- Yes (complete)
- Lesion # from ultrasound:  (e.g. UR1, UB1, UL1, UR2, etc.)

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

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

- Right breast  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)

**Institution** \_\_\_\_\_ **Institution No.** \_\_\_\_\_

**Participant Initials** \_\_\_\_\_ **Case No.** \_\_\_\_\_

**28h. Lesion Description Mammography**

- (check all that apply)
- Mass (select worse margin feature present)
    - Circumscribed
    - Fat-containing
    - Not fat-containing
    - Microlobulated
    - Obscured
    - Indistinct
    - Spiculated
  - Asymmetry (code type of asymmetry)
    - Focal
    - Asymmetry seen on
      - One view
      - Both views
    - Global
  - Calcifications (code morphology and distribution)
 

Morphology of calcifications (check all that apply)

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

Distribution of calcifications (check all that apply)

    - Clustered
    - Multiple clusters (same morphology)
    - Regional
    - Linear
    - Segmental
    - Diffuse scattered
    - In mass or asymmetry
  - Architectural Distortion

**29. Sonographic Lesion Description**

**29a. Was ultrasound performed 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  (if not applicable code 998)
- Lesion # 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)

**29c. Was lesion enumerated on any prior study ultrasound?**

- No (complete)
  - Simple cyst (proceed to Q30)
  - Not a simple cyst and not visible in retrospect (assign next sequential sonogram lesion #)
  - Not a simple cyst and now visible in retrospect (assign next sequential sonogram lesion #)
- New lesion #
- Yes (complete)
- Lesion # from prior ultrasound:  (e.g. UR1, UB1, UL1, UR2, etc.)

**29d. Was lesion enumerated on any study mammogram (including views obtained today)?**

- No
- Yes (complete)
- Lesion # from mammogram  (e.g. MR1, MB1, ML1, MR2, etc.)



Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

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

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

**29f. Lesion Size**

<b>Largest Horizontal Meas (mm) D1</b>	<b>Measured Plane</b>	<b>Vertical A-P meas (mm) D2</b>	<b>Horizontal Perpendicular Meas (mm) D3</b>	<b>Second Measured Plane</b>	<b>Volume D1XD2XD3 ÷ 2</b>
____ mm	<input type="radio"/> Trv <input type="radio"/> Sag <input type="radio"/> Rad <input type="radio"/> Arad <input type="radio"/> Oblique	<b>X</b> ____ mm <b>X</b>	____ mm	<input type="radio"/> Trv <input type="radio"/> Sag <input type="radio"/> Rad <input type="radio"/> Arad <input type="radio"/> Perpendicular Oblique	____ mm <sup>3</sup>

**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)

- No
- Yes (detail below then proceed to Q29p)
  - Complicated Cyst (**Note:** Do not use this term for "complex cystic masses". For complex cystic masses code "no" for Q29g, proceed to Q29h and indicate "complex cystic" at 29l).
    - 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 \_\_\_\_\_

**29h. Shape**

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

**29i. Orientation**

- Parallel to skin
- Not parallel (includes round)

**29j. Margin**

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

**29k. Boundary Zone**

- Abrupt Interface
- Echogenic Halo

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**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)
  - Macrocalcifications (> 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 mammo
    - Excisional biopsy
    - US-guided biopsy, if US negative, MRI guided biopsy
  - Additional Imaging**
    - Targeted ultrasound (lesion seen on mammography)
    - Comparison to prior mammogram is required
    - Additional mammographic projections

**31e. Is this lesion assessed as probably benign AND recommended for intervention?**

- No (proceed to Q32)
- Yes (specify dominant reason)
  - Participant preference
  - Cancer present now
    - In this breast
    - In opposite breast
  - Patient risks factors
  - Vaguely palpable
  - Follow-up not reasonable
  - Interval increase (>20% in volume for masses)
  - Interval suspicious change
  - Investigator uncertainty

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

- No (proceed to Q16)
- Yes (proceed to Q33)

**II. Results (by lesion)**

Please complete Mammographic Lesion Description and Sonographic Lesion Description for each lesion being followed and for any new findings on this follow-up examination.

33A. Lesion # from prior MRI:  (e.g. GR1, GL1, GL2, etc.)  
(if not applicable code 998)

**33. Mammographic Lesion Description**

**33a. Were mammographic views obtained of this finding on this follow-up evaluation?**

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

**33b. Change in this lesion from prior mammogram(s)?**

- New
- Gone (complete then proceed to Q34)
- Lesion # from prior mammogram 
  - (if not applicable code 998)
  - Lesion # 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)

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

**33d. Was lesion enumerated on any prior study ultrasound?**

- No
  - Simple cyst
  - Not a simple cyst
- Yes (complete)
  - Lesion # from ultrasound: 
    - (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  Upper
- Left breast  Lower
- Bilateral, multiple  Inner
- Axillary tail  Outer
- Retroareolar  Central

**33f. Distance from nipple  cm by Mammography**

**33g. Size of lesion by Mammography:**

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

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**33h. Lesion Description Mammography**

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

Architectural Distortion

**34. Sonographic Lesion Description**

**34a. Was ultrasound performed of this lesion on this follow-up evaluation?**

- No (specify reason and proceed to Q35)
  - Not recommended
  - Participant refused
  - Not needed after additional mammographic views
  - Scheduling constraints; participant rescheduled
  - Other
- Yes (check all that apply)
  - Targeted only
  - Whole breast

**34b. Change in this lesion from prior ultrasound?**

- New
- Gone (complete then proceed to Q35)
- Lesion # from prior mammogram 
  - (if not applicable code 998)
  - Lesion # 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)

**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 #
- Yes (complete)
  - Lesion # from prior ultrasound: 
    - (e.g. UR1, UB1, UL1, UR2, etc.)

**34d. Was lesion enumerated on any study mammogram (including views obtained today)?**

- No
- Yes (complete)
  - Lesion # from mammogram 
    - (e.g. MR1, MB1, ML1, MR2, etc.)

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

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

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

**34f. Lesion Size**

<u>Largest Horizontal Meas (mm) D1</u>	<u>Measured Plane</u>	<u>Vertical A-P meas (mm) D2</u>	<u>Horizontal Perpendicular Meas (mm) D3</u>	<u>Second Measured Plane</u>	<u>Volume D1XD2XD3 ÷ 2</u>
____ mm	o Trv o Sag o Rad o Arad o Oblique	<b>X</b> ____ mm <b>X</b>	____ mm	o Trv o Sag o Rad o Arad o Perpendicular Oblique	____ mm <sup>3</sup>

**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.

**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 34i).
    - 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

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**34l. 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

**Section III.****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
- Gone (complete then proceed to Q39)

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)

**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**

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

**38f. Distance from nipple    cm by Mammography****38g. Size of lesion by Mammography:**

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

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**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 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)

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)

**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 #)

New lesion #  **U**

- Yes (complete)

Lesion # from prior ultrasound:  **U**

(e.g. UR1, UB1, UL1, UR2, etc.)

**39d. 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.)

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**39e.**  Check if this "lesion" is multiple bilateral circumscribed masses. Describe largest mass in Q39e and Q39f then proceed to Q39g.

