A C R

# American College of Radiology Imaging Network Forms Index

ACRIN Study 6666
Screening Breast Ultrasound on High Risk Women
Case #: \_\_\_\_\_

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A C R I

# American College of Radiology Imaging Network Forms Package Index

**ACRIN Study 6666** 

	<u>Version Date</u>	*Submission <u>Date</u>
	Cost Effectiveness	<u>5 4.15</u>
CC	Cost Effectiveness Coversheet	
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V3	Willingness to Pay Ultrasound	
V4	Willingness to Pay Ultrasound	
V5	Willingness to Pay Ultrasound10-20-03	

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

"Copyright 2008" ACRIN 6666 10-17-08 2 of 2

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

<sup>&</sup>lt;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.

<sup>\*&</sup>quot;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 Study 6666 Case#

### **PLACE LABEL HERE**

<b>D</b> .		4	4.5	_
Re	ais	itra	atic	าก

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

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

	te the worksheet <b>prior</b> to consent/registration of the participant. A response coded <b>other than that prompted ()</b> renders a tudy enrollment. If assistance is needed regarding eligibility, please contact ACRIN Data Management at 215-574-3150.
_ 1.     I	Institutional person randomizing case (Name of individual randomizing case)
_ 2. (	(Y) Has the eligibility checklist (worksheet) been completed?
	(Y) Patient eligible for this study? Participant meets at least one of the six high-risk criteria defined in section 5.3)
	Date the study-specific consent form signed (Must be prior to study entry)
_ 5.	Participant's initials (Last, First) (L,F)
_ 6. \	Verifying physician
	Patient ID # ( <b>Optional</b> ; this is an institution's method of internally tracking a participant to a protocol case number; may code a series of 9's)
 _8. [	Date of birth (must be ≥ 25 years old)
1	Ethnic Category  1 Hispanic or Latino 2 Not Hispanic or Latino 9 Unknown
(10. 0	Omitted)
	Gender 2 Female
1 2 3	Participant's Country of Residence (if country of residence is <i>other</i> , complete Q18)  United States  Canada  Other  Unknown
_ 13. 2	Zip Code (US residents 5 digit zip code)
() 2 3 4 5 6 7	Participant's Insurance Status O Other Private Insurance Medicare Medicare and Private Insurance Medicaid Medicaid Medicaid Medicaid and Medicare Military or Veteran's Administration Self Pay No means of payment Unknown/Decline to answer

### ACRIN Study 6666 Case #

#### PLACE LABEL HERE

Institution \_\_\_\_\_ Institution No. Registration Participant's Name\_\_\_\_\_\_ Participant's I.D. No. \_ \_\_\_\_ 15. Any care at VA or military hospital Yes 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

### Eligibility Checklist Worksheet

### ACRIN Study 6666 Case#

### PLACE LABEL HERE

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

			Participant's Name	Participant's I.D. No
	25.	(N) Is participant enrolled in the first year of the any contrast-enhanced breast MRI trials, tomos breast ultrasound agents, or any breast cance	synthesis trial, any other trial of	
	26.	(N) Has the participant undergone contrast-end within the past 12 months?	hanced breast MRI or bilateral v	whole breast ultrasound
	27.	(N) Has the participant had any breast procedu breast surgical procedure) within the past 12 i		ation, core biopsy, or other
	28.	(N) Is the participant aware of any palpable ab of the breast(s) and or nipple(s), bloody disch		
	29.	(Y) Does the participant meet at least one of the	ne high-risk criteria as defined in	Section 5.3 of the protocol?
	30.	(N) Has the participant had breast cancer diag metastases from breast cancer or have known		s or have known distant
	31.	(N) Excluding breast cancer, basal cell or squa participant been diagnosed with cancer in the last five years or has residual dis	ast five years or has the particip	pant had a recurrence of
	32.	(N) Does the participant have breast implant(s)	) in the study breast(s)?	
	33.	(N) Is the participant pregnant, nursing, or does does she plan to become pregnant within the r		e she may be pregnant or
	34.	(Y) Does the participant understand and agree of the protocol?	to the follow-up requirements a	as outlined in Section 4.10
 mm dd y	35. /yyy	Date* study mammogram scheduled (mammogram performed at the same site)	gram and sonogram must be w	ithin 2 weeks of each other and
 mm dd y	36. /yyy	Date* of study sonogram scheduled (sonogram and performed at the same site)	m and mammogram must be wi	thin 2 weeks of each other
	37.	(N/Y) Is this the participant's first mammogram	? (If yes, answer Q38 and skip 0	Q39, if no, answer Q38 and Q39)
	38.	(Y) Is this a routine annual mammogram visit?		
	39.	(Y) Are the breast(s) heterogeneously dense of Section 5.3 of the protocol? (leave blank if no		defined in
Participant	Signature	)		
Signature o	r person	responsible for the datae or Principal Investigator)		
Date of forn	n complet	ted (mm-dd-yyyy)		
Signature o	f person	entering data on the web		
		ogram and or sonogram have been scheduled pleave the question blank.	ease provide the dates. If the im	aging appointments have not beer

## **I1**

### **ACRIN 6666**

## Screening Breast Ultrasound Initial Evaluation Form

### ACRIN Study 6666 PLACE LABEL HERE

1					
	Institution	Institution No			
	Participant Initials ————	Case No			

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

1.	<b>Date of birth</b> (mm/dd/yyyy) (age must be ≥ 25 years)
2.	Have you had a prior mammogram?  o No o Yes (If yes, complete Q2a and Q2b)
	2a. Date of last mammogram (record the last <u>annual</u> standard view exam date; if date unknown, code 12-2100) mm yyyy
	2b. Facility where mammogram was performed (Internal use only)  City, State (if not known, record "unknown" for Q2b)
3.	Have you had a prior breast ultrasound?  o No (Proceed to Q4) o Yes (If yes, complete Q3a, 3b, and 3c)
	3a. Type of breast ultrasound (check all that apply) (leave blank if unknown)  □ Targeted Right □ Targeted Left □ Whole breast Right □ Whole breast Left
	<b>3b.</b> Date of most recent breast ultrasound (if date unknown, code 12-2100) mm yyyy
	3c. Facility where breast ultrasound was performed (Internal use only) City, State (if not known, record "unknown" for Q3c)
4.	Have you had a prior MRI of the breast(s) with contrast?  o No o Yes (If yes, complete Q4a, 4b, and 4c)
	<ul><li>4a. Check which breast imaged with MR</li><li>☐ Right</li><li>☐ Left</li></ul>
	<b>4b.</b> Date of breast MRI (if date unknown, code 12-2100) mm yyyy
	4c. Facility where breast MRI performed (Internal use only) City, State (if not known, record "unknown" for Q4c)
5.	Age at first menstrual period (If unknown, code "99")
6.	How long ago was your last menstrual period?  o Within the last month o Less than 1 year ago o More than one year ago o Surgical menopause: year (If year is unknown code "2100") o Unknown/I cannot remember

1   ACRIN 6666		ACRIN Study 6666 PLACE LABEL HERE			
				Institution	Institution No
7.	Number of live bir	rths		Participant Initials	Case No
	7a. Age at	first live birth (If unkr	nown, code " <b>99</b> ")		
8.	0 A 0 B 0 C 0 D	reasts are different siz			
9.		ne use: ceed to Q10) mplete Q9a)			
	Hormone Use Co 1 Current 2 Not currently usin 3 Never used				
	Tamoxife Raloxifen Aromatas Birth Con Soy/over	e (EVISTA) e Inhibitor (e.g. Arin	Numbe Numbe nidex) Numbe Numbe	er of years and months.	used used used used used
10.	10. Have you had cosmetic breast surgery?  o No (proceed to Q11) o Yes (Complete Q10a)				
	10a. Record year	of most recent cos	smetic surgery (If the	year unknown, code "2100")	
		Right Breast	Left Breast		
	Reduction	[ (уууу)	(yyyy)		
	Lift	[уууу]	[уууу]		
	Implant placed	[уууу]	(yyyy)		
	Implant removed	[ (уууу)	[ (уууу)		

CONTINUED ON NEXT PAGE...

ACRIN 6666			ACRIN Study 6666 PLACE LABEL HERE
11. Prior Diagnosis of Breast	Cancer	Institution	Institution No
o No (proceed to		Participant Ini	itials Case No
o Yes			
	report is available report is not available eed to Q12)		
11a. Pathology (If year of	Pathological diagnosis unknown, c	ode "2100")	Pathology Code Table (Q11a)
Year Breast (see	Pathology Lymph nodes code table Q11a)	involved?	<ul> <li>1 Malignant, NOS</li> <li>2 Invasive ductal carcinoma*</li> <li>3 DCIS</li> </ul>
		o Unknown	<ul><li>Invasive ductal carcinoma and DCIS</li><li>Invasive lobular carcinoma</li></ul>
		Unknown	6 Invasive ductal and lobular carcinoma
	oN oY (	Unknown	7 Lymphoma 8 Metastatic from outside breast
		o Unknown	9 Other
		Olikilowii	Unknown     Invasive ductal carcinoma includes: medullary, colloid, mucinous, tubular
11b. Treatment (If year of	breast cancer treatment unknown, o	code "2100")	NOTE: LCIS (lobular carcinoma in situ) is not cancer, but a high-risk lesion to be listed in Q12.
<u>Year</u> <u>Breast</u>	Treatment Code Ta	abla (011b)	
LLL OR OL	1 Lumpectomy and ra		
	2 Lumpectomy alone		
	3 Mastectomy and ra 4 Mastectomy alone	diation	
11c. Was chemotherapy g	iven?	Г	Benign Biopsy result Code table A (Q12b)
o No o Yes (If yes, coo	de time point)		1 LCIS (lobular carcinoma in situ)
o Prior to su			2 Atypical lobular hyperplasia (ALH) 3 Lobular neoplasia, NOS
o After surg	• •		<ul><li>3 Lobular neoplasia, NOS</li><li>4 LCIS and ADH</li></ul>
o Both before	re and after surgery	1	5 Atypical ductal hyperplasia (ADH)
			6 Atypical Papilloma 7 Radial scar/complex sclerosing lesion
12. Prior cyst excision and/or			8 Atypical cytology (FNA)
Right breast	Left breast	1	9 Atypical, unsure of type
o Not on study o Never	o Not on study o Never	1	<ul><li>10 Columnar alteration with atypia</li><li>11 Papilloma</li></ul>
0 1	0 1		12 Sclerosing Adenosis
o 2 or 3	o 2 or 3	1	13 Fibroadenoma 14 Fibrocystic changes
o 4 or more	o 4 or more	1	15 Stromal fibrosis
		1	16 PASH
<u>-</u>	r benign biopsies other than cyst	(3)	17 Benign, unsure of details 99 Unknown
	nt occurrences If on worst lesion present, code table ag significance; if year of biopsy is unkl	L	
Year Breas	st Biopsyresult 1	ype of Biopsy	
<u>iear</u> <u>biea</u> :		ee code table B)	Type of Biopsy code table B (Q12b)  1 Fine needle aspiration (FNA) only
o R o	L		2 Core biopsy +/- initial FNA 3 Excision
o R o	L		4 Any needle biopsy and excision 99 Unknown

o R o L

o R o L

11 ACRIN 6666		tudy 6666 ABEL 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	ble C (Q13b)	
	east e 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, on the second sec	, 35)	
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)	

