ACRIN Study 6666
PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

13. Family History of Breast Cancer

- o No (proceed to Q14)
- o Yes (complete Q13a and Q13b)
- o 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)
☐ Relative 1 w/breast cancer	☐☐	☐
☐ Relative 2 w/breast cancer	☐☐	☐
☐ Relative 3 w/breast cancer	☐☐	☐
☐ Relative 4 w/breast cancer	☐☐	☐

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

14. Family History of Ovarian Cancer

- o No (proceed to Q15)
- o Yes (complete Q14a and Q14b)
- o 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)
☐ Relative 1 w/ovarian cancer	☐☐
☐ Relative 2 w/ovarian cancer	☐☐
☐ Relative 3 w/ovarian cancer	☐☐
☐ Relative 4 w/ovarian cancer	☐☐

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

I1 **ACRIN 6666**

ACRIN Study 6666
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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

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

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

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

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

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

Yes, check all gene changes that apply:
- ☐ HNPCC
- ☐ PTEN
- ☐ p5
- ☐ Other

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

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

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

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

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

18c. Hodgkin's disease
- o No
- o Yes
- o Other, specify _____

19. Lifetime risk for breast cancer by **Gail Model:**

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

20. Lifetime risk for breast cancer by **Claus Model:**

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

Sign, date and proceed to I2 form

Comments: _____

_____ _____-_____-_____

Signature of person responsible for data[1] Date form completed (mm-dd-yyyy)

_____

Signature of person entering data onto the web[2]

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

I2 ACRIN 6666 Initial Evaluation Form Supplement

ACRIN Study 6666
PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

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

Instructions: The **I2** is completed through participant interview in addition to the **I1**. Both the RA and participant's signatures must appear on the completed form. If the participant is eligible based on 5-year Gail model risk (Q22 or Q23), then a printout of the Gail model risk must be included in the participant file.

21. Have you had a clinical breast examination in the past year?

o No (proceed to Q21a)
o Yes, provide date: ____-____ (mm-yyyy) (code 12/2100 if unknown)

21a. Do you perform regular self breast examination?

o No (proceed to Q22)
o Yes, monthly (proceed to Q22)
o 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?

o No (stop and sign form)
o Yes (proceed)

Please multiply the 5-year Gail Model risk (per Q22) by 1.5 and record value: |__|__|.|__| %

STOP and sign form.

Comments: _____

_____

_____

_____ _____-_____-_____

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

_____ _____

Signature of person entering data onto web [2] Participant signature

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

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

IA **ACRIN 6666**

Mammography Interpretation

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.** _____

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

1. Radiologist ID ☐☐☐☐☐☐☐

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

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

3a. Record actual months since study entry ☐☐

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

3c. Image Presentation
- o Film-Screen
- o Digital

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

4a. Date of most Recent Prior Standard View Mammogram

____-____-____(mm-dd-yyyy)

☐ Check box if date of prior Standard View Mammogram is unknown

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

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

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

8. Density of Breast Parenchyma (current exam)

8a. Subjective rating of % of breast where tissue is dense.

☐ R	☐ L
o Less than 25%	o Less than 25%
o 26-40%	o 26-40%
o 41-60%	o 41-60%
o 61-80%	o 61-80%
o Greater than 80%	o Greater than 80%
o Not applicable	o Not applicable

8b. Where is parenchyma dense? (check all that apply)

R	L	
☐	☐	Diffusely dense
☐	☐	Anteriorly
☐	☐	UOQ
☐	☐	Scattered focal areas
☐	☐	Not dense
☐	☐	Other, Specify_____

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

9a. Total number of lesion(s) you wish to describe (up to 4 separate lesions in each breast).
Note: If there are multiple bilateral benign appearing findings to be described, code as one lesion and describe largest one.

Right Breast ☐ **Left Breast** ☐

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

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

10b. Change in this lesion from prior mammogram?
- o New
- o Gone
- o Decreasing
- o Stable
- o Fluctuating bilateral circumscribed masses
- o Increasing
- o Other suspicious change
- o Increasing and other suspicious change
- o Not applicable, no prior

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

10d. Location (check all that apply)
Note: for multiple bilateral findings with similar appearances, check "bilateral, multiple" and indicate specific location of the largest such finding.

o Right	☐ upper
o Left	☐ lower
☐ Bilateral, multiple	☐ inner
☐ Axillary tail	☐ outer
☐ Retroareolar	☐ Central

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

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)
- o Circumscribed (select one)
  - o Fat-containing
  - o Not fat-containing
- o Microlobulated
- o Obscured
- o Indistinct
- o Spiculated

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

☐ Asymmetry (code type)
- o Focal (complete)

Asymmetry seen on
- o One view
- o Both views

- o Global

☐ Calcifications (code morphology and distribution)

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

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

☐ Architectural Distortion

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

11. Assessment/Recommendations for this lesion

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

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

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

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

12. Are there additional lesions you wish to describe?
- o No (proceed to Q13)
- o 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

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

13c. Recommendation for right breast

- o Routine screening in 1 year
- o Diagnostic follow-up in 1 year
- o Short-interval follow-up in 6 months with mammography
- o Intervention and/or Additional Imaging (detail intervention and/or additional imaging)
  - ☐ **Intervention** (complete)
    - o Aspiration w/core biopsy if solid
    - o US-guided core biopsy
    - o Vacuum-assisted biopsy, guidance by US
    - o Vacuum-assisted biopsy, guidance by mammography
    - o Excisional biopsy
  - ☐ **Additional Imaging** (check all that apply)
    - ☐ 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

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

14c. Recommendation for left breast

- o Routine screening in 1 year
- o Diagnostic follow-up in 1 year
- o Short-interval follow-up in 6 months with mammography
- o Intervention and/or Additional Imaging (detail intervention and/or additional imaging)
  - ☐ **Intervention** (complete)
    - o Aspiration w/core biopsy if solid
    - o US-guided core biopsy
    - o Vacuum-assisted biopsy, guidance by US
    - o Vacuum-assisted biopsy, guidance by mammography
    - o Excisional biopsy
  - ☐ **Additional Imaging** (check all that apply)
    - ☐ 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 [1]

_____-_____-_____

Date Form Completed (mm-dd-yyyy)

_____

Signature of person entering data onto web [2]

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. _____

15. Additional Lesion Description

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

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

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.

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

15g. Is this lesion at the site of prior biopsy?
- o No
- o Yes (if yes, select procedure)
  - o Core/vacuum biopsy site with clip
  - o Core/vacuum biopsy site without clip
  - o Surgical biopsy site (select diagnosis)
    - o Benign
    - o Atypical/high-risk lesion
    - o Cancer site
    - o Unknown
  - o Biopsy details unknown
  - o FNAB
- o Not applicable, multiple bilateral circumscribed masses

16. Assessment/Recommendations for this lesion

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

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

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

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

17. Are there additional lesions you wish to describe?
- o No (proceed to Q13)
- o Yes (proceed to Q18)

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. _____

18. Additional Lesion Description

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

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

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.

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

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

19. Assessment/Recommendations for this lesion

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

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

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

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

20. Are there additional lesions you wish to describe?
- o No (proceed to Q13)
- o Yes (proceed to Q21)