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

**39f. Lesion Size**

<u>Largest</u> <u>Horizontal</u> <u>Meas (mm) D1</u>	<u>Measured Plane</u>	<u>Vertical A-P</u> <u>meas (mm) D2</u>	<u>Horizontal</u> <u>Perpendicular Meas</u> <u>(mm) D3</u>	<u>Second</u> <u>Measured Plane</u>	<u>Volume D1XD2XD3 ÷ 2</u>
_____ mm	<input type="radio"/> Trv <input type="radio"/> Sag <input type="radio"/> Rad <input type="radio"/> Arad <input type="radio"/> Oblique	<b>X</b> _____ mm <b>X</b>	_____ mm	<input type="radio"/> Trv <input type="radio"/> Sag <input type="radio"/> Rad <input type="radio"/> Arad <input type="radio"/> Perpendicular Oblique	_____ mm <sup>3</sup>

**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.

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

- No
- Yes (detail below then proceed to Q39p)
  - Complicated Cyst (**Note:** Do not use this term for "complex cystic masses".  
For complex cystic masses code "no" for Q39g, proceed to Q39h and indicate "complex cystic" at 39l).
    - Homogenous low-level echoes
    - Fluid debris level
    - Mobile internal echoes
    - Multiple bilateral complicated cysts in company of simple cysts
  - Multiple bilateral solid oval, circumscribed masses
  - Mass in or on skin
  - Clustered microcysts
  - Intraductal mass
  - Lymph node
  - Calcifications without a mass
  - Foreign body
  - Post-surgical scar
  - Other, specify \_\_\_\_\_

**39h. Shape**

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

**39i. Orientation**

- Parallel to skin
- Not parallel (includes round)

**39j. Margin**

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

**39k. Boundary Zone**

- Abrupt Interface
- Echogenic Halo

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**39l. Echo Pattern**

- Anechoic
- Hyperechoic
- Complex cystic
- Hypoechoic with few tiny cystic areas
- Isoechoic to fat
- Mixed hyperechoic and hypoechoic
- Hypoechoic to fat

**39m. Posterior Features**

- None
- Enhancement
- Combined shadowing/enhancement
- Shadowing

**39n. Surrounding Tissue**

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

**39o. Vascularity (flow)**

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

**39p. Calcifications on ultrasound**

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

**39q. Was lesion palpable in retrospect during sonography?**

- No
- Yes, in retrospect
- Yes, participant presented with lump

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

- No (proceed to Q41)
- Yes (If yes, select procedure)
  - Core/vacuum biopsy site with clip
  - Core/vacuum biopsy site without marker
  - Surgical biopsy site (select diagnosis)
    - Benign
    - Atypical/high-risk lesion
    - Cancer site
    - Unknown
  - Biopsy details unknown
  - FNAB
- Not applicable, multiple bilateral circumscribed masses

**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 (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

**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?**

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

**43b. Change in this lesion from prior mammogram(s)?**

- New
- Gone (complete then proceed to Q44)  
Lesion # from prior mammogram   
(if not applicable code 998)  
Lesion # 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)

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

**43d. Was lesion enumerated on any prior study ultrasound?**

- No
  - Simple cyst
  - Not a simple cyst
- Yes (complete)  
Lesion # from ultrasound:   
(e.g. UR1, UB1, UL1, UR2, etc.)

**43e. Location on Mammography:** (check all that apply)

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

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

**43f. Distance from nipple  cm by Mammography**

**43g. Size of lesion by Mammography:**

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

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**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
  - Architectural Distortion

**44. Sonographic Lesion Description**

**44a. Was ultrasound performed of this lesion on this follow-up evaluation?**

- 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)
  - Targeted only
  - Whole breast

**44b. Change in this lesion from prior ultrasound?**

- New
- Gone (complete then proceed to Q45)  
Lesion # from prior mammogram   
(if not applicable code 998)  
Lesion # 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)

**44c. Was lesion enumerated on any prior study ultrasound?**

- No (complete)
  - Simple cyst (proceed to Q45)
  - Not a simple cyst and not visible in retrospect (assign next sequential sonogram lesion #)
  - Not a simple cyst and now visible in retrospect (assign next sequential sonogram lesion #)  
New lesion #
- Yes (complete)  
Lesion # from prior ultrasound:   
(e.g. UR1, UB1, UL1, UR2, etc.)

**44d. Was lesion enumerated on any study mammogram (including views obtained today)?**

- No
- Yes (complete)  
Lesion # from mammogram   
(e.g. MR1, MB1, ML1, MR2, etc.)

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

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

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

44f. **Lesion Size**

<u>Largest</u> <u>Horizontal</u> <u>Meas (mm) D1</u>	<u>Measured Plane</u>	<u>Vertical A-P</u> <u>meas (mm) D2</u>	<u>Horizontal</u> <u>Perpendicular Meas</u> <u>(mm) D3</u>	<u>Second</u> <u>Measured Plane</u>	<u>Volume D1XD2XD3 ÷ 2</u>
____ ____ ____  mm	o Trv o Sag o Rad o Arad o Oblique	<b>X</b> ____ ____ ____  mm <b>X</b>	____ ____  mm	o Trv o Sag o Rad o Arad o Perpendicular Oblique	____ ____ ____  mm <sup>3</sup>

**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.

44g. **Special Case** (see choices below)

- No
- Yes (detail below then proceed to Q44p)
  - 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 44i).
    - 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 \_\_\_\_\_

44h. **Shape**

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

44i. **Orientation**

- Parallel to skin
- Not parallel (includes round)

44j. **Margin**

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

44k. **Boundary Zone**

- Abrupt Interface
- Echogenic Halo

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**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

**Section III.****46. Assessment/Recommendations**46a.     % likelihood of malignancy for this lesion (best guess from 0-100)**46b. Assessment for this lesion**

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

**46c. Known benign by prior biopsy?**

- No (proceed to Q46d)
- Yes (complete)
  - < 1 year ago
  - 1-2 years ago
  - > 2 years ago

**46d. Recommendation(s) for this lesion**

- Return to routine screening
- Diagnostic follow-up to coincide with next annual exam
- Short-interval follow-up in 6 months with US
- Short-interval follow-up in 6 months with mammography
- Short-interval follow-up in 6 months with MRI
- Intervention and/or Additional Imaging (detail intervention and/or additional imaging)
  - Intervention**
    - Aspiration with core biopsy if solid
    - US-guided core biopsy
    - Vacuum-assisted biopsy, guidance by US
    - Vacuum-assisted biopsy, guidance by 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

**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?**

- No (specify reason and proceed to Q49)
  - Not recommended
  - Participant refused
  - Not needed after targeted US
  - Scheduling constraints; participant rescheduled
  - Other
- Yes

**48b. Change in this lesion from prior mammogram(s)?**

- New
- Gone (complete then proceed to Q49)  
Lesion # from prior mammogram   
(if not applicable code 998)  
Lesion # 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)

**48c. Was lesion enumerated on any prior study mammogram?**

- No and not visible in retrospect (assign next sequential mammogram lesion #)
- No but now visible in retrospect (assign next sequential mammogram lesion #)  
New lesion #
- Yes  
Lesion # from prior mammogram:   
(e.g. MR1, MB1, ML1, MR2, etc.)

**48d. Was lesion enumerated on any prior study ultrasound?**

- No
  - Simple cyst
  - Not a simple cyst
- Yes (complete)  
Lesion # from ultrasound:   
(e.g. UR1, UB1, UL1, UR2, etc.)

**48e. Location on Mammography:** (check all that apply)

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

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

**48f. Distance from nipple  cm by Mammography**

**48g. Size of lesion by Mammography:**

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

**Institution** \_\_\_\_\_ **Institution No.** \_\_\_\_\_

**Participant Initials** \_\_\_\_\_ **Case No.** \_\_\_\_\_

**48h. Lesion Description Mammography**

- (check all that apply)
- Mass (select worse margin feature present)
    - Circumscribed
    - Fat-containing
    - Not fat-containing
    - Microlobulated
    - Obscured
    - Indistinct
    - Spiculated
  - Asymmetry (code type of asymmetry)
    - Focal  
Asymmetry seen on
      - One view
      - Both views
    - Global
  - Calcifications (code morphology and distribution)
 

Morphology of calcifications (check all that apply)

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

Distribution of calcifications (check all that apply)

    - Clustered
    - Multiple clusters (same morphology)
    - Regional
    - Linear
    - Segmental
    - Diffuse scattered
    - In mass or asymmetry
  - Architectural Distortion

**49. Sonographic Lesion Description**

**49a. Was ultrasound performed of this lesion on this follow-up evaluation?**

- No (specify reason and proceed to Q50)
  - Not recommended
  - Participant refused
  - Not needed after additional mammographic views
  - Scheduling constraints; participant rescheduled
  - Other
- Yes (check all that apply)
  - Targeted only
  - Whole breast

**49b. Change in this lesion from prior ultrasound?**

- New
- Gone (complete then proceed to Q50)  
Lesion # from prior mammogram   
(if not applicable code 998)  
Lesion # 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)

**49c. Was lesion enumerated on any prior study ultrasound?**

- No (complete)
  - Simple cyst (proceed to Q50)
  - Not a simple cyst and not visible in retrospect (assign next sequential sonogram lesion #)
  - Not a simple cyst and now visible in retrospect (assign next sequential sonogram lesion #)  
New lesion #
- Yes (complete)  
Lesion # from prior ultrasound:   
(e.g. UR1, UB1, UL1, UR2, etc.)