	11	ACRIN 6666	PLACE LABEL HERE		
_			Institution		itution No.
fami		ou willing to answer questions about ial genetic tests?  No (proceed to Q18)		Initials Case No	
	0		17b. List 4 (d	closest) relatives:	
	15a.	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)	Code table for F  1 Mother  2 Sister  3 Daughter  4 Maternal Grandmot  5 Paternal Grandmot	6 Maternal Aunt 7 Paternal Aunt 8 Father ther 9 Other	Gene code table (Q17b)  1 BRCA-1  2 BRCA-2  99 Unknown or not sure  Gene
6.	Gene 0 0	Yes (complete Q16a-Q16c)	Family memb	per A with change per B with change per C with change per D with change	
	16a. 16b.	Changes in BRCA-1 gene o No o Yes o Unknown  Changes in BRCA-2 gene o No o Yes o Unknown	18. Prior radiation mediastinum  o No o Ye o Ur	_	, 18b and 18c) o Q19)
		Changes in other gene o No (proceed to Q17) o Yes o Unknown (proceed to Q17) check all gene changes that apply:  HNPCC PTEN p5 Other	if unkn 18c. Hodgk o No o Ye o Ot	record year of last r nown code "2100") kin's disease	
7.		Ny member (blood relative) with change in A-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)  Number of relatives with change in BRCA-1 or BRCA-2	Code 98 if no 35 and /or ha  20. Lifetime risk to which with the code 98 if no 35 and /or had a code 98 and /or had a code 98 if no 35 and /or had a code 98 if no 35 and /or had a code 98 if no 35 and /or had a code 98 if no 35 and /or had a code 98 if no 35 and /or had a code 98 if no 35 and /or had a code 98 if no 35 and /or had a code 98 if no 35 and /or had a code 98 if no 35 and /or had a code 98 if no 35 and /or had a code 98 if no 35 and /or had a code 98 if no 35 and /or had a code 98 if no 35 and /or had a code 98 if no 35 and /or had a code 98 if no 35 and /or had a code 9	is personal history of for breast cancer by ich printout) of applicable (e.g. no r and/or participant	Claus Model:
Si	gn, da	te and proceed to I2 form			
Cc	ommen	nts:			
Sig	gnatur	e of person responsible for data¹		Date form	completed (mm-dd-yyyy)
Si	gnatur	e of person entering data onto the web <sup>2</sup>			
		mation reported directly on the form has been obtained through of the participant must appear below.	participant interview or p	participant self-comple	etion,

Participant signature

## ACRIN 6666 Initial Evaluation Form Supplement

## ACRIN Study 6666 PLACE LABEL HERE

	Institution	Institution No
For revised or corrected form check box and fax to 215-717-0936.	Participant Initials	Case No
<b>Instructions:</b> The <b>I2</b> is completed through participant interview in addit form. If the participant is eligible based on 5-year Gail model risk (Q22 or		
21. Have you had a clinical breast examination in the past yea o No (proceed to Q21a) o Yes, provide date: (mm-yyyy) (code 12/2)		
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 h stop and sign form)	nas personal history of breast cal	ncer or LCIS, code 98.0,
If the 5-year risk by Gail Model is < 1.7%, stop and sign form	1.	
<ul> <li>23. Does the participant have extremely dense breast(s) (&gt;75</li> <li>o No (stop and sign form)</li> <li>o Yes (proceed)</li> </ul>	% dense) on prior mammograp	hy?
Please multiply the 5-year Gail Model risk (per Q22) by 1.5	5 and record value:	%
Comments:		
Signature of Person responsible for the data <sup>1</sup>	Date Fo	 rm Completed (mm-dd-yyyy)
Signature of person entering data onto web <sup>2</sup>	Participa	ant signature
The "person responsible for the data" refers to the individual who has	collated the data on this specific da	ata form
<sup>2</sup> The "person entering data" is the individual who enters the data from t	the specific form into the web data f	form.

### Mammography Interpretation

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

ACRIN Study 6666 PLACE LABEL HERE		
Institution	Institution No.	
Participant Initials	Case No	

winge per to	thin <b>2 weeks</b> of the sonogram and at the <u>same</u> site. The Radiol rforms(ed) the initial survey ultrasound and must <u>not</u> have reviewed	udy mammogram completes this form. Study mammogram must be ogist completing this form must <u>not</u> be the same Radiologist who study US prior to completing this form. Please note that comparison ent US examinations should be reviewed at the time of annual study		
1. Radiologist ID  2. Date of Study Interpretation		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 bilatera  10a. Lesion # (e.g. MR1, MB1, ML1 etc.) (Use # from previous exam if new use next sequential # Describe any new or suspicious findings first.)		
		O New O Gone O Decreasing O Stable O Fluctuating bilateral circumscribed masses O Increasing O Other suspicious change		
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	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.]		
8.	Density of Breast Parenchyma (current exam)  8a. Subjective rating of % of breast where tissue is dense.    R	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		

IA	If this is a revised or corrected form, please check (√) box and fax to 215-717-0936.
10f.	
10g.	□ 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  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 Not applicable, multiple bilateral circumscribed masses

### ACRIN Study 6666 PLACE LABEL HERE

Institution		_ Institution No		
Participant Initials		Case No.		
11. Asse	ssment/Recomme	ndations for this lesion		
11a.	% Likeli (best guess from (	ihood of malignancy for this lesion 0-100)		
11b.	Assessment for the control of the co	enign sion of Malignancy		
11c. Recommendation o Routine screening o Diagnostic follow-u o Short-interval follow o Intervention and/or (detail intervention ☐ Intervention (o o Aspiration w/o o US-guided co o Vacuum-assis o Vacuum-assis o Excisional bio ☐ Additional Ima ☐ Targeted Ultra ☐ Comparison to		in 1 year p in 1 year v-up in 6 months with mammography Additional Imaging and/or additional imaging) complete) core biopsy if solid re biopsy ted biopsy, guidance by US ted biopsy, guidance by mammography		
o No (	recommended for o No (proceed to Q1 o Yes (specify domin o Participant prefe o Cancer present o In this breast o In opposite br o Patient risk facto o Vaguely palpabl o Follow-up not re o Interval increase o Investigator und	2) nant reason) erence now east ors e easonable (>20% in volume for masses) us change		

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.
<ul> <li>13. Final assessment of right breast</li> <li>□ Not on study (proceed to Q14)</li> <li>13a.  \( \begin{align*} \begin{align*} \limits &amp; \text{Likelihood of malignancy for } \end{align*}</li> </ul>	14. Final assessment of left breast  Not on study (form complete, sign and date below)
right breast (best guess from 0-100)	14a. Likelihood of malignancy for left 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	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
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	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>	

IA	box and fax to 215-717-0936.	ACRIN Study 0000
	<u> </u>	PLACE LABEL HERE
15. Addi	itional Lesion Description	Institution Institution No
15a	Lesion # (e.g. MR1, MB1, ML1 etc.)	Participant Initials Case No
. ou.	(Use # from previous exam if new use next sequential #	
	Describe any new or suspicious findings first.)	15g. Is this lesion at the site of prior biopsy?
15b.	1 0	o No o Yes (if ves. select procedure)
	o New	o Yes (if yes, select procedure) o Core/vacuum biopsy site with clip
	o Gone o Decreasing	o Core/vacuum biopsy site without clip
	o Stable	o Surgical biopsy site (select diagnosis)
	o Fluctuating bilateral circumscribed masses	o Benign
	o Increasing	o Atypical/high-risk lesion o Cancer site
	Other suspicious change     Increasing and other suspicious change	o Unknown
	o Not applicable, no prior	o Biopsy details unknown
	I I I I I I I I I I I I I I I I I I I	o FNAB
15c.	mm X mm	o Not applicable, multiple bilateral circumscribed masses
	(largest diameter) (largest perpendicular dimension)	16. Assessment/Recommendations for this lesion
15d.	Location (check all that apply)	
	<b>Note:</b> for multiple bilateral findings with similar appearances, check "bilateral, multiple" and indicate	16a.
	specific location of the largest such finding.	16b. Assessment for this lesion
	o Right ☐ upper	o 1 Negative
	o Left	o 2 Benign
	☐ Bilateral, multiple ☐ inner☐ Axillary tail ☐ outer☐	o 3 Probably Benign
	□ Retroareolar □ Central	o 4A Low Suspicion of Malignancy
		o 4B Intermediate Suspicion o 4C Moderately High Suspicion
15e.	Distance from the nipple cm	o 5 Highly Suggestive of Malignancy
15f.	Lesion type (check all that apply)	16c. Recommendation for this lesion
	☐ Mass (select worst margin feature present)	o Routine screening in 1 year
	<ul><li>o Circumscribed (select one)</li><li>o Fat-containing</li></ul>	o Diagnostic follow-up in 1 year
	o Not fat-containing	o Short-interval follow-up in 6 months with mammography
	o Microlobulated	<ul> <li>Intervention and/or Additional Imaging (detail intervention and/or additional imaging)</li> </ul>
	o Obscured o Indistinct	□ Intervention (complete)
	o Spiculated	o Aspiration w/core biopsy if solid
	Associated features	o US-guided core biopsy
	0 No	o Vacuum-assisted biopsy, guidance by US
	<ul> <li>o Yes (check all that apply)</li> <li>□ Calcifications (detail below)</li> </ul>	o Vacuum-assisted biopsy, guidance by mammograph o Excisional biopsy
	☐ Architectural distortion	☐ <b>Additional Imaging</b> (check all that apply)
	☐ Skin thickening	☐ Targeted Ultrasound (lesion seen on mammography)
	☐ Dilated duct(s) ☐ Asymmetry (code type)	□ Comparison to prior mammograms is required
	o Focal (complete)	☐ Additional mammographic projections
	Asymmetry seen on	16d. Is this lesion assessed as probably benign AND
	o One view o Both views	recommended for intervention?
	o Global	o No (proceed to Q17)
	☐ Calcifications (code morphology and distribution)	o Yes (specify dominant reason)
	Morphology of calcifications (check all that apply)	o Participant preference
	☐ Coarse typically benign ☐ Milk of calcium	o Cancer present now
	☐ Coarse heterogenous	o In this breast o In opposite breast
	☐ Punctate (<0.5 mm, uniformly round)	o Patient risk factors
	☐ Amorphous/Indistinct	o Vaguely palpable
	<ul><li>☐ Pleomorphic</li><li>☐ Branching/Fine linear</li></ul>	o Follow-up not reasonable
	Distribution of calcifications (check all that apply)	o Interval increase (>20% in volume for masses)
	☐ Clustered	o Interval suspicious change
	☐ Multiple clusters (same morphology)	o Investigator uncertainty
	☐ Regional ☐ Linear	17. Are there additional lesions you wish to describe?
	☐ Segmental	O No (proceed to Q13)
	☐ Diffuse scattered	O Yes (proceed to Q18)
	☐ In mass or asymmetry ☐ Architectural Distortion	