**49d. Was lesion enumerated on any study mammogram (including views obtained today)?**

- No
- Yes (complete)  
Lesion # from mammogram   
(e.g. MR1, MB1, ML1, MR2, etc.)

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

49e.  Check if this "lesion" is multiple bilateral circumscribed masses. Describe largest mass in Q49e and Q49f then proceed to Q49g.

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

49f. **Lesion Size**

<u>Largest</u> <u>Horizontal</u> <u>Meas (mm) D1</u>	<u>Measured Plane</u>	<u>Vertical A-P</u> <u>meas (mm) D2</u>	<u>Horizontal</u> <u>Perpendicular Meas</u> <u>(mm) D3</u>	<u>Second</u> <u>Measured Plane</u>	<u>Volume D1XD2XD3 ÷ 2</u>
____ ____  mm	o Trv o Sag o Rad o Arad o Oblique	<b>X</b> ____ ____  mm <b>X</b>	____ ____  mm	o Trv o Sag o Rad o Arad o Perpendicular Oblique	____ ____  mm <sup>3</sup>

**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 49l).
    - 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

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**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 (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

**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.**



**ACRIN 6666**  
**Diagnostic Non Surgical**  
**Breast Biopsy and Pathology Form**

ACRIN Study 6666  
**PLACE LABEL HERE**

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_  
 Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**Instructions:** Form **BX** is designed to capture results of percutaneous biopsies and aspirations. Complete a separate form for **each** lesion biopsied. If surgery was performed as the initial diagnostic procedure, the **NL** form is to be completed. Section I may be completed by the site RA, Sections II, III and IV are completed by the Radiologist performing the biopsy. Complete another IM if additional diagnostic imaging is performed at the time of the planned procedure (not already reported), particularly if no biopsy is performed.

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

**I. GENERAL INFORMATION**

**1. Was any percutaneous procedure performed?**

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

**2. Date of Procedure** \_\_\_\_-\_\_\_\_-\_\_\_\_ (mm-dd-yyyy)

**2a. Time point in study prompting this biopsy**

- Initial screening
- 6 month follow-up
- 12 month screening
- 18 month follow-up
- 24 month screening
- 30 month follow-up
- 36 month follow-up
- Other, specify \_\_\_\_\_

**3. Radiologist name** \_\_\_\_\_

**4. Total number of lesions biopsied**   (please complete a separate **BX** form for each lesion biopsied)

**5. Pathology Specimen ID#**  (If no specimen, code xxxx)

**5a. Were slides sent for central review and results obtained?**

- No (proceed to Q6)
- Yes (complete Q5b)
- Pending (proceed to Q6)

**5b. Did central review change management?**

- No (proceed to Q6) **Local result**  **Central result**  (reference code table)
- Yes (complete)
  - Upgrade from  to
  - Downgrade from  to

**6a. Guidance method:**

- US
- Stereotactic prone
- Stereotactic upright
- Mammographic
- MRI
- No image guidance (e.g. palpable or duct excision)
- Other, specify \_\_\_\_\_

**6b. Biopsy of this lesion prompted by (check all that apply)**

- Mammogram
- US
- MRI
- Clinical
- Patient concern
- Other, specify \_\_\_\_\_

**Code Table for Q1**

- 1 Lesion resolved (complete IM)
- 2 Participant refusal
- 3 Participant did not return
- 4 Unable to be performed and rescheduled
- 5 BX attempted, but unable to be performed; surgery scheduled
- 6 Other
- 7 BX NOT attempted and surgical biopsy performed/scheduled
- 8 Lesion appears probably benign and follow-up planned
- 9 Lesion appears benign
- 10 Lesion gone/appears benign on pre-biopsy MRI

**Code Table for Q5b (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



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

**PLACE LABEL HERE**

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**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**                      **Distance from Nipple**                      **Size (largest dimension)**

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

- axilla
- retroareolar
- central

R    L

o' clock   **OR**

cm

mm

**8. Lesion type** (check all that apply)

- Mass                                       Focus on MRI
- Asymmetry                               Non-mass enhancement on MRI
- Calcifications                               Not seen on any imaging
- 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)
  - Felt to be at site
  - Within 1 cm of site
  - 1-2 cm from lesion
  - >2 cm from lesion

**11. Any clinically significant complications from the biopsy procedure?**

- No
- Yes  
 If yes, specify \_\_\_\_\_





**PLACE LABEL HERE**

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**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



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

**PLACE LABEL HERE**

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**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 <sup>1</sup>

\_\_\_\_\_  
Date Form Completed (mm-dd-yyyy)

\_\_\_\_\_  
Signature of person entering data onto web <sup>2</sup>



**ACRIN 6666**  
**Diagnostic Needle Localization**  
**Surgical Biopsy Form**

**ACRIN Study 6666**  
**PLACE LABEL HERE**

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**Instructions:** Submit a separate form for each separate lesion undergoing needle localization. If this lesion is malignant and no further surgery will be performed, please complete form **S1** also at this time. The **NL** form should also be used when a palpable mass or duct is excised directly in a diagnostic surgery. Section **I** may be completed by the site **RA**, Sections **II** through **IV** are completed by the **Radiologist** performing the localization procedure.

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

**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  to

6. **Guidance method:**  to

- US
- Stereotactic prone
- Stereotactic upright
- Mammographic
- MRI
- No image guidance (e.g. palpable or duct excision)
- Other, specify \_\_\_\_\_

**Code Table for Q1**

- 1 Lesion resolved/biopsy not indicated
- 2 Participant refusal
- 3 Participant did not return
- 4 Unable to be performed and rescheduled
- 5 Unable to be performed; lesion will be followed
- 6 Participant not a surgical candidate
- 7 Other

**Code Table for Q5b (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

**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**

**Distance from Nipple**

**Size (largest dimension)**

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

- axilla
- retroareolar
- central

R  L

o' clock **OR**

cm

mm



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

ACRIN Study 6666  
**PLACE LABEL HERE**

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**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 \_\_\_\_\_



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

ACRIN Study 6666  
**PLACE LABEL HERE**

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**14. Malignant**

- No (proceed to Q16)
- Yes (check all that apply)

**NOTE:** If core or excision malignant and no further treatment surgery for cancer is planned, please complete form **S1** also at this time.

- Invasive (infiltrating) ductal carcinoma

**Grade**

- Grade cannot be assessed/ not reported
- Low (Grade I)
- Intermediate (Grade II)
- High (Grade III)
- Insufficient specimen

**Pattern(s)**

- Tubular
- Colloid/Mucinous
- Medullary
- Cribriform
- Micropapillary
- NOS
- Unknown
- Other \_\_\_\_\_
- Invasive lobular carcinoma
- Invasive with mixed ductal/lobular features
- Ductal carcinoma in situ

**Grade**

- Grade cannot be assessed/ not reported
- Low (Grade I)
- Intermediate (Grade II)
- High (Grade III)
- Insufficient specimen

**Central Necrosis**

- Present
- Absent
- Unknown
- Check if cancerization of lobules present
- Other malignant (specify): \_\_\_\_\_

**15. Lymphovascular invasion present?**

- Possible or definite
- Not reported
- Not applicable

**16. Microcalcifications**

- Not present
- Not detailed
- In cancer
- In benign areas only
- In benign and malignant areas

**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 <sup>1</sup>

\_\_\_\_\_-\_\_\_\_\_-\_\_\_\_\_  
Date Form Completed (mm-dd-yyyy)

Signature of person entering data onto web <sup>2</sup>

**S1****ACRIN 6666  
Therapeutic Surgery Form**

ACRIN Study 6666

**PLACE LABEL HERE**

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**Instructions:** Complete a separate **S1** form for **each** separate area of each breast excised with the **intent to treat a cancer** (e.g. each lumpectomy or mastectomy). May be completed by study RA or study Radiologist; original pathology report should be submitted. Lymph nodes excised on the same date as the breast treatment surgery can be reported on the same **S1** form as the main breast surgery. If an axillary dissection is performed at a later date, or re-excision of margins is performed, please complete a separate form **S1**.

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

**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 \_\_\_\_\_
- Already performed, reported previously (on prior S1 form)

**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**Code Table for Q1b**

- 1 Not indicated (other medical problems)
- 2 Participant refusal
- 3 Participant did not return
- 4 Unable to be performed and rescheduled
- 5 Other

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

4. Pathology Specimen ID# \_\_\_\_\_

4a. Were slides sent for central review and results obtained?

- No (proceed to Q5)
- Yes (complete Q4b)
- Pending (proceed to Q5)

4b. Did central review change management?

- No (proceed to Q5)
- Yes (complete)
 

<u>Local result</u>	_____	to	<u>Central result</u>	_____	(reference code table)
	<input type="text"/>			<input type="text"/>	
	<input type="text"/>			<input type="text"/>	
- Upgrade from \_\_\_\_\_ to \_\_\_\_\_
- 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

<u>Breast</u>	<u>Clockface or specify Location</u> <small>(report on hour and 1/2 hour e.g. 7:00=0700, 12:30=1230)</small>	<u>Distance from Nipple</u>	<u>Size (largest dimension)</u>	<u>Lesion number</u> <small>(e.g. MR1, UL2, GR1, etc)</small>
o R o L	_____ o' clock	OR <ul style="list-style-type: none"> <li><input type="radio"/> axilla</li> <li><input type="radio"/> retroareolar</li> <li><input type="radio"/> central</li> </ul>	_____ mm	_____

Provide pathology at this surgery for the lesion described above

- Cancer
- Atypical/high-risk
- Benign
- Unsure of correlation with final surgical specimen

5b. Was there another previously enumerated lesion removed from this breast during this surgery?

- No (proceed to Q6)
- Yes (proceed to Q13)

6. Final Margin Status (check all that apply)

- Margins clear
  - 10 mm or more
  - 4-9 mm
  - 1-3 mm
  - < 1 mm
  - Unknown
- Margins equivocal
- Invasive tumor at margin
- DCIS at margin
- Not applicable, no cancer found

7. Will additional surgery be needed for this breast or axilla (other than cosmetic surgery)?

- No
- Yes (please complete another S1 when performed)
- Unknown

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**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 99 if unknown)Total number of slides   (code 99 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 99 if unknown)
  - (Detail below. Note: code mixed invasive and intraductal as invasive)
    - Invasive ductal carcinoma
    - Invasive lobular carcinoma
    - Invasive with mixed ductal/lobular features
    - DCIS only
    - Invasive, not of breast origin
    - Unknown
- Yes (proceed to Q11)
- Unknown (proceed to Q11)



**S1**If this is a revised or corrected form, please check box ACRIN Study 6666  
**PLACE LABEL HERE**

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**11. TNM Stage****11a. Has staging already been reported on another S1?**

- No (proceed to Q11c)
- Yes

**11b. Did the results of this surgery change the staging of this cancer?**

- No (proceed to Q12)
- Yes (proceed to Q11c)

**11c. T Stage (Primary Tumor)**

- TX Primary Tumor cannot be assessed  
Reason \_\_\_\_\_
- T0 No evidence of primary tumor
- Tis Ductal carcinoma in situ
- T1 Tumor 2 cm or less in greatest dimension
  - T1 mic Microinvasive tumor,  $\leq 0.1$  cm in greatest diameter
  - T1a Invasive tumor,  $0.1 < x \leq 0.5$  cm in greatest diameter
  - T1b Invasive tumor,  $0.5 < x \leq 1.0$  cm in greatest diameter
  - T1c Invasive tumor,  $1.0 < x \leq 2.0$  cm in greatest diameter
- T2 Invasive tumor,  $2.0 < x \leq 5.0$  cm in greatest diameter
- T3 Invasive tumor,  $> 5$  cm in greatest diameter
- T4 Tumor of any size with:
  - Direct extension to chest wall, T4a
  - 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
  - Both skin and chest wall extension, T4c
  - Dermal lymphatics involved, inflammatory cancer, T4d

**11d. N Stage (Regional Lymph Nodes)**

- NX Regional lymph nodes cannot be assessed (e.g., previously removed)
- N0 No regional lymph node metastasis
  - pN0 No regional lymph node metastasis histologically, no additional examination for isolated tumor cells (ITC)<sup>(3)</sup>
  - pN0(i-) No regional lymph node metastasis histologically, negative IHC
  - pN0(i+) No regional lymph node metastasis histologically, positive IHC cluster greater than 0.2 mm
- N1 Metastasis in moveable ipsilateral lymph node(s)
  - pN1mi Micrometastasis (greater than 0.2 mm, none greater than 2.0 mm)
  - pN1a Metastasis in 1 to 3 axillary lymph nodes
  - pN1b Metastasis in internal mammary nodes with microscopic disease detected by sentinel lymph node dissection but not clinically apparent<sup>(5)</sup>
  - 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<sup>(5, 6)</sup>
- N2 Metastases in ipsilateral axillary lymph nodes fixed or matted, or in clinically apparent<sup>(1)</sup> ipsilateral internal mammary nodes in the *absence* of clinically evident axillary lymph node metastasis
  - N2a Metastasis in ipsilateral axillary lymph nodes fixed to one another (matted) or to other structures
  - N2b Metastasis only in clinically apparent<sup>(1)</sup> ipsilateral internal mammary nodes and in the *absence* of clinically evident axillary lymph node metastasis
  - pN2 Metastasis in 4-9 axillary lymph nodes, or in clinically apparent<sup>(1)</sup> internal mammary lymph nodes in the absence of axillary lymph node metastasis
    - pN2a Metastasis in 4-9 axillary lymph nodes (at least one tumor deposit greater than 2.0 mm )
    - pN2b Metastasis in clinically apparent<sup>(1)</sup> internal mammary lymph nodes in the absence of axillary lymph node metastasis
- N3 Metastasis in ipsilateral infraclavicular lymph node(s) with or without axillary lymph node involvement, or in clinically apparent<sup>(1)</sup> 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
  - N3a Metastasis in ipsilateral infraclavicular lymph node(s) and axillary lymph node(s)
  - N3b Metastasis in ipsilateral internal mammary lymph node(s) and axillary lymph node(s)
  - N3c Metastasis in ipsilateral supraclavicular lymph node(s)
  - pN3 Metastasis in 10 or more axillary lymph nodes, or in infraclavicular lymph nodes, or in clinically apparent<sup>(1)</sup> 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
    - pN3a Metastasis in 10 or more axillary lymph nodes (at least one tumor deposit greater than 2.0 mm), or metastasis to the infraclavicular lymph nodes
    - pN3b Metastasis in clinically apparent<sup>(1)</sup> 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 and in internal mammary lymph nodes with microscopic disease detected by sentinel lymph node dissection but not clinically apparent<sup>(5)</sup>
    - pN3c Metastasis in ipsilateral supraclavicular lymph node(s)

**11e. M Stage (Distant Metastasis)**

- MX Presence of distant metastasis cannot be assessed
- M0 No evidence of distant metastasis
- M1 Distant metastasis (includes metastasis to ipsilateral supraclavicular lymph node(s))