box and fax to 215-717-0936.			PLACE LABEL HERE			
12	Addit	ional Lesion Descripti	ion	Inatitutia		
10.	Addit	ional Lesion Descripti	ion	Institutio	n	Institution No
	18a.		e.g. MR1, MB1, ML1 etc.)	Participa	nt Initials	Case No
		` .	exam if new use next sequential #. r suspicious findings first.)	18g	j. Is this lesion	n at the site of prior biopsy?
	18b.	Change in this lesion	n from prior mammogram?		o No	test massed way
		o New				es, select procedure) acuum biopsy site with clip
		o Gone o Decreasing			o Core/va	acuum biopsy site without clip
		o Stable				al biopsy site (select diagnosis)
		o Fluctuating bilateral of	circumscribed masses		o Beni o Atvp	gri ical/high-risk lesion
		<ul><li>o Increasing</li><li>o Other suspicious cha</li></ul>	ange		o Can	cer site
		o Increasing and other			o Unki	nown details unknown
		o Not applicable, no pri	or		o FNAB	details distributi
	18c.	mm X	C   mm		<ul> <li>Not applicat</li> </ul>	ole, multiple bilateral circumscribed masses
	100.	(largest diameter)	(largest perpendicular dimension)	19. Ass	sessment/Reco	ommendations for this lesion
	18d.	Location (check all th				
			ateral findings with similar	19a		Likelihood of malignancy for this lesion
			"bilateral, multiple" and indicate		(best guess	from 0-100)
		-	ne largest such finding.	19b	. Assessment	t for this lesion
		•	] upper ] lower		o 1 Nega	
			inner		o 2 Beni o 3 Prob	gn pably Benign
		☐ Axillary tail	outer			Suspicion of Malignancy
		☐ Retroareolar ☐	] Central		o 4B Inter	mediate Suspicion
	186	Distance from the ni	ipple cm			erately High Suspicion lly Suggestive of Malignancy
					· ·	
	18f.	Lesion type (check a	margin feature present)	19c		dation for this lesion eening in 1 year
		o Circumscribed (se	elect one)			follow-up in 1 year
		o Fat-containing o Not fat-contair			o Short-interva	al follow-up in 6 months with mammography
		o Microlobulated	Tilling			and/or Additional Imaging vention and/or additional imaging)
		<ul><li>o Obscured</li><li>o Indistinct</li></ul>				ation (complete)
		o Spiculated				ion w/core biopsy if solid
		Associated features	3			ded core biopsy n-assisted biopsy, guidance by US
		o No o Yes (check all	that apply)			m-assisted biopsy, guidance by mammograph
			ns (detail below)			nal biopsy
		<ul><li>☐ Architectura</li><li>☐ Skin thicker</li></ul>				nal Imaging (check all that apply) ed Ultrasound (lesion seen on mammography)
		☐ Dilated duct	t(s)			arison to prior mammograms is required
		<ul><li>Asymmetry (code ty o Focal (complete)</li></ul>			☐ Additio	nal mammographic projections
		Asymmetry seen	•	194	l le thie lesion	assessed as probably benign AND
		o One view o Both views		150		ed for intervention?
		o Global			o No (proceed	,
			e morphology and distribution) ifications (check all that apply)			y dominant reason) nt preference
		☐ Coarse typical			o Cancer p	·
		<ul><li>☐ Milk of calciur</li><li>☐ Coarse hetero</li></ul>			o In this	
			5 mm, uniformly round)		o In oppo o Patient ris	osite breast sk factors
		☐ Amorphous/In	distinct		o Vaguely p	
		☐ Pleomorphic ☐ Branching/Find	e linear			not reasonable
		Distribution of calcit	fications (check all that apply)			ncrease (>20% in volume for masses) uspicious change
		☐ Clustered ☐ Multiple cluste	ers (same morphology)			for uncertainty
		☐ Regional	(	20 Ara	there addition	nal lesions you wish to describe?
		□ Linear □ Segmental			No (proceed to Q1	_
		☐ Diffuse scatter	red		Yes (proceed to C	•
		☐ In mass or asy			(1	,
		☐ Architectural Distor	uon	<u></u>		

IA	If this is a revised o box and fax to 215	r corrected form, please check (√)	ACRIN Study 6666 PLACE LABEL HERE			
21. Addit	21. Additional Lesion Description				Institution No	
21a.	Lesion # M (Use # from previo	(e.g. MR1, MB1, ML1 etc.) us exam if new use next sequential #.	1 \	t Initials	Case No	
		or suspicious findings first.)	21g.		at the site of prior biopsy?	
21b.	o New o Gone o Decreasing o Stable o Fluctuating bilater o Increasing o Other suspicious	her suspicious change		o Core/vac o Core/vac o Surgical o Benigr o Atypic o Cance o Unkno o Biopsy d o FNAB	al/high-risk lesion er site own letails unknown	
21c.	(largest diameter)	X mm (largest perpendicular dimension)	22 Asse		e, multiple bilateral circumscribed masses  nmendations for this lesion	
21d.	Note: for multiple appearances, che	Il that apply) bilateral findings with similar ck "bilateral, multiple" and indicate f the largest such finding.	22a.	1 1 1 1	ikelihood of malignancy for this lesio	
21e. 21f.	o Right o Left □ Bilateral, multiple □ Axillary tail □ Retroareolar  Distance from the Lesion type (chec		22b. 22c.	o 4A Low S o 4B Interm o 4C Moder o 5 Highly	ive	
	o Circumscribed o Fat-contail o Not fat-col o Microlobulate o Obscured o Indistinct o Spiculated Associated featu o No o Yes (check	ning ntaining ed  ures all that apply) titions (detail below) tural distortion ckening duct(s)		o Routine scree o Diagnostic fol o Short-interval o Intervention ar (detail interventi o Aspiratio o US-guide o Vacuum- o Vacuum- o Excisiona	ning in 1 year low-up in 1 year follow-up in 6 months with mammography ind/or Additional Imaging intion and/or additional imaging) on (complete) in w/core biopsy if solid ed core biopsy i-assisted biopsy, guidance by US assisted biopsy, guidance by mammograpla al biopsy il Imaging (check all that apply) I Ultrasound (lesion seen on mammography son to prior mammograms is required	
	o Focal (compl Asymmetry se o One vie o Both vie	ete) een on w	22d.	Is this lesion a	al mammographic projections assessed as probably benign AND d for intervention?	
	Morphology of c  Coarse typ  Milk of cal  Coarse he  Punctate (  Amorphous  Pleomorph Branching/ Distribution of c	cium terogenous <0.5 mm, uniformly round) s/Indistinct nic Fine linear alcifications (check all that apply) usters (same morphology)  I uttered asymmetry	0 No	o Participant o Cancer pre o In this br o In oppos o Patient risk o Vaguely pa o Follow-up r o Interval inci o Investigator	dominant reason) preference esent now east ite breast factors lipable not reasonable rease (>20% in volume for masses) spicious change uncertainty  I lesions you wish to describe?	

	If this is a revised or corrected form, please check ( $\checkmark$ ) box and fax to 215-717-0936.	ACRIN Study 6666 PLACE LABEL HERE			
24. Addit	Additional Lesion Description			Institution No	
24a.	Lesion # (e.g. MR1, MB1, ML1 etc.) (Use # from previous exam if new use next sequential #.	Participan	t Initials	Case No	
24b.	Describe any new or suspicious findings first.)  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	24g.	o No o Yes (if yes, s o Core/vacuu o Core/vacuu o Surgical bio o Benign o Atypical/ o Cancer s o Unknowl o Biopsy deta o FNAB	n ails unknown	
24c.	(largest diameter) mm (largest perpendicular dimension)	25 Asse		multiple bilateral circumscribed r	
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.	25. Asse 25a.		selihood of malignancy for t	
	o Right	25b.	o 4B Intermed		
24e.	Distance from the nipple cm			uggestive of Malignancy	
24f.	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)	25c.	o Intervention and (detail intervention and (detail intervention or Aspiration or US-guided or Vacuum-as or Vacuum-as or Excisional I    Additional I    Comparison	ng in 1 year w-up in 1 year llow-up in 6 months with mamn /or Additional Imaging on and/or additional imaging) n (complete) w/core biopsy if solid core biopsy ssisted biopsy, guidance by US ssisted biopsy, guidance by ma	mmography ) mography)
	Asymmetry seen on o One view o Both views o Global	25d.	recommended f	sessed as probably benign or intervention?	AND
	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	O No	o Interval suspi o Investigator u	minant reason) reference ent now est breast actors able reasonable ase (>20% in volume for massectious change	,

IA	If this is a revised or corrected form, please check (√) box and fax to 215-717-0936.	ACRIN Study 6666 PLACE LABEL HERE		
27. Addit	27. Additional Lesion Description		Institution No.	
27a.	Lesion # (e.g. MR1, MB1, ML1 etc.) (Use # from previous exam if new use next sequential #	1 (	als Case No	
27b.	Describe any new or suspicious findings first.)  Change in this lesion from prior mammogram?  o New	0	is lesion at the site of prior biopsy? No Yes (if yes, select procedure)	
	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		Core/vacuum biopsy site with clip     Core/vacuum biopsy site without clip     Surgical biopsy site (select diagnosis)     o Benign     o Atypical/high-risk lesion     o Cancer site     o Unknown     Biopsy details unknown     FNAB	
27c.	(largest diameter) X (largest perpendicular dimension)		ot applicable, multiple bilateral circumscribed masses	
27d.	<b>Location</b> (check all that apply) <b>Note:</b> for multiple bilateral findings with similar appearances, check "bilateral, multiple" and indicate specific location of the largest such finding.	<b>28a.</b> (bes	% Likelihood of malignancy for this lesion t guess from 0-100)	
	o Right	0 0 0	essment for this lesion  Negative Benign Probably Benign  Low Suspicion of Malignancy Intermediate Suspicion	
27e.	Distance from the nipple cm	0	<ul><li>4C Moderately High Suspicion</li><li>Highly Suggestive of Malignancy</li></ul>	
27f.	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 Ro o Di o Sh o Int (d	commendation for this lesion continue screening in 1 year agnostic follow-up in 1 year cont-interval follow-up in 6 months with mammography cervention and/or Additional Imaging cetail 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	
	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	o No (proc	is lesion assessed as probably benign AND ommended for intervention? (proceed to Q29) (proceed to Q30)	

IA	If this is a revised or corrected form, please check (	ACRIN Study 6666 PLACE LABEL HERE		
30. Addi	tional Lesion Description	Institution Institution No		
30a.	Lesion # (e.g. MR1, MB1, ML1 etc.) (Use # from previous exam if new use next sequential #. Describe any new or suspicious findings first.)	Participant Initials Case No		
30b.	Change in this lesion from prior mammogram?  O New O Gone O Decreasing O Stable O Fluctuating bilateral circumscribed masses O Increasing O Other suspicious change O Increasing and other suspicious change O Not applicable, no prior	30g. Is this lesion at the site of prior biopsy?  o No o Yes (if yes, select procedure) o Core/vacuum biopsy site with clip o Core/vacuum biopsy site without clip o Surgical biopsy site (select diagnosis) o Benign o Atypical/high-risk lesion o Cancer site o Unknown o Biopsy details unknown o FNAB		
30c.	(largest diameter) X   mm (largest diameter) (largest perpendicular dimension)	o Not applicable, multiple bilateral circumscribed masses		
30d.		31. Assessment/Recommendations for this lesion  31a. Likelihood of malignancy for this lesion (best guess from 0-100)		
30e.	o Right	31b. Assessment for this lesion  o 1 Negative o 2 Benign o 3 Probably Benign o 4A Low Suspicion of Malignancy o 4B Intermediate Suspicion o 4C Moderately High Suspicion o 5 Highly Suggestive of Malignancy		
30f.	Lesion type (check all that apply)			
	Mass (select worst margin feature present)         o Circumscribed (select one)         o Fat-containing         o Not fat-containing         o Microlobulated         o Obscured         o Indistinct         o Spiculated         Associated features         o No         o Yes (check all that apply)	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		
	Asymmetry (code type)     o Focal (complete)     Asymmetry seen on     o One view	<ul> <li>☐ Comparison to prior mammograms is required</li> <li>☐ Additional mammographic projections</li> <li>31d. Is this lesion assessed as probably benign AND</li> </ul>		
	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)	recommended for intervention?  o No (proceed to Q32) o Yes (specify dominant reason) o Participant preference o Cancer present now o In this breast o In opposite breast o Patient risk factors o Vaguely palpable o Follow-up not reasonable o Interval increase (>20% in volume for masses) o Interval suspicious change o Investigator uncertainty		
	☐ Regional ☐ Linear ☐ Segmental ☐ Diffuse scattered ☐ In mass or asymmetry ☐ Architectural Distortion	<ul> <li>32. Are there additional lesions you wish to describe?</li> <li>O No (proceed to Q13)</li> <li>O Yes (proceed to Q33)</li> </ul>		

	Α	If this is a revised or corrected form, please check (√) box and fax to 215-717-0936.	ACRIN Study 6666 PLACE LABEL HERE		
33.	Additi	ional Lesion Description	Institution		Institution No
	33a.	Lesion # (e.g. MR1, MB1, ML1 etc.) (Use # from previous exam if new use next sequential #. Describe any new or suspicious findings first.)	Participan	t Initials	Case No
	33b.	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		O No Yes (if yes, sele O Core/vacuum O Core/vacuum O Surgical biops O Benign O Atypical/hig O Cancer site O Unknown O Biopsy details	biopsy site with clip biopsy site without clip sy site (select diagnosis) th-risk lesion sy unknown
	33c.	mm X   mm (largest diameter)			Itiple bilateral circumscribed masses
	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.	34a.		ihood of malignancy for this lesion 0-100)
		o Right □ upper o Left □ lower □ Bilateral, multiple □ inner □ Axillary tail □ outer □ Retroareolar □ Central	(		enign sion of Malignancy
		Distance from the nipple cm  Lesion type (check all that apply)	(		e Suspicion High Suspicion gestive of Malignancy
	331.		(	o Intervention and/or (detail intervention   Intervention (or Aspiration w/or US-guided correction or Vacuum-assis or Vacuum-assis or Excisional bio   Additional Image   Targeted Ultra	in 1 year up in 1 year w-up in 6 months with mammography Additional Imaging and/or additional imaging) complete) core biopsy if solid re biopsy sted biopsy, guidance by US sted biopsy, guidance by mammography upsy aging (check all that apply) asound (lesion seen on mammography)
		o Focal (complete) Asymmetry seen on o One view o Both views	34d.	☐ Additional ma	o prior mammograms is required mmographic projections ssed as probably benign AND
		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	I C	recommended for No (proceed to Fin O Yes (specify domin O Participant prefe O Cancer present O In this breast O In opposite br O Patient risk facto O Vaguely palpablo O Follow-up not re O Interval increase O Investigator unc	intervention?  all Assessment(s) Q13, Q14 etc.)  pant reason)  prence now  east ors e exasonable e (>20% in volume for masses) us change ertainty
		☐ In mass or asymmetry ☐ Architectural Distortion	Proceed to	o Final Assessm	ent(s), Q13, Q14

### **ACRIN 6666 Annual Survey Ultrasound Interpretation Form**

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: To be completed by the Radiologist who performs and interprets the survey breast ultrasound. Radiologist must not have seen or interpreted the participant's current routine mammogram, report, or IA form. Please note that comparison to prior breast ultrasound examinations is encouraged; however, neither prior nor current

t A. All Screenings (pages 1-3) JItrasound Equipment	4a. Was the scheduled exam performed?  O No (complete and stop, sign form)  Specify		
L. Marie Control	O Yes		
I. Manufacturer			
(check manufacturer and provide model in space provided)	5. Date of scan		
☐ Philips/ATL Model	mm-dd-yyyy		
☐ Siemens/Acuson Model	5a. Date of Interpretation		
☐ GE Model	mm-dd-yyyy		
□ Toshiba	22 ////		
☐ Other, specify	Note: Time recorded in Q6 is the (hr:min) format, e.g. 01:45.		
Tropodycese willingd			
. Transducers utilized	6. Time Radiologist entered room.		
2a. Center Frequency . MHz and Range:	o rime Radiologist emerca room.		
	Time scan initiated		
(high end) MHz to	Time scan completed		
(low end) MHz linear array			
iow ond) witz illiodi diray	Time Radiologist exited room		
2b. Transducer Width (at least 38mm)	7 Oursell and the second of th		
☐ 38 mm	7. Survey scanning was performed (check all that apply)		
□ 50 mm	☐ Conventional mode		
☐ Other, specify : ☐ ☐ mm	☐ With spatial compounding		
2c. Was a second transducer used?	☐ With tissue harmonic imaging		
O No (proceed to Q3)	8. Which breast(s) evaluated?		
O Yes (proceed to Q2d and Q2e)	O Bilateral		
	O Right breast only		
2d. Center frequency MHz and range	O Left breast only		
	On District the willer		
(high end) MHz to	8a. Did you scan the axilla?		
L L (low end) MHz	O Yes (If yes, code side scanned)		
, ,	O Bilateral		
2e. Transducer width of second transducer	O Right axilla only		
□ 38 mm	O Left axilla only		
□ 50 mm	9. Comparison is made to prior US?		
☐ Other, specify: ☐☐☐ mm	O None (never had US)		
	O Not available		
3. Reader ID#	O Yes (check all that apply)		
	☐ Targeted Right		
3a. Radiologist performing exam	☐ Targeted Left ☐ Whole breast Right		
	Date of prior study:		
	☐ Whole breast Left		
(Last, First)	Date of prior study: (if different from right		
Time point in study     Initial screening			
o 12 month screening			
o 24 month screening			

IS		nis is a revis m, please ch	sed or corrected neck box				ACRIN Study PLACE LAB	
						Institution _		Institution No.
10. Grea	atest o	depth (thic	kness) of Brea	st by ultraso	und	Participant	Initials	Case No.
0 2 0 3 0 4 0 5 0 6		cm ccm ccm ccm ccm ccm ccm ccm ccm ccm	eft 0 < 2 cm 0 2.0-2.9 cm 0 3.0-3.9 cm 0 4.0-4.9 cm 0 5.0-5.9 cm 0 6.0-6.9 cm 0 >7 cm 0 not applicabl	e				
	_	nd Echote	xture					
	H   D   F   <b>R</b>	lomogeneous biffusely Heterocally Hetero kight Lef 1000	erogeneous ogeneous (If foca f <u>t</u> IOQ IQ OQ	ally heterogeno	us, code <u>all</u> applica	able quadrants)		
o No	o (prod	ceed to Q1	sts identified? 2c) d to Q12a)					
	12a.	□ Right □ Left	o Solitary o Solitary		0 numerous (≥4) 0 numerous (≥4)			
	12b.	Detail Lar	-				Depth from	
	,	<u>Breast</u>	(report	<b>kface</b> on hour and 1/2 0=0700, 12:30=1		ple	skin to center of cyst	<b>Largest Dimension</b>
		o <b>R</b> o <b>L</b>	0.9.7.0	o' clock	1 1	cm	to nearest 0.5 cm)	L   mm
	12c.	O No (pr O Yes (l	roceed to Q13) f yes, detail bel Number or	previously encession # oncession # oncessi	ons from any prion	s now gone s	since last annual scre	ening.
0 No 0 Yo 0 0	o (prodes (col Bilatera Right b	ceed to Q1 mplete and			sts identified?			

If this is a revised or corrected	ACRIN Study 6666
If this is a revised or corrected form, please check box	PLACE LABEL HERE
	Institution Institution No
	Participant Initials Case No
14. Final Assessment of Right Breast	17. Final Assessment of Left Breast
<b>14a.</b> □ <b>Not on study</b> (proceed to Q17)	<b>17a.</b> □ <b>Not on study</b> (sign and date form)
14b. Likelihood of malignancy for the right breast (best guess from 0-100)	17b. Likelihood of malignancy for the left breast (best guess from 0-100)
15. Final assessment for the entire right breast	18. Final assessment for the entire <u>left</u> 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  16. Recommendation for right breast o Routine screening in one year	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  19. Recommendation for left breast o Routine screening in one year
o Diagnostic follow-up in one year o Short-interval follow-up in 6 months with US o Intervention and/or Additional Imaging (detail intervention and/or additional imaging)    Intervention   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 Mammo   O 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	o Diagnostic follow-up in one year o Short-interval follow-up in 6 months with US o Intervention and/or Additional Imaging (detail intervention and/or additional imaging)    Intervention   OAspiration w/core biopsy if solid   OUS-guided core biopsy   OVacuum-assisted biopsy, guidance by US   OVacuum-assisted biopsy, guidance by Mammo   OExcisional 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>	
Signature of person entering data onto web <sup>2</sup>	

	S If this is a re form, please	vised or corrected check box		n	ACRIN Study 6	
	ioiiii, picase			_  P	PLACE LABEI	
Dort	B Positivo Eine	dings (pages 4-27)	as pooded	Institution	In	stitution No.
				Participant Init	ialsC	ase No
20.		han simple cysts (maxim	, ,			
		findings/lesions other than re multiple bilateral similar-a				
	,	1	•		,-	
	20b. Lesion # U	(e.g. UR1, UB1, UL1 umbering from initial study s		is the first examination	on, begin with R1 for the	first lesion in the right
	breast, R2 for th	e second lesion in the right	t breast etc. If the finding	g is new since a prio	r study sonogram, use r	next sequential #. Describe
	any new or susp for <u>all</u> reportable	picious findings first. <u>Locatio</u> e findings).	on, distance from nipple,	depth to lesion cen	ter and <u>measurements</u> a	are <u>completed</u>
	<del>-</del> ·	esion" seen on a previo	us sonogram includin	g any sonograms	performed prior to s	study enrollment?
	o Not appli	icable, no prior breast sono		3 4 7 4 4 3 4 4		,
	o No o Yes					
	o Gone					
		ased in size since previous in size since previous exa				
	o Multipl	le bilateral circumscribed m				
		e since previous exam sed in size since previous	evam			
	o Other	suspicious change				
		sing and other suspicious on multiple bilateral circ		ves describe locat	tion and measurement	of largest mass
	o No	in muniple bilateral circ	umscribeu masses: n	yes, describe local	non and measurement	or largest mass.
	o Yes	Clockface	Distance from		from skin to	
	<u>Breast</u>	(report on the hour) (report on hour and 1/2 hour	<u>the nipple</u>		er of lesion erest 0.5 cm)	
		e.g. 7:00 = 0700, 12:30 = 1230)	)	<u>(50 1105</u>		
	o <b>R</b> o <b>L</b>	o' clock	cm		cm	
	20c. Lesion Size			Horizontal	Second	
	<u>Largest</u> <u>Horizontal</u>	() ITV —		oendicular Meas	Measured Plane o Trv	
	Meas (mm) D1	o Sag	as (mm) D2	(mm) D3	o Sag	Volume D1XD2XD3 ÷ 2
	<sub>mm</sub>	o Rad	<b>X</b>	mm	o Rad	
		o Arad			o Arad	Note: Volume is pro
	On the distribution of	o Oblique	0		o Perpendicular Obliq	ue grammed to be calcu- lated on line; however
	o No	at the site of prior biops	y ?			as verification, pleas
		es, select prior procedure)		ot diagnasia)		calculate volume base on horizontal, vertica
		racuum biopsy with clip (if pr racuum biopsy without marke				and perpendicular mea
	o Surgic o Ben	al biopsy site (if procedure w	vas performed, select dia	gnosis)		surements as a valida tion.
	o Atyp	oical/high-risk lesion				
	o Can o Unk	ncer site nown				
		details unknown				
	o FNAB o Not appli	icable, multiple bilateral circ	umscribed masses			
	20e. Special Case (	see choices below)				
	o No	on datail balow than proce	ad to 020a)			
		es, detail below then proce Case Features	ed to Q2011)			
		nplicated Cyst (Note: Do no				220: )
		complex cystic masses coor Homogeneous low-level e		ed to Qzor and maic	ate complex cystic at t	<b>√20</b> j.)
		Fluid-Debris Level				
		Mobile internal echoes  Multiple bilateral complica	ted cysts in company of	simple cysts		
		Multiple bilateral solid oval, o		, ,		
		Mass in or on skin Clustered microcysts				
	o Ir	ntraductal mass				
		ymph node Calcifications without a mas	S			
	o F	oreign body				
		Post-Surgical scar Other, specify:		_		
		, - <sub>1</sub>		_		