**S1**If this is a revised or corrected form, please check box 

**ACRIN Study 6666**  
**PLACE LABEL HERE**

**Institution** \_\_\_\_\_ **Institution No.** \_\_\_\_\_

**Participant Initials** \_\_\_\_\_ **Case No.** \_\_\_\_\_

**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)?**

- No
- Yes

**Comments:** \_\_\_\_\_

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**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

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**13. Detail additional enumerated lesion this specimen****13a. Lesion Location**  Check if this lesion ONLY seen on MRI

<u>Breast</u>	<u>Clockface or specify Location</u> <small>(report on hour and 1/2 hour e.g. 7:00=0700, 12:30=1230)</small>	<u>Distance from Nipple</u>	<u>Size (largest dimension)</u>	<u>Lesion number</u> <small>(e.g. MR1, UL2, GR1, etc)</small>	
O R O L	<input type="text"/> o' clock	OR <input type="radio"/> axilla <input type="radio"/> retroareolar <input type="radio"/> central	<input type="text"/> cm	<input type="text"/> mm	<input type="text"/>

**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

<u>Breast</u>	<u>Clockface or specify Location</u> <small>(report on hour and 1/2 hour e.g. 7:00=0700, 12:30=1230)</small>	<u>Distance from Nipple</u>	<u>Size (largest dimension)</u>	<u>Lesion number</u> <small>(e.g. MR1, UL2, GR1, etc)</small>	
O R O L	<input type="text"/> o' clock	OR <input type="radio"/> axilla <input type="radio"/> retroareolar <input type="radio"/> central	<input type="text"/> cm	<input type="text"/> mm	<input type="text"/>

**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

<u>Breast</u>	<u>Clockface or specify Location</u> <small>(report on hour and 1/2 hour e.g. 7:00=0700, 12:30=1230)</small>	<u>Distance from Nipple</u>	<u>Size (largest dimension)</u>	<u>Lesion number</u> <small>(e.g. MR1, UL2, GR1, etc)</small>	
O R O L	<input type="text"/> o' clock	OR <input type="radio"/> axilla <input type="radio"/> retroareolar <input type="radio"/> central	<input type="text"/> cm	<input type="text"/> mm	<input type="text"/>

**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**

# M3 Initial MRI Assessment Form

ACRIN Study 6666  
PLACE LABEL HERE

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_  
Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

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

**INSTRUCTIONS:** This form is completed **only for the initial MRI of the study breast** and submitted to the ACR. Interpretation is done blind to 24 month mammogram and US. Please pay particular attention when identifying findings so that consistency among forms is maintained. **A separate form is completed for each finding or enhancement on study; in addition a separate form is to be completed for EACH breast even if no finding is identified in that breast.** Reports are dated MM/DD/YYYY. Measurements are reported in mm. Nonenhancing cysts and nonenhancing scars do not have to be numbered: use comments.

DE

## I. GENERAL INFORMATION

**1a. Breast reported on this form**  
 Right Breast  
 Left Breast

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

**2. Was an MRI done?**  
 No; If no, specify reason from code table   
 (stop and sign form)  
 Yes (complete Q2a and continue with form)

Code table for Q2	
1	Breast not on study
2	Patient unable to tolerate
3	Scanner failure
4	Injection failure
5	Other, detail in comments

**2a. Are there any findings in the breast reported in Q1a for which recommendation is other than routine follow-up?**  
 No  
 Yes

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

**3a. Participant's last menstrual period**  
 \_\_\_\_ - \_\_\_\_ - \_\_\_\_ (mm-dd-yyyy)  
**If < 1 month ago. Note: Code 12-12-2100 if not applicable or unknown**

**3b. Date of MRI Interpretation**  
 \_\_\_\_ - \_\_\_\_ - \_\_\_\_ (mm-dd-yyyy)

**3c. Reader ID#**            
**Radiologist Name** \_\_\_\_\_  
 (Last, First)

**3d. Background tissue enhancement**  
 None/minimal  
 Moderate, patchy  
 Moderate, uniform  
 Marked

**3e. Significant artifacts for this breast?**  
 No (proceed to Q4)  
 Yes (check all that apply then proceed to Q4)  
 Motion  
 Large breast, abuts coil  
 Inhomogeneous fat suppression  
 Clips/sutures  
 Other, specify \_\_\_\_\_

**4.    Total number of findings for this breast on MRI.**  
 (If zero (0), skip to Q12) (Note: Multiple foci can be reported as one lesion if all felt to be the same process)

**5.    Data recorded represents finding #.**  
 (A separate form must be completed for each finding. **Note:** Code GR1 for the first lesion in right breast, GL1 for the first lesion in the left breast, etc.)

## II. FINDING

**6a. Signal on T2 for this finding**  
 Purely cystic/fluid  
 Moderately hyperintense (at least partially solid)  
 Slightly hyperintense  
 Hypointense or not seen

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

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

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

**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 \_\_\_\_\_

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

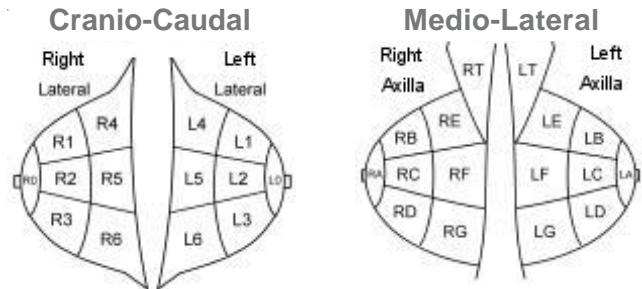
Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**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.



- |                             |                             |                             |                             |
|-----------------------------|-----------------------------|-----------------------------|-----------------------------|
| <input type="checkbox"/> R0 | <input type="checkbox"/> L0 | <input type="checkbox"/> RT | <input type="checkbox"/> LT |
| <input type="checkbox"/> R1 | <input type="checkbox"/> L1 | <input type="checkbox"/> RA | <input type="checkbox"/> LA |
| <input type="checkbox"/> R2 | <input type="checkbox"/> L2 | <input type="checkbox"/> RB | <input type="checkbox"/> LB |
| <input type="checkbox"/> R3 | <input type="checkbox"/> L3 | <input type="checkbox"/> RC | <input type="checkbox"/> LC |
| <input type="checkbox"/> R4 | <input type="checkbox"/> L4 | <input type="checkbox"/> RD | <input type="checkbox"/> LD |
| <input type="checkbox"/> R5 | <input type="checkbox"/> L5 | <input type="checkbox"/> RE | <input type="checkbox"/> LE |
| <input type="checkbox"/> R6 | <input type="checkbox"/> L6 | <input type="checkbox"/> RF | <input type="checkbox"/> LF |
|                             |                             | <input type="checkbox"/> RG | <input type="checkbox"/> LG |

**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

**M3**

Revision

ACRIN Study 6666  
**PLACE LABEL HERE**

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**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:** \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_  
Signature of person responsible for the data <sup>1</sup>

Date form completed<sup>3</sup> \_\_\_\_-\_\_\_\_-\_\_\_\_ (mm-dd-yyyy)

\_\_\_\_\_  
Signature of person entering data onto the web <sup>2</sup>



# MRI Short Interval Assessment Form

ACRIN Study 6666  
**PLACE LABEL HERE**

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

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

**INSTRUCTIONS:** This form is completed **only for the follow-up MRI of the study breast** and submitted to the ACR. Please pay particular attention when identifying findings so that consistency among forms is maintained. **A separate form is completed for each finding or enhancement on study; in addition a separate form is to be completed for EACH breast even if no finding is identified in that breast.** Reports are dated MM/DD/YYYY. Measurements are reported in mm. Nonenhancing cysts and nonenhancing scars do not have to be numbered: use comments.