If this is a revised or corrected form, please check box	ACRIN Study 6666 PLACE LABEL HERE
	Institution Institution No
	Participant Initials Case No
20f. Shape O Oval O Two or three gentle lobulations O Round O Irregular	20n. Calcifications  O None  O Present (check all that apply)  ☐ Macrocalcifications (> 0.5 mm)  ☐ Microcalcifications in mass
20g. Orientation O Parallel to skin O Not parallel (includes round)	<ul> <li>☐ Microcalcifications outside mass</li> <li>20o. Lesion palpable in retrospect during sonography?</li> <li>O No</li> <li>O Yes</li> </ul>
20h. Margin  O Circumscribed  O Not circumscribed (If not circumscribed, choose dominant feature)  Indistinct  Angular  Microlobulated  Spiculated  20i. Boundary Zone	21. Likelihood of malignancy for this lesion (best guess from 0-100)  21a. Assessment for this lesion  o 1 Negative  o 2 Benign (complete Q21b)  o 3 Probably Benign  o 4A Low Suspicion of Malignancy  o 4B Intermediate Suspicion  o 4C Moderately High Suspicion
O Abrupt Interface O Echogenic Halo	o 5 Highly Suggestive of Malignancy  21b. Known benign by prior biopsy?
20j. Echo Pattern  O Anechoic  O Hyperechoic  O Complex cystic  O Hypoechoic with few tiny cystic areas	(only complete if Q21a = Benign) o No (proceed to Q22) o Yes (complete) o < 1 year ago o 1-2 years ago o > 2 years ago
O Isoechoic to fat O Mixed hyperechoic and hypoechoic O Hypoechoic to fat	22. Recommendation for this lesion  o Routine screening in one year o Diagnostic follow-up in one year o Short-interval follow-up in 6 months with US o Intervention and/or Additional Imaging
20k. Posterior Features  O None O Enhancement O Combined shadowing/enhancement O Shadowing	<ul> <li>(detail intervention and/or additional imaging)</li> <li>☐ Intervention</li> <li>o Aspiration w/core biopsy if solid</li> <li>o US-guided core biopsy</li> <li>o Vacuum-assisted biopsy, guidance by US</li> <li>o Vacuum-assisted biopsy, guidance by Mammo</li> <li>o Excisional biopsy</li> </ul>
20I. Surrounding Tissue  O No effect O Effect (check all that apply)  □ Duct changes □ Edema	□ 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
On an arda Para are at distanting	23. Is this lesion assessed as probably benign AND recommended for intervention?  o No (proceed to Q24) o Yes (specify dominant reason)
20m. Vascularity (flow)  O None  O Yes (check all that apply)  □ Present in lesion  □ Present immediately adjacent to lesion  □ Increased in surrounding tissue  O Not performed	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 Increased (> 20% in volume for masses) o Interval suspicious change o Investigator uncertainty

IS	If this is a revised or corrected form, please check box		N Study 6666 LABEL HERE
		Institution	Institution No.
		Participant Initials	Case No
24 For	locion evaluation, techniques used (check all th	act apply)	
	<b>lesion evaluation, techniques used</b> (check all the onventional imaging	ιαι αρριγ)	
	patial compounding		
	ower Doppler		
	issue Harmonic Imaging anoramic display		
	anoramic display		
24a	. If spatial compounding was used, what was	its influence? (please answer the follow	ving questions)
	o No influence (proceed to Q25)		
	o Influenced (please answer the following qu	uestions in bold)	
	Margin depiction		
	o Better		
	o Same		
	o Worse		
	Internal structure depiction		
	o Better		
	o Same		
	o Worse		
	Posterior feature depiction		
	o Better		
	o Same		
	o Worse		
	Confidence in lesion characterization		
	o Better		
	o Same		
	o Worse		
24b	. Change in likelihood of malignancy with spatia	al compounding?	
	o None		
	o Looks more benign with spatial compounding		
	O Looks more malignant with spatial compounding		
25. Are	there additional lesions you wish to describe?	•	
-U. A.C	o (proceed to Q14)		
o N			

		s is a revised or corrected please check box		P	ACRIN Study 66 LACE LABEL		
						titution No.	
26.	Additional <u>les</u>	ions other than simple cysts (	maximum of 4 per breas	t)		se No	
		l I		Participant initi	als Cas	se No	
	breast, R2 any new of for <u>all</u> rep	sion numbering from initial study s 2 for the second lesion in the right or suspicious findings first. <u>Locatio</u> ortable <u>findings</u> ).	curvey sonogram. If this is breast etc. If the finding on, distance from nipple, on	is new since a prior depth to lesion cente	study sonogram, use next r and <u>measurements</u> are <u>i</u>	sequential #. Describe completed	
	o Not a o No o Yes o Go o De o Sta o Mu o Inc o Ot o Inc	ecreased in size since previous exable in size since previous examaltiple bilateral circumscribed mass creased in size since previous exaber suspicious change creasing and other suspicious char "lesion" multiple bilateral circums of the size of t	ams ses fluctuating in size sin am ange umscribed masses? If	ce previous exam yes, describe locatio	on and measurement of la		
	Breast	<u>Clockface</u>	<u>Distance from</u>		om skin to		
		(report on the hour) (report on hour and 1/2 hour	the nipple		of lesion		
		e.g. 7:00 = 0700, 12:30 = 1230)		(to near	est 0.5 cm)		
	o <b>R</b> ol	L o' clock	cm		cm		
	26c. Lesion S	size					
	Larges			<u>Horizontal</u>	Second		
	Horizont	al Measured Plane Ve		endicular Meas	Measured Plane	Volume D1XD2XD3 ÷ 2	
	Meas (mm)	D1 o Trv mea	as (mm) D2	(mm) D3	o Trv		
		o Sag 🗸			o Sag		
		」mm oRad ▲ L	mm <b>X</b>	mm	o Rad	mm <sup>3</sup>	
		o Arad			o Arad	Note: Volume is pro-	
		o Oblique			o Perpendicular Oblique	grammed to be calcu-	
	26d. Is this le	sion at the site of prior biopsy	y?			lated on line; however, as verification, please calculate volume based	
	o No					on horizontal, vertical	
		es (if yes, select prior procedure) Core/vacuum biopsy with clip (if p	procedure performed as	act diagnosis)		and perpendicular mea-	
		Core/vacuum biopsy with clip (ii p				surements as a valida- tion.	
		Surgical biopsy site (if procedure					
		o Benign					
		o Atypical/high-risk lesion					
		o Cancer site o Unknown					
		Biopsy details unknown					
		FNAB					
	o No	ot applicable, multiple bilateral circu	umscribed masses				
	26e. Special C	Case (see choices below)					
	o No						
		es (if yes, detail below then procee	ed to Q26n)				
		<pre>pecial Case Features) o Complicated Cyst (Note: Do no</pre>	ot use this term for "com	olex cystic masses".			
		For complex cystic masses cod			e "complex cystic" at Q26	ij.)	
		☐ Homogeneous low-level e	choes				
		<ul><li>☐ Fluid-Debris Level</li><li>☐ Mobile internal echoes</li></ul>					
		☐ Multiple bilateral complicat	ted cysts in company of s	imple cysts			
		o Multiple bilateral solid oval, c					
		o Mass in or on skin					
		o Clustered microcysts					
		o Intraductal mass o Lymph node					
		<ul> <li>Lymph node</li> <li>Calcifications without a mass</li> </ul>	S				
		o Foreign body	-				
		o Post-Surgical scar					
	o Other, specify:						

If this is a revised or corrected form, please check box	ACRIN Study 6666 PLACE LABEL HERE
	Institution Institution No
	Participant Initials Case No
26f. Shape  O Oval O Two or three gentle lobulations O Round O Irregular  26g. Orientation O Parallel to skin O Not parallel (includes round)  26h. Margin O Circumscribed O Not circumscribed (If not circumscribed, choose dominant feature) Indistinct Angular	26n. Calcifications  O None O Present (check all that apply)  Macrocalcifications (> 0.5 mm)  Microcalcifications in mass  Microcalcifications outside mass  26o. Lesion palpable in retrospect during sonography? O No O Yes  27. Likelihood of malignancy for this lesion (best guess from 0-100)  27a. Assessment for this lesion O 1 Negative
☐ Microlobulated ☐ Spiculated	o 2 Benign (complete Q27b) o 3 Probably Benign o 4A Low Suspicion of Malignancy o 4B Intermediate Suspicion
26i. Boundary Zone O Abrupt Interface O Echogenic Halo	o 4C Moderately High Suspicion o 5 Highly Suggestive of Malignancy  27b. Known benign by prior biopsy?
26j. Echo Pattern O Anechoic O Hyperechoic O Complex cystic	(only complete if Q27a = Benign) o No (proceed to Q28) o Yes (complete) o < 1 year ago o 1-2 years ago o > 2 years ago
O Hypoechoic with few tiny cystic areas O Isoechoic to fat O Mixed hyperechoic and hypoechoic O Hypoechoic to fat	28. Recommendation for this lesion  o Routine screening in one year o Diagnostic follow-up in one year o Short-interval follow-up in 6 months with US o Intervention and/or Additional Imaging
26k. Posterior Features  O None O Enhancement O Combined shadowing/enhancement O Shadowing  26l. Surrounding Tissue O No effect O Effect (check all that apply)  □ Duct changes □ Edema	(detail intervention and/or additional imaging)  □ Intervention  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 Mammo  o 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
□ Cooper's ligament distortion □ Architectural distortion □ Skin thickening □ Skin retraction  26m. Vascularity (flow)  O None  O Yes (check all that apply) □ Present in lesion □ Present immediately adjacent to lesion □ Increased in surrounding tissue O Not performed	29. Is this lesion assessed as probably benign AND recommended for intervention?  o No (proceed to Q30) 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 Increased (> 20% in volume for masses) o Interval suspicious change o Investigator uncertainty

I	If this is a revised or corrected form, please check box		N Study 6666 LABEL HERE
		Institution	
		Participant Initials	Case No
0.	For lesion evaluation, techniques used (check all that app  ☐ Conventional imaging ☐ Spatial compounding	oly)	
	☐ Power Doppler ☐ Tissue Harmonic Imaging		
	□ Panoramic display		
	<b>30a.</b> If spatial compounding was used, what was its inf o No influence (proceed to Q31)	luence? (please answer the following	ng questions)
	o Influenced (please answer the following question	s in bold)	
	Margin depiction o Better		
	o Same		
	o Worse		
	Internal structure depiction		
	o Better o Same		
	o Worse		
	Posterior feature depiction		
	o Better		
	o Same o Worse		
	Confidence in lesion characterization		
	o Better		
	o Same o Worse		
	30b. Change in likelihood of malignancy with spatial com	pounding?	
	o None		
	<ul> <li>Looks more benign with spatial compounding</li> <li>Looks more malignant with spatial compounding</li> </ul>		
	Are there additional lesions you wish to describe?		
4	Are there additional lesions you wish to describe?		
1.	O No (proceed to Q14)		

_							
	If this is a revised or corrected form, please check box			ACRIN Study 6666 PLACE LABEL HERE			
32	Addition	nal lesions (	other than simple cysts	(maximum of 4 per breast)	Institution	In:	stitution No.
ŭ <u>-</u> .		1		(maximum of 4 per breast)	Participant Initi	als Ca	ase No
	brea any	ast, R2 for th	e second lesion in the righ picious findings first. <u>Location</u>	l etc.) survey sonogram. If this is th t breast etc. If the finding is on, distance from nipple, dep	new since a prior s	tudy sonogram, use nex	t sequential #. Describe
	o o	Not application Not application Not application Not application Not Yes of Gone of Decreasion Office Stable in Office Not Application Not Appl	ed in size since previous e size since previous exam- bilateral circumscribed mas d in size since previous ex- spicious change ag and other suspicious cha	xam ses fluctuating in size since am	previous exam s, describe location		
	<u>Bre</u>	<u>east</u>	(report on the hour) (report on hour and 1/2 hour)	the nipple	<u>center</u> c	of lesion	
			e.g. 7:00 = 0700, 12:30 = 1230		<u>(to neare</u>	<u>st 0.5 cm)</u>	
	o <b>I</b>	RoL	o' clock	cm		cm	
	Ho Meas	o No o Yes (if y o Core/\(\) o Core/\(\) o Surgio o Ben o Atyl o Can o Unk o Biopsy o FNAB o Not appli	o Try o Sag o Arad o Oblique  at the site of prior biops res, select prior procedure) racuum biopsy with clip (if racuum biopsy without mar ral biopsy site (if procedure righ bical/high-risk lesion neer site	ertical A-P Perpendas (mm) D2 (r	, select diagnosis)	Second Measured Plane O Trv O Sag O Rad O Arad O Perpendicular Oblique	Wolume D1XD2XD3 - 2
		o No o Yes (if y  (Special o Cor For  o M o M o M o L o C o F o F	es, detail below then proce  Case Features)  nplicated Cyst (Note: Do not complex cystic masses con Homogeneous low-level of Fluid-Debris Level  Mobile internal echoes	ot use this term for "comple de "No" for Q32e, proceed to echoes ated cysts in company of sim- circumscribed masses	o Q32f and indicate	geroomplex cystic at Q32	<u>2j.)</u>

If this is a revised or corrected form, please check box	ACRIN Study 6666 PLACE LABEL HERE
	Institution Institution No
	Participant Initials Case No
32f. Shape O Oval O Two or three gentle lobulations O Round O Irregular	32n. Calcifications  O None  O Present (check all that apply)  ☐ Macrocalcifications (> 0.5 mm)  ☐ Microcalcifications in mass
32g. Orientation O Parallel to skin O Not parallel (includes round)	☐ Microcalcifications outside mass  320. Lesion palpable in retrospect during sonography?  0 No 0 Yes
32h. Margin O Circumscribed O Not circumscribed (If not circumscribed, choose dominant feature) ☐ Indistinct ☐ Angular ☐ Microlobulated ☐ Spiculated	33. Likelihood of malignancy for this lesion (best guess from 0-100)  33a. Assessment for this lesion  o 1 Negative  o 2 Benign (complete Q33b)  o 3 Probably Benign  o 4A Low Suspicion of Malignancy
32i. Boundary Zone O Abrupt Interface O Echogenic Halo	o 4B Intermediate Suspicion o 4C Moderately High Suspicion o 5 Highly Suggestive of Malignancy  33b. Known benign by prior biopsy?
32j. Echo Pattern  O Anechoic  O Hyperechoic  O Complex cystic  O Hypoechoic with few tiny cystic areas	(only complete if Q33a = Benign) o No (proceed to Q34) o Yes (complete) o < 1 year ago o 1-2 years ago o > 2 years ago
O Isoechoic to fat O Mixed hyperechoic and hypoechoic O Hypoechoic to fat	<ul> <li>34. Recommendation for this lesion</li> <li>o Routine screening in one year</li> <li>o Diagnostic follow-up in one year</li> <li>o Short-interval follow-up in 6 months with US</li> <li>o Intervention and/or Additional Imaging</li> </ul>
<ul><li>32k. Posterior Features</li><li>O None</li><li>O Enhancement</li><li>O Combined shadowing/enhancement</li><li>O Shadowing</li></ul>	(detail intervention and/or additional imaging)  □ Intervention  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 Mammo
32I. Surrounding Tissue  O No effect O Effect (check all that apply)  Duct changes Edema	<ul> <li>Excisional biopsy</li> <li>Additional Imaging (check all that apply)</li> <li>Comparison to current mammogram is required (lesion seen on US)</li> <li>Comparison to prior mammograms is required</li> <li>Additional mammographic projections</li> </ul>
□ Cooper's ligament distortion     □ Architectural distortion     □ Skin thickening     □ Skin retraction	<ul> <li>35. Is this lesion assessed as probably benign AND recommended for intervention?</li> <li>o No (proceed to Q36)</li> <li>o Yes (specify dominant reason)</li> </ul>
32m. Vascularity (flow)  O None  O Yes (check all that apply)  □ Present in lesion  □ Present immediately adjacent to lesion  □ Increased in surrounding tissue  O Not performed	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 Increased (> 20% in volume for masses) o Interval suspicious change o Investigator uncertainty

If this is a revised or corrected form, please check box		Study <b>6666</b> LABEL HERE	
	Institution	Institution No	
	Participant Initials	Case No	
For lesion evaluation, techniques used (check all that ap	ply)		
☐ Conventional imaging			
☐ Spatial compounding ☐ Power Doppler			
☐ Tissue Harmonic Imaging			
☐ Panoramic display			
36a. If spatial compounding was used, what was its in	fluence? (please answer the follow	ving questions)	
o No influence (proceed to Q37)			
o Influenced (please answer the following question	ns in bold)		
Margin depiction			
o Better			
o Same			
o Worse			
Internal structure depiction			
o Better			
o Same			
o Worse			
Posterior feature depiction			
o Better			
o Same			
o Worse			
Confidence in lesion characterization			
o Better			
o Same			
o Worse			
36b. Change in likelihood of malignancy with spatial con	npounding?		
o None			
<ul> <li>Looks more benign with spatial compounding</li> </ul>			
<ul> <li>Looks more malignant with spatial compounding</li> </ul>			

37. Are there additional lesions you wish to describe?

o No (proceed to Q14)

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o Yes (proceed to Q38)

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	IS	If this is a reform, please	evised or corrected e check box				ACRIN PLACE I	Study 66 ABEL	
						Institution		Inst	itution No
38.	Additio	nal <u>lesions</u> o	ther than simple	cysts (maximum	of 4 per breas	Participant	Initials	Cas	se No
	bre	east, R2 for the	cious findings first.	study survey sor he right breast et	tc. If the finding	the first examina	ation, begin with R rior study sonogra	1 for the firs m, use next	t lesion in the right sequential #. Describe
	(	o Not applicable o No o Yes o Gone o Decrease o Stable in o Multiple b o Increased o Other sus o Increasing	d in size since previous ilateral circumscribe in size since previous change and other suspicious change multiple bilater  Clockfac	vious exam exam ed masses fluctuous exam ous change al circumscribe	ating in size sind	ce previous exam ves, describe loc	n cation and measu	rement of la	
	<u>Br</u>	<u>east</u>	(report on the (report on hour an e.g. 7:00 = 0700, 12	e <b>hour)</b> d 1/2 hour	Distance from the nipple	_	Depth from skin center of lesio to nearest 0.5 c	<u>n</u>	
		0 <b>R</b> 0 <b>L</b>		o' clock	cm			m	
	38c. Le	sion Size		O CIOCK		l		···	
	Ho Meas	this lesion at o No o Yes (if ye o Core/va o Core/va o Surgica o Beni o Atyp o Cand o Unkr	ical/high-risk lesion cer site	cedure) clip (if procedure out marker (if pro	P Perper D2  mm X  e performed, selectedure performed	ed, select diagno	o Trv o Sag o Rad o Arad o Perpendicu	<u>Plane</u>	words and the properties of t
			cable, multiple bilate	ral circumscribed	d masses				
	38e. Sp	o No o Yes (if ye  (Special o Com For (	see choices below)  ss, detail below ther  Case Features)  plicated Cyst (Note complex cystic mas  Homogeneous low  Fluid-Debris Level  Mobile internal ech  Multiple bilateral solid  ass in or on skin  ustered microcysts  traductal mass  mph node  alcifications without  oreign body  ost-Surgical scar  ther, specify:	: Do not use this ses code "No" fo -level echoes oes omplicated cysts oval, circumscril	s term for "compor Q38e, proceed in company of s	I to Q38f and ind		stic" at Q38j	.)

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If this is a revised or corrected form, please check box	ACRIN Study 6666 PLACE LABEL HERE			
	Institution	Institution No		
	Participant Initials	Case No		
38f. Shape	38n. Calcifications			
0 Oval	O None			
O Two or three gentle lobulations	O Present (check a	,		
0 Round	☐ Macrocalcificat	,		
O Irregular	☐ Microcalcificati			
38g. Orientation	☐ Microcalcificati	ons outside mass		
O Parallel to skin	38o. Lesion palpable	in retrospect during sonography?		
O Not parallel (includes round)	O No			
	O Yes			
38h. Margin				
O Circumscribed	39. Kikelihoo this lesion (best guess	d of malignancy for		
O Not circumscribed (If not circumscribed, choose dominant feature)				
□ Indistinct	39a. Assessment for	this lesion		
☐ Angular	o 1 Negative o 2 Benign (com	nplete Q39b)		
☐ Microlobulated	o 3 Probably Be			
☐ Spiculated	o 4A Low Suspic	ion of Malignancy		
38i. Boundary Zone	o 4B Intermediate o 4C Moderately	e Suspicion High Suspicion		
O Abrupt Interface		right Suspicion Jestive of Malignancy		
O Echogenic Halo	0, 00	,		
	<b>39b.</b> Known benign by (only complete if			
38j. Echo Pattern	o No (proceed to C			
O Anechoic	o Yes (complete)	,		
O Hyperechoic	o < 1 year ago			
O Complex cystic	o 1-2 years ago o > 2 years ago			
O Hypoechoic with few tiny cystic areas	0 > 2 years ago			
O Isoechoic to fat	40. Recommendation for the			
O Mixed hyperechoic and hypoechoic	o Routine screening in o Diagnostic follow-up in			
O Hypoechoic to fat	o Short-interval follow-u			
20k Bactarian Factures	o Intervention and/or Ad	0 0		
38k. Posterior Features	(	d/or additional imaging)		
O None	☐ Intervention o Aspiration w/core	hioney if solid		
O Enhancement O Combined shadowing/enhancement	o US-guided core I			
O Shadowing		biopsy, guidance by US		
O Shadowing	o Vacuum-assisted o Excisional biopsy	biopsy, guidance by Mammo		
38I. Surrounding Tissue		ng (check all that apply)		
O No effect		urrent mammogram is required		
O Effect (check all that apply)	(lesion seen on L			
☐ Duct changes		ior mammograms is required		
☐ Edema	□ Additional mamm	ographic projections		
☐ Cooper's ligament distortion ☐ Architectural distortion	41. Is this lesion assessed	as probably benign AND		
☐ Skin thickening	recommended for inter	vention?		
☐ Skin retraction	o No (proceed to Q42)			
	o Yes (specify dominant r o Participant preference			
38m. Vascularity (flow)	o Cancer present now	-		
O None	o In this breast			
O Yes (check all that apply)	o In opposite breast			
☐ Present in lesion	o Patient risk factors o Vaguely palpable			
☐ Present immediately adjacent to lesion	o Follow-up not reasona	able		
☐ Increased in surrounding tissue	o Increased (> 20% in v			
O Not performed	o Interval suspicious ch o Investigator uncertain	S .		
	o investigator uncertain	· y		