DE

## 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)

Code table for Q2	
1	Breast not on study
2	Patient unable to tolerate
3	Scanner failure
4	Injection failure
5	Other, detail in comments

### 2a. Follow-up MRI timepoint

- 3 months
- 6 months
- Other, specify \_\_\_\_\_

(Note: Immediate/repeat MRI needs to be reported on form M3)

### 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  $\leq$  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,  largest diameter in mm
- 2-3
- $\geq$  4

### 7. Mass size encompassed by Gd enhancement

(record three dimensions)

x mm     y mm     z 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 \_\_\_\_\_

**ACRIN Study 6666  
PLACE LABEL HERE**

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

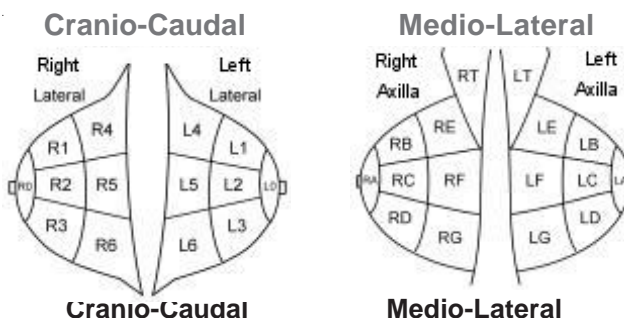
Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**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.



- |                             |                             |                             |                             |
|-----------------------------|-----------------------------|-----------------------------|-----------------------------|
| <input type="checkbox"/> R0 | <input type="checkbox"/> L0 | <input type="checkbox"/> RT | <input type="checkbox"/> LT |
| <input type="checkbox"/> R1 | <input type="checkbox"/> L1 | <input type="checkbox"/> RA | <input type="checkbox"/> LA |
| <input type="checkbox"/> R2 | <input type="checkbox"/> L2 | <input type="checkbox"/> RB | <input type="checkbox"/> LB |
| <input type="checkbox"/> R3 | <input type="checkbox"/> L3 | <input type="checkbox"/> RC | <input type="checkbox"/> LC |
| <input type="checkbox"/> R4 | <input type="checkbox"/> L4 | <input type="checkbox"/> RD | <input type="checkbox"/> LD |
| <input type="checkbox"/> R5 | <input type="checkbox"/> L5 | <input type="checkbox"/> RE | <input type="checkbox"/> LE |
| <input type="checkbox"/> R6 | <input type="checkbox"/> L6 | <input type="checkbox"/> RF | <input type="checkbox"/> LF |
|                             |                             | <input type="checkbox"/> RG | <input type="checkbox"/> LG |

**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



Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**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 <sup>1</sup>Date form completed<sup>3</sup> \_\_\_\_-\_\_\_\_-\_\_\_\_ (mm-dd-yyyy)\_\_\_\_\_  
Signature of person entering data onto the web <sup>2</sup>



**ACRIN 6666  
MRI-US-Mammo Integration**

**ACRIN Study 6666  
PLACE LABEL HERE**

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

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

**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?

- None
- Right breast only
- Left breast only
- Both breasts

3b. Requiring short interval follow-up?

- None
- Right breast only
- Left breast only
- Both breasts

3c. Requiring biopsy?

- None
- Right breast only
- Left breast only
- Both breasts

4. Are any findings considered benign or probably benign by US that require biopsy based on MRI?

- No
- Yes

5. Are any findings considered benign or probably benign by Mammography that require biopsy based on MRI?

- No
- Yes

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**6. Taking together all breast imaging on this participant, final assessment by breast:****Final Assessment of Right Breast**6a.  **Not on study** (proceed to Q7)6b.     % **Combined reading likelihood of malignancy for right breast** (best guess from 0-100)**6c. Assessment for right breast**

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

**6d. Recommendation for right breast****Follow-up**

- Routine screening in 1 year
- Diagnostic follow-up in 1 year
- Short-interval follow-up in 6 months with US
- Short-interval follow-up in 6 months with mammography
- Short-interval follow-up MRI in 6 months

 **Intervention and/or Additional Imaging** (detail intervention and/or additional imaging) **Intervention**

- Aspiration with core biopsy if solid
- US-guided core biopsy
- Vacuum-assisted biopsy, guidance by US
- Vacuum-assisted biopsy, guidance by mammography
- Excisional biopsy
- MRI-guided vacuum assisted biopsy if not US biopsy

 **Additional Imaging** (check all that apply)

- Additional evaluation
  - Comparison to prior mammogram is required
  - Targeted ultrasound (lesion seen on mammography)
  - Ultrasound targeted to MRI abnormality
  - Additional mammographic projections
- Repeat ultrasound
  - Technique/interpretation in question
  - Possibly abnormal
- Repeat mammogram
  - Incomplete
  - Motion artifact/other technical problem
- Repeat MRI
  - Motion artifact or other technical problem
  - Incomplete
  - Abnormalities likely due to phase in cycle

**7. Final Assessment of Left Breast**7a.  **Not on study** (stop and sign below)7b.     % **Combined reading likelihood of malignancy for left breast** (best guess from 0-100)**7c. Assessment for left breast**

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

**7d. Recommendation for left breast****Follow-up**

- Routine screening in 1 year
- Diagnostic follow-up in 1 year
- Short-interval follow-up in 6 months with US
- Short-interval follow-up in 6 months with mammography
- Short-interval follow-up MRI in 6 months

 **Intervention and/or Additional Imaging** (detail intervention and/or additional imaging) **Intervention**

- Aspiration with core biopsy if solid
- US-guided core biopsy
- Vacuum-assisted biopsy, guidance by US
- Vacuum-assisted biopsy, guidance by mammography
- Excisional biopsy
- MRI-guided vacuum assisted biopsy if not US biopsy

 **Additional Imaging** (check all that apply)

- Additional evaluation
  - Comparison to prior mammogram is required
  - Targeted ultrasound (lesion seen on mammography)
  - Ultrasound targeted to MRI abnormality
  - Additional mammographic projections
- Repeat ultrasound
  - Technique/interpretation in question
  - Possibly abnormal
- Repeat mammogram
  - Incomplete
  - Motion artifact/other technical problem
- Repeat MRI
  - Motion artifact or other technical problem
  - Incomplete
  - Abnormalities likely due to phase in cycle

COMMENTS: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Signature of person responsible for the data

Date form completed \_\_\_\_-\_\_\_\_-\_\_\_\_ (mm-dd-yyyy)

Signature of person entering data onto the web



**ACRIN 6666  
Screening Breast US  
Follow-up Assessment Form**

**ACRIN Study 6666  
PLACE LABEL HERE**

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**Instructions: The F1 form is completed at 12, 24 and 36 months post initial on study mammography and ultrasound by the Radiologist or RA.** Report all interim information related to the time period, e.g. imaging, biopsy, surgery and/or non-protocol related treatment. The form is completed whether or not there was any activity and is designed primarily to capture imaging and biopsy events at facilities other than the study imaging site. **Include only items that have not previously been reported.**  
**NOTE: For a "6-month" follow-up (performed at study site) after any annual exam, complete form F6 instead of F1, for additional views use IM, for core biopsies use BX, etc.**

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

**1. Time point of this follow-up**

- 12 months
- 24 months
- 36 months

1a. Record actual elapsed months since study entry

2. Date of follow-up contact or attempt \_\_\_\_\_-\_\_\_\_\_-\_\_\_\_\_  
mm dd yyyy

**3. Method of contact**

- At appointment
- By telephone
- Other, specify \_\_\_\_\_

**4. Participant Status**

- Alive (proceed to Q5)
- Dead (complete Q4a)
- Lost to follow-up; unable to contact (proceed to Q4b)

4a. Date of death \_\_\_\_\_-\_\_\_\_\_-\_\_\_\_\_  
mm dd yyyy

If date of death unknown code 12-12-2100  
If exact date is unknown, choose the 15th of that month.