If this is a revised or corrected form, please check box	ACRIN Study 6666 PLACE LABEL HERE		
	Institution	Institution No.	
	Participant Initials	Case No	
42. For lesion evaluation, techniques used (check all that a Conventional imaging Spatial compounding Power Doppler Tissue Harmonic Imaging Panoramic display  42a. If spatial compounding was used, what was its to No influence (proceed to Q43) Influenced (please answer the following question Better  O Better  O Same O Worse  Internal structure depiction O Better	influence? (please answer the follow	ving questions)	
o Same o Worse  Posterior feature depiction o Better o Same			
o Worse  Confidence in lesion characterization o Better o Same o Worse			
<ul> <li>42b. Change in likelihood of malignancy with spatial cool</li> <li>0 None</li> <li>0 Looks more benign with spatial compounding</li> <li>0 Looks more malignant with spatial compounding</li> </ul>	ompounding?		

- o No (proceed to Q14)
- o Yes (proceed to Q44)

	If this is a reform, please	evised or corrected e check box		P	ACRIN Study 66	
				Institution	Ins	titution No.
44. Addit	ional <u>lesions</u> of	ther than simple cysts (maxim	num of 4 per breast)	Participant Init	ialsCa	se No
( b	reast, R2 for the	(e.g. UR1, UB1, UL1 etc.) mbering from initial study survey e second lesion in the right breas cious findings first. Location, dis findings).	st etc. If the finding is	e first examination new since a prior s	, begin with R1 for the firs	t lesion in the right sequential #. Describe
44b. V	o Not applicable o No O Yes O Gone O Decrease O Stable in O Multiple bo Increased O Other sus O Increasing	n" seen on a previous sono de, no prior breast sonograms d in size since previous exam size since previous exam illateral circumscribed masses flu in size since previous exam spicious change g and other suspicious change n" multiple bilateral circumscri	nctuating in size since	previous exam		
<u> </u>	<u>Breast</u>	Clockface (report on the hour) (report on hour and 1/2 hour e.g. 7:00 = 0700, 12:30 = 1230)	Distance from the nipple	cent	n from skin to der of lesion arest 0.5 cm)	
	o <b>R</b> o <b>L</b>	o' clock	cm		cm	
44c. L	esion Size					
<u>Me</u>	s this lesion at 0 No 0 Yes (if ye 0 Core/va 0 Surgica 0 Beni 0 Atypi 0 Canc 0 Unkr 0 Biopsy 0 FNAB	ical/high-risk lesion cer site	mm X  dure performed, select procedure performed, select diag	select diagnosis)	Measured Plane o Trv o Sag o Rad o Arad o Perpendicular Oblique	wolume D1XD2XD3 - 2  mm³  Note: Volume is programmed to be calculated on line; however, as verification, please calculate volume based on horizontal, vertical and perpendicular measurements as a validation.
44e. \$	Special Case (s o No o Yes (if ye (Special o Com For (	ee choices below)  s, detail below then proceed to Case Features) plicated Cyst (Note: Do not use complex cystic masses code "Note Homogeneous low-level echoes Fluid-Debris Level Mobile internal echoes Multiple bilateral complicated cysultiple bilateral solid oval, circums ass in or on skin ustered microcysts traductal mass mph node alcifications without a mass oreign body ost-Surgical scar her, specify:	Q44n) this term for " <b>comple</b> : " for Q44e, proceed to	Q44f and indicate	e "complex cystic" at Q44	j.)

If this is a revised or corrected form, please check box	ACRIN Study 6666 PLACE LABEL HERE			
	Institution Institution No			
	Participant Initials Case No			
44f. Shape  O 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	44n. Calcifications  O None  O Present (check all that apply)  Macrocalcifications (> 0.5 mm)  Microcalcifications in mass  Microcalcifications outside mass  44o. Lesion palpable in retrospect during sonograpl  O No  O Yes  45. Likelihood of malignancy for this lesion (best guess from 0-100)  45a. Assessment for this lesion  O 1 Negative  O 2 Benign (complete Q45b)  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  (only complete if Q45a = Benign)  O No (proceed to Q46)  O Yes (complete)  O < 1 year ago  O 1-2 years ago			
O Hypoechoic with few tiny cystic areas O Isoechoic to fat O Mixed hyperechoic and hypoechoic O Hypoechoic to fat  44k. Posterior Features O None O Enhancement O Combined shadowing/enhancement O Shadowing  44l. Surrounding Tissue O No effect O Effect (check all that apply) Duct changes Edema Cooper's ligament distortion Architectural distortion Skin retraction  44m. Vascularity (flow) O None O Yes (check all that apply) Present in lesion Present immediately adjacent to lesion Increased in surrounding tissue O Not performed	46. Recommendation for this lesion  o Routine screening in one year o Diagnostic follow-up in one year o Short-interval follow-up in 6 months with US o Intervention and/or Additional Imaging (detail intervention and/or additional imaging)    Intervention   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 Mammo   o 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)   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 Increased (> 20% in volume for masses)   o Interval suspicious change   o Investigator uncertainty			

If this is a revised or corrected form, please check box		RIN Study 6666 LABEL HERE
	Institution	Institution No
	Participant Initials	Case No
3. For lesion evaluation, techniques used (check all t	that apply)	
<ul><li>☐ Conventional imaging</li><li>☐ Spatial compounding</li></ul>		
☐ Power Doppler ☐ Tissue Harmonic Imaging		
☐ Panoramic display		
<b>48a. If spatial compounding was used, what was</b> o No influence (proceed to Q49)	s its influence? (please answer the follow	wing questions)
o Influenced (please answer the following q	uestions in bold)	
Margin depiction	•	
o Better		
o Same		
o Worse		
Internal structure depiction		
o Better		
o Same o Worse		
o worse		
Posterior feature depiction		
o Better		
o Same		
o Worse		
Confidence in lesion characterization		
o Better		
o Same		
o Worse		
48b. Change in likelihood of malignancy with spati	ial compounding?	
o None		
O Looks more benign with spatial compounding		
<ul> <li>Looks more malignant with spatial compounding</li> </ul>		

o No (proceed to Q14)

o Yes (proceed to Q50)

_									
	IS	If this is a reform, please	evised or corrected check box				ACRINS PLACE L	Study 66 ABEL	
						Institution		Inst	itution No
50.	Additio	nal <u>lesions</u> ot	ther than simple cys	ts (maximum of	f 4 per breast	Participant	Initials	—— Cas	se No.
	bre any	ast, R2 for the	cious findings first. Loc	dy survey sonog right breast etc.	If the finding	the first examina s new since a pr	ition, begin with R1	for the first	t lesion in the right sequential #. Describe
	(	Not applicable No Yes O Gone O Decreased O Multiple bi O Increased O Other sus O Increasing	n" seen on a previous le, no prior breast sono din size since previous exailateral circumscribed rin size since previous picious change and other suspicious multiple bilateral control of the size since previous picious change and other suspicious ringulateral control of the size since previous picious change and other suspicious ringulateral control of the size since previous picious change and other suspicious ringulateral control of the size since previous pictures and the size since previous pictures and the size since previous pictures and the size since previous previ	s exam am nasses fluctuatir exam change circumscribed	ng in size sind	e previous exam res, describe loc	ation and measure	ement of la	
	<u>Br</u>	<u>east</u>	Clockface (report on the ho		istance froi the nipple	_	epth from skin to center of lesion	2	
			(report on hour and 1/	2 hour	the mpple		nearest 0.5 cm	)	
		o <b>R</b> o <b>L</b>	e.g. 7:00 = 0700, 12:30 =	elock	cm		cn	ı	
	50c. Les	sion Size							
	Ho Meas	this lesion at o No o Yes (if yea o Core/va o Core/va o Surgica o Benig o Atypi o Canc o Unkn o Biopsy o FNAB	o Sag o Rad o Arad o Oblique the site of prior bid s, select prior procedu accuum biopsy with clip accuum biopsy site (if proced gn cal/high-risk lesion eer site	ure) (if procedure p marker (if proce dure was perfori	Perpe	ed, select diagno	o Trv o Sag o Rad o Arad o Perpendicul	<u>'lane</u>	Volume D1XD2XD3 - 2  mm³  Note: Volume is programmed to be calculated on line; however, as verification, please calculate volume based on horizontal, vertical and perpendicular measurements as a validation.
	50e. Sp	o No o Yes (if yes (Special o Comp For c  o Mu o Ma o Clu o Lyi o Ca o Fo o Po	see choices below) s, detail below then pr Case Features) plicated Cyst (Note: Do complex cystic masses Homogeneous low-lev Fluid-Debris Level Mobile internal echoes Multiple bilateral comp ultiple bilateral solid over ass in or on skin ustered microcysts raductal mass mph node alcifications without a regin body sst-Surgical scar her, specify:	o not use this te code "No" for C rel echoes dicated cysts in a	erm for " <b>comp</b> Q50e, proceed company of si	to Q50f and ind		tic" at Q50j	.)