4b. Date of last contact \_\_\_\_\_-\_\_\_\_\_-\_\_\_\_\_  
mm dd yyyy

**Section I. Clinical Status**

**5. Was a clinical breast exam of the breast(s) performed since the last annual screening visit?**

- No (provide reason in Q5a)
- Yes (complete then proceed to Q5b and Q5c)
  - Right (complete Qs 5b and 5c)
  - Left (complete Qs 5b and 5d)
  - Both (complete Qs 5b-5d)
- Unknown (proceed to Q6)

**5a. Provide reason CBE not done** (then proceed to Q6):

- Patient missed appointment
- Patient unable to be located
- Patient pregnant or lactating
- Patient refused
- Referring physician's choice
- Expired
- Other, specify \_\_\_\_\_

5b. Date of follow-up CBE \_\_\_\_\_-\_\_\_\_\_-\_\_\_\_\_  
mm yyyy

**5c. Have there been any clinically significant changes in the right breast since the last annual examination?**

- No or breast not on study
- Yes (check all clinical changes that apply)
  - Palpable mass (complete location)  
Location of abnormality  
 o'clock or specify location:
    - Axilla
    - Retroareolar
    - Unknown
  - Nipple discharge (detail):
    - Bloody
    - Clear spontaneous
    - Other
  - Other, specify: \_\_\_\_\_

**5d. Have there been any clinically significant changes in the left breast since the last annual examination?**

- No or breast not on study
- Yes (check all clinical changes that apply)
  - Palpable mass (complete location)  
Location of abnormality  
 o'clock or specify location:
    - Axilla
    - Retroareolar
    - Unknown
  - Nipple discharge (detail):
    - Bloody
    - Clear spontaneous
    - Other
  - Other, specify: \_\_\_\_\_

**6. Current use of hormones?**

- No (proceed to Q7)
- Yes (complete Q6a)

6a. Specify hormone(s) \_\_\_\_\_

**7. Has any interval breast imaging been performed since last visit?** (consider only items not previously reported on forms IM, F6, etc., per instructions.)

- No (proceed to Section III)
- Yes (complete Q7a)

**7a. Check all breast imaging performed since last visit:**

- Mammogram (complete Q8)
- Ultrasound (complete Q11)
- MRI (complete Q14)
- Other (complete Q17)
- Do not recall details (proceed to Q20)

**F1****ACRIN 6666**For revised or corrected form, check box and fax to 215-717-0936. ACRIN Study 6666  
**PLACE LABEL HERE****Section II. Interval Imaging****8. Mammogram***(If no mammogram performed proceed to Q11)***Identify the study breast(s) on which a mammogram was performed in the past 11 months.****NOTE:** Interval mammography at study site should be reported on forms **IM** and/or **F6** as appropriate.

- Right (Complete Qs 8a, 8b and 9)
- Left (Complete Qs 8a, 8b and 10)
- Both (Complete Qs 8a-10a)

**8a. Date of most recent mammogram** \_\_\_\_-\_\_\_\_  
mm      yyyy**8b. Specify basis for decision to obtain the Mammogram**

Recommended by:

- Screening site
- MD who referred you for screening
- Another physician  
(identify type of physician)
  - Internist
  - Surgeon
  - Ob/Gyn
  - Other or unknown
- Family Member
- Someone else  
(specify relationship of this person to you)

**9. Mammographic Assessment of Right Breast**If No evaluation of Right Breast performed, proceed to Q10  
If outside study codes "4, suspicious", code as 4B.**9a. Reported Assessment for right breast**

- 1 Negative
- 2 Benign
- 3 Probably Benign
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion
- 5 Highly Suggestive of Malignancy
- Assessment unknown or incomplete  
(unable to obtain reported assessment, done at another imaging facility, BIRADS 0, or partial report)

**10. Mammographic Assessment of Left Breast**If No evaluation of Left Breast performed, proceed to Q11  
If outside study codes "4, suspicious", code as 4B**10a. Reported Assessment for left breast**

- 1 Negative
- 2 Benign
- 3 Probably Benign
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion
- 5 Highly Suggestive of Malignancy
- Assessment unknown or incomplete  
(unable to obtain reported assessment, done at another imaging facility, BIRADS 0, or partial report)

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**11. Ultrasound***(If no ultrasound performed proceed to Q14)***Identify the study breast(s) on which an Ultrasound was performed in the past 11 months.****NOTE:** Interval ultrasound at study site should be reported on forms **IM** and/or **F6** as appropriate.

- Right (Complete Qs 11a, 11b and 12)
- Left (Complete Qs 11a, 11b and 13)
- Both (Complete Qs 11a-13a)

**11a. Date of most recent ultrasound** \_\_\_\_-\_\_\_\_  
mm      yyyy**11b. Specify basis for decision to obtain the Ultrasound**

Recommended by:

- Screening site
- MD who referred you for screening
- Another physician  
(identify type of physician)
  - Internist
  - Surgeon
  - Ob/Gyn
  - Other or unknown
- Family Member
- Someone else  
(specify relationship of this person to you)

**12. Ultrasound Assessment of Right Breast**If No evaluation of Right Breast performed, proceed to Q13  
If outside study codes "4, suspicious", code as 4B**12a. Assessment for right breast**

- 1 Negative
- 2 Benign
- 3 Probably Benign
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion
- 5 Highly Suggestive of Malignancy
- Assessment unknown or incomplete  
(unable to obtain reported assessment, done at another imaging facility, BIRADS 0, or partial report)

**13. Ultrasound Assessment of Left Breast**If No evaluation of Left Breast performed, proceed to Q14  
If outside study codes "4, suspicious", code as 4B**13a. Assessment for left breast**

- 1 Negative
- 2 Benign
- 3 Probably Benign
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion
- 5 Highly Suggestive of Malignancy
- Assessment unknown or incomplete  
(unable to obtain reported assessment, done at another imaging facility, BIRADS 0, or partial report)

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PLACE LABEL HERE**

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**14. Contrast-enhanced breast MRI***(If no breast MRI performed proceed to Q17)***Identify the study breast(s) on which an MRI was performed in the past 11 months?**

- Right (Complete Qs 14a, 14b, and 15)
- Left (Complete Qs 14a, 14b and 16)
- Both (Complete Qs 14a-16a)

14a. Date of most recent breast MRI \_\_\_\_\_ - \_\_\_\_\_  
mm      yyyy**14b. Specify basis for decision to obtain the MRI**

Recommended by:

- Screening site
- MD who referred you for screening
- Another physician  
(identify type of physician)
  - Internist
  - Surgeon
  - Ob/Gyn
  - Other or unknown
- Family Member
- Someone else  
(specify relationship of this person to you)

**15. MRI Assessment of Right Breast**If No evaluation of Right Breast performed, proceed to Q16  
If outside study codes as "4, suspicious", code as 4B**15a. Assessment for right breast**

- 1 Negative
- 2 Benign
- 3 Probably Benign
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion
- 5 Highly Suggestive of Malignancy
- Assessment unknown or incomplete  
(unable to obtain reported assessment, done at another imaging facility, 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
- Another physician  
(identify type of physician)
  - Internist
  - Surgeon
  - Ob/Gyn
  - Other or unknown
- Family Member
- Someone else  
(specify relationship of this person to you)

**18. Other Imaging Assessment of Right Breast**If No evaluation of Right Breast performed, proceed to Q19  
If outside study codes as "4, suspicious", code as 4B**18a. Assessment for right breast**

- 1 Negative
- 2 Benign
- 3 Probably Benign
- 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion
- 5 Highly Suggestive of Malignancy
- Assessment unknown or incomplete  
(unable to obtain reported assessment, done at another imaging facility, 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)

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

Section III. Intervention

20. Were there any cyst aspirations, biopsies or surgeries on the study breast(s) in the past 11 months?

- No (Proceed to Q21)
- Yes, not previously reported (Complete Q20a)
- Yes, previously reported (Proceed to Q21)
- Unknown (Proceed to Q21)

**NOTE:** If yes and the procedures have not previously been reported, complete Q20a and Form(s) **BX**, **NL**, and **S1** as appropriate.

20a. Specify intervention and date (list all that apply below) If an intervention is on both breasts, list each breast on a separate line.

Intervention Code Table (Q20a)	
1	Cyst Aspiration
2	FNAB (complete <b>BX</b> )
3	Core Needle Biopsy (complete <b>BX</b> )
4	Excisional Biopsy (complete <b>NL</b> )
5	Lumpectomy (complete <b>S1</b> )
6	Sentinel Lymph Node (complete <b>S1</b> )
7	Axillary Lymph Node Dissection (complete <b>S1</b> )
8	Mastectomy (complete <b>S1</b> )
10	Other, specify (in details)
99	Specifics Unknown

Intervention	Date (mm-yyyy)	Details	R	L	N/A
<input type="text"/>	____-____	_____	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="text"/>	____-____	_____	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="text"/>	____-____	_____	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="text"/>	____-____	_____	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="text"/>	____-____	_____	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Section IV. Summary/Treatment

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

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

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

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

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

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

21c. Site of breast cancer

- Right
- Left
- Bilateral

**F1****ACRIN 6666**For revised or corrected form, check box and fax to 215-717-0936. ACRIN Study 6666  
**PLACE LABEL HERE**

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**22. Additional treatment for disease of the study breast(s)**

- No (Proceed to Q23)
- Yes, not previously reported (Complete Q22a)
- Yes, previously reported (Proceed Q23)
- 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.****Intervention Code Table (Q22a)**

- 1 Radiation Therapy
- 2 Systemic Chemotherapy
- 3 Other hormone manipulation
- 9 Other, specify (in details)
- 99 Specifics Unknown

Intervention	Date (mm-yyyy)	Details	R	L	N/A
<input type="text"/>	____-____	_____	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="text"/>	____-____	_____	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="text"/>	____-____	_____	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="text"/>	____-____	_____	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="text"/>	____-____	_____	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**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?**

- No (Stop and sign form)
- Yes (Complete Q23a)
- Unknown (Stop and sign form)

**23a. Provide name of trial** \_\_\_\_\_**Comments:** \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_  
Signature of person responsible for the data <sup>1</sup>\_\_\_\_\_  
Date Form Completed (mm-dd-yyyy)\_\_\_\_\_  
Signature of person entering data onto web <sup>2</sup>





ACRIN 6666

Post 36 Month Follow-up Form

ACRIN Study 6666

PLACE LABEL HERE

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

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

**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)



**ACRIN 6666**  
**Post 36 Month Follow-up Form**

ACRIN Study 6666  
**PLACE LABEL HERE**

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_  
 Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

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

**3. Does the suspicious abnormality correspond to a finding previously reported?**

- No (create a new lesion number on the BX form to report)
- Yes, detail lesion number: \_\_\_\_\_ (e.g. UR3, ML2, GR1, etc.)

**4. Will any biopsies be performed on any study breast(s) at this time?**

- No, detail reason: \_\_\_\_\_ (STOP and sign form)
- Yes, detail which breast (check all that apply):
  - Right (please complete a BX form for each biopsy)
  - Left (please complete a BX form for each biopsy)
- Unknown (STOP and sign form)

**Comments:** \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

\_\_\_\_\_  
 Signature of person responsible for the data

\_\_\_\_\_  
 Date Form Completed (mm-dd-yyyy)

\_\_\_\_\_  
 Signature of person entering data on web



# ACRIN Adverse Event Form

ACRIN Study

Case #

**PLACE LABEL HERE**

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

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.

AE Description	AE Short Name CTCAE v3.0	CTCAE Grade	Attribution	1 = Expected 2 = Unexpected	AdEERS Submitted for SAEs	Action Taken	Outcome	Date of AE Onset and Resolution  (mm-dd-yyyy); check box "on-going" if the AE is on-going at the time of report  <input type="checkbox"/> On-going
		1 = Mild 2 = Moderate 3 = Severe 4 = Life threatening or disabling 5 = Fatal	1 = Unrelated 2 = Unlikely 3 = Possible 4 = Probable 5 = Definite		1 = No 2 = Yes	1 = None 2 = Medication Therapy 3 = Procedure 4 = Hospitalization 5 = Other	1 = Recovered 2 = Improved 3 = Ongoing 4 = Death 5 = Unknown	
1								Start date: ____ - ____ - ____  Resolution date: ____ - ____ - ____  <input type="checkbox"/> On-going
2								Start date: ____ - ____ - ____  Resolution date: ____ - ____ - ____  <input type="checkbox"/> On-going
3								Start date: ____ - ____ - ____  Resolution date: ____ - ____ - ____  <input type="checkbox"/> On-going

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.  
 <<Page \_\_\_\_ of \_\_\_\_>>

Investigator Signature \_\_\_\_\_

Date Form Completed (mm-dd-yyyy) \_\_\_\_\_



**Screening Breast US  
Protocol Variation Form**

ACRIN Study 6666 Case #  
**PLACE LABEL HERE**

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant's Initials \_\_\_\_\_ Case No. \_\_\_\_\_

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

**INSTRUCTIONS:** In the instance a protocol requirement is not met please record the necessary information below. Complete a separate form for each case and for each event. Fax a copy to ACRIN Headquarters @ (215) 717-0936. If the protocol variation is found upon data or image review by headquarters staff, a copy of the headquarters generated PR form will be faxed to the site RA. Retain the form in the case study file.

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

- 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:
    - Initial
    - 12 months
    - 24 months
    - 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.

- Participant withdrew consent for MRI substudy only. Date of withdrawal: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_ (mm-dd-yyyy)
  - No further contact or follow-up per participant
  - No further contact, follow-up or permission to use data per participant
- MRI ineligible participant registered for MRI substudy
- 24 month study screening MRI interpretation done by radiologist not approved as a qualified MRI investigator in protocol 6666
- MRI participant had MRI more than 8 weeks after 24 month study ultrasound and mammogram (detail reason in Q2)
- Case enrolled under expired IRB approval/FWA
- Other, specify: \_\_\_\_\_  
\_\_\_\_\_

**2. Describe The Protocol Event Reported Above** \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

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

**3. Deviations**

- None
- Breast density insufficient
- Incorrect US transducer utilized
- No images documenting flow
- Images without spatial compounding not performed
- Images with spatial compounding not performed
- Mammogram image quality insufficient
- US image quality insufficient
- MRI image quality insufficient
- Imaging not done within 2 weeks of each other
- Mammogram images lost, unable to archive, date of exam \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_ (mm-dd-yyyy)
- US images lost, unable to archive, date of exam \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_ (mm-dd-yyyy)
- Fewer than the required number of mammogram images received, date of exam \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_ (mm-dd-yyyy)
- Fewer than the required number of US images received, date of exam \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_ (mm-dd-yyyy)

**4. Comments** \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_  
Person responsible for data

Date form completed \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_ (mm-dd-yyyy)

**HQ Use Only**

\_\_\_\_\_  
HQ Research Associate

Date form completed \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_ (mm-dd-yyyy)



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
O 1 No
O 2 Yes

4b. 2nd review date \_\_\_\_-\_\_\_\_-\_\_\_\_
Acceptable
O 1 No
O 2 Yes

5. US SYSTEM UNDER REVIEW:
O Philips/ATL Model \_\_\_\_\_
O Siemens/Acuson Model \_\_\_\_\_
O GE Model \_\_\_\_\_
O Toshiba Model \_\_\_\_\_
O Other specify \_\_\_\_\_

IMAGE QUALITY

6. DOES IMAGING MEET PROTOCOL SPECIFICATIONS?
O 1 No, Detail \_\_\_\_\_
O 2 Yes

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

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

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

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

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

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

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

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

10. OVERALL US IMAGE QUALITY
O Unacceptable (proceed to Q10a)
O Minor deficiencies, but acceptable (proceed to Q10a)
O Acceptable (proceed to Q11)
O Good (proceed to Q11)

10a. Image size or field of view
O Too shallow
O Too deep
O Meets Standards

10b. Focal Zones
O Too anterior
O Too posterior
O Too many
O Meets Standards

10c. Gain
O Too Low
O Too high
O Meets Standards

Case # \_\_\_\_\_

Site # \_\_\_\_\_

**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** \_\_\_\_-\_\_\_\_-\_\_\_\_