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If this is a revised or corrected form, please check box	ACRIN Study 6666 PLACE LABEL HERE
	Institution Institution No
	Participant Initials Case No
50f. Shape O Oval O Two or three gentle lobulations O Round O Irregular	<ul> <li>50n. Calcifications</li> <li>0 None</li> <li>0 Present (check all that apply)</li> <li>☐ Macrocalcifications (&gt; 0.5 mm)</li> <li>☐ Microcalcifications in mass</li> </ul>
50g. Orientation O Parallel to skin O Not parallel (includes round)	□ Microcalcifications outside mass  50o. Lesion palpable in retrospect during sonography?  ○ No
50h. Margin  O Circumscribed  O Not circumscribed (If not circumscribed, choose dominant feature)  ☐ Indistinct ☐ Angular ☐ Microlobulated ☐ Spiculated	51.
50i. Boundary Zone O Abrupt Interface O Echogenic Halo	o 4B Intermediate Suspicion o 4C Moderately High Suspicion o 5 Highly Suggestive of Malignancy  51b. Known benign by prior biopsy?
50j. Echo Pattern O Anechoic O Hyperechoic O Complex cystic O Hypoechoic with few tiny cystic areas	(only complete if Q51a = Benign) o No (proceed to Q52) o Yes (complete) o < 1 year ago o 1-2 years ago o > 2 years ago
O Isoechoic to fat O Mixed hyperechoic and hypoechoic O Hypoechoic to fat	<ul> <li>52. Recommendation for this lesion</li> <li>o Routine screening in one year</li> <li>o Diagnostic follow-up in one year</li> <li>o Short-interval follow-up in 6 months with US</li> <li>o Intervention and/or Additional Imaging</li> </ul>
<ul><li>50k. Posterior Features</li><li>0 None</li><li>0 Enhancement</li><li>0 Combined shadowing/enhancement</li><li>0 Shadowing</li></ul>	<ul> <li>(detail intervention and/or additional imaging)</li> <li>☐ Intervention</li> <li>o Aspiration w/core biopsy if solid</li> <li>o US-guided core biopsy</li> <li>o Vacuum-assisted biopsy, guidance by US</li> <li>o Vacuum-assisted biopsy, guidance by Mammo</li> </ul>
50I. Surrounding Tissue  O No effect O Effect (check all that apply)  □ Duct changes □ Edema	<ul> <li>Excisional biopsy</li> <li>Additional Imaging (check all that apply)</li> <li>Comparison to current mammogram is required (lesion seen on US)</li> <li>Comparison to prior mammograms is required</li> <li>Additional mammographic projections</li> </ul>
<ul> <li>□ Cooper's ligament distortion</li> <li>□ Architectural distortion</li> <li>□ Skin thickening</li> <li>□ Skin retraction</li> </ul>	<ul> <li>53. Is this lesion assessed as probably benign AND recommended for intervention?</li> <li>o No (proceed to Q54)</li> <li>o Yes (specify dominant reason)</li> </ul>
50m. Vascularity (flow)  O None  O Yes (check all that apply)  □ Present in lesion  □ Present immediately adjacent to lesion  □ Increased in surrounding tissue  O Not performed	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 Increased (> 20% in volume for masses) o Interval suspicious change o Investigator uncertainty

S	If this is a revised or corrected form, please check box		ACRIN Study 6666 CE LABEL HERE
		Institution	Institution No.
		Participant Initials_	Case No
☐ Coi ☐ Spa ☐ Pov ☐ Tis: ☐ Par	esion evaluation, techniques used (check all that apply) nventional imaging atial compounding wer Doppler sue Harmonic Imaging noramic display  If spatial compounding was used, what was its influer o No influence (proceed to Q55) o Influenced (please answer the following questions in Margin depiction o Better o Same o Worse		ollowing questions)
	Internal structure depiction o Better o Same o Worse		
	Posterior feature depiction o Better o Same o Worse		
	Confidence in lesion characterization o Better o Same o Worse		
54b.	Change in likelihood of malignancy with spatial compout O None O Looks more benign with spatial compounding	nding?	

O Looks more malignant with spatial compounding

### 55. Are there additional lesions you wish to describe?

- o No (proceed to Q14)
- o Yes (proceed to Q56)

	S		evised or corrected e check box			F	ACRIN Study 6 PLACE LABE	
					I	nstitution	Ir	nstitution No
56.		ĺ	ther than simple cyst	s (maximum of 4 per		Participant Init	ialsC	ase No
	bre	ast, R2 for the	e second lesion in the ricious findings first. Loc	ly survey sonogram. If ight breast etc. If the fi	nding is ne	w since a prior	n, begin with R1 for the study sonogram, use nerestand measurements are	ext sequential #. Describe
	1	o Not applicate o No o Yes o Gone o Decrease o Stable in o Multiple b o Increased o Other sus o Increasing	d in size since previous size since previous exa illateral circumscribed m I in size since previous expicious change g and other suspicious	grams s exam m nasses fluctuating in si exam change ircumscribed masse  Distanc ur) the ni	ze since pose. s? If yes, efrom	evious exam  describe location  Dep  cel	on and measurement of the from skin to nter of lesion nearest 0.5 cm)	
		o <b>R</b> o <b>L</b>	o' c	lock	cm		cm	
	56c. Le	sion Size						
	Ho Meas	this lesion at o No o Yes (if ye o Core/va o Surgica o Beni o Atyp o Cana o Unka o Biopsy o FNAB o Not applicecial Case (so No o Yes (if ye o No o Yes (if ye	o Sag o Rad o Arad o Oblique  t the site of prior bic es, select prior procedu acuum biopsy with clip acuum biopsy site (if proced gn ical/high-risk lesion cer site	re) (if procedure performe narker (if procedure pure was performed, so	Perpendi (mr	select diagnosis)	Second Measured Plane O Trv O Sag O Rad O Arad O Perpendicular Obliqu	wolume D1XD2XD3 - 2
		o Com For o  M O M O Ci O Ly O Fo O Po	plicated Cyst (Note: Do	code "No" for Q56e, pel echoes icated cysts in comparal, circumscribed mass	roceed to	Q56f and indica	te "complex cystic" at Q	56j.)

If this is a revised or corrected form, please check box	ACRIN Study 6666 PLACE LABEL HERE
	Institution Institution No
	Participant Initials Case No
56f. Shape	56n. Calcifications
O Oval	O None
O Two or three gentle lobulations O Round	O Present (check all that apply)
O Irregular	☐ Macrocalcifications (> 0.5 mm) ☐ Microcalcifications in mass
o mogala.	☐ Microcalcifications outside mass
56g. Orientation	
O Parallel to skin	56o. Lesion palpable in retrospect during sonography
O Not parallel (includes round)	O No O Yes
56h. Margin	
0 Circumscribed	57. Likelihood of malignancy for this lesion (best guess from 0-100)
O Not circumscribed (If not circumscribed, choose dominant feature)	tills lesion (best guess from 0-100)
☐ Indistinct	57a. Assessment for this lesion
☐ Angular ☐ Microlobulated	o 1 Negative o 2 Benign (complete Q57b)
☐ Spiculated	o 3 Probably Benign
	o 4A Low Suspicion of Malignancy
56i. Boundary Zone	o 4B Intermediate Suspicion o 4C Moderately High Suspicion
O Abrupt Interface	o 5 Highly Suggestive of Malignancy
O Echogenic Halo	57b. Known benign by prior biopsy?
FO: Falsa Pattarra	(only complete if Q57a = Benign)
56j. Echo Pattern O Anechoic	o No (proceed to Q58)
O Hyperechoic	o Yes (complete) o < 1 year ago
O Complex cystic	o 1-2 years ago
O Hypoechoic with few tiny cystic areas	o > 2 years ago
O Isoechoic to fat	58. Recommendation for this lesion
O Mixed hyperechoic and hypoechoic	o Routine screening in one year
O Hypoechoic to fat	<ul> <li>Diagnostic follow-up in one year</li> <li>Short-interval follow-up in 6 months with US</li> </ul>
	o Intervention and/or Additional Imaging
56k. Posterior Features	(detail intervention and/or additional imaging)
O None O Enhancement	<ul> <li>☐ Intervention</li> <li>o Aspiration w/core biopsy if solid</li> </ul>
O Combined shadowing/enhancement	o US-guided core biopsy
O Shadowing	o Vacuum-assisted biopsy, guidance by US
3	<ul> <li>Vacuum-assisted biopsy, guidance by Mammo</li> <li>Excisional biopsy</li> </ul>
56I. Surrounding Tissue	☐ <b>Additional Imaging</b> (check all that apply)
O No effect	☐ Comparison to current mammogram is required
O Effect (check all that apply)	(lesion seen on US)  ☐ Comparison to prior mammograms is required
☐ Duct changes ☐ Edema	☐ Additional mammographic projections
☐ Cooper's ligament distortion	59. Is this lesion assessed as probably benign AND
☐ Architectural distortion	recommended for intervention?
☐ Skin thickening ☐ Skin retraction	o No (proceed to Q60)
	o Yes (specify dominant reason)
56m. Vascularity (flow)	o Participant preference o Cancer present now
O None	o In this breast
O Yes (check all that apply)	o In opposite breast
☐ Present in lesion	o Patient risk factors o Vaguely palpable
☐ Present immediately adjacent to lesion	o Follow-up not reasonable
☐ Increased in surrounding tissue  O Not performed	<ul><li>o Increased (&gt; 20% in volume for masses)</li><li>o Interval suspicious change</li></ul>
o Not penomed	o Investigator uncertainty

Institution			
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)	IS	ACRIN Study 6666 PLACE LABEL HERE	If this is a revised or corrected form, please check box
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)    O No influence (proceed to Q61)     O Influenced (please answer the following questions in bold)     Margin depiction     O Better     O Same     O Worse     Internal structure depiction     O Better     O Same     O Worse     Posterior feature depiction     O Better     O Better     O Same     O Worse     Posterior feature depiction     O Better     O Better		Institution Institution No.	
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) o No influence (proceed to Q61) o Influenced (please answer the following questions in bold) Margin depiction o Better o Same o Worse  Internal structure depiction o Better o Same o Worse  Posterior feature depiction o Better		Participant Initials Case No	
Confidence in lesion characterization  o Better o Same o Worse  60b. Change in likelihood of malignancy with spatial compounding?  o None o Looks more benign with spatial compounding o Looks more malignant with spatial compounding	60.	old)	<ul> <li>□ Conventional imaging</li> <li>□ Spatial compounding</li> <li>□ Power Doppler</li> <li>□ Tissue Harmonic Imaging</li> <li>□ Panoramic display</li> <li>60a. If spatial compounding was used, what was its is one influence (proceed to Q61)</li> <li>○ Influenced (please answer the following question one influence influe</li></ul>

IS		e check box		P	ACRIN Study 66 LACE LABEL	
62 Ad	Iditional lesions o	other than simple cysts (m	aximum of 4 per breast)	Institution	Ins	stitution No
02. A	lantional <u>iesions</u> e	I	aximum of 4 per breasty	Participant Initi	alsCa	se No
62	breast, R2 for the	(e.g. UR1, UB1, UL1 e umbering from initial study su e second lesion in the right bicious findings first. Location in findings).	rvey sonogram. If this is to preast etc. If the finding is	he first examination new since a prior s	, begin with R1 for the fir	est lesion in the right at sequential #. Describe
62	o Not application Not Not of Yes of Gone of Decrease of Stable in of Multiple to Increasin of Increasin Is this "lesion of Yes Breast"	ed in size since previous example size size size since previous example size size size size size size size siz	es fluctuating in size since n  ge mscribed masses? If ye  Distance from the nipple	e previous exam es, describe location <u>Depth</u> cent		
	0 <b>R</b> 0 <b>L</b>	o' clock	cm	L	cm	
62	Meas (mm) D1  d. Is this lesion a o No o Yes (if your or Core/your or Core/your or Core/your or Can or Unk or Biopsyon or FNAB or Not applice. Special Case (so No	o Trv o Sag o Rad o Arad o Oblique  at the site of prior biopsy es, select prior procedure) accuum biopsy with clip (if procedum biopsy site (if procedure via biopsy site (if procedure v	mm X  rocedure performed, select dia mscribed masses	d, select diagnosis)	Second Measured Plane o Trv o Sag o Rad o Arad o Perpendicular Oblique	wolume D1XD2XD3 - 2    mm³  Note: Volume is programmed to be calculated on line; however, as verification, please calculate volume based on horizontal, vertical and perpendicular measurements as a validation.
	(Special o Com For  □ □ □ o M o M	Case Features) Implicated Cyst (Note: Do not complex cystic masses code Homogeneous low-level ec Fluid-Debris Level Mobile internal echoes Multiple bilateral complicate fluitiple bilateral solid oval, circlass in or on skin	use this term for "comple". "No" for Q62e, proceed hoes d cysts in company of sin	to Q62f and indicate	e "complex cystic" at Q6	2j.)

If this is a revised or corrected form, please check box		N Study 6666 LABEL HERE
	Institution	Institution No
62f. Shape	Participant Initials	Case No
0 Oval	( p	
O Two or three gentle lobulations		
0 Round	62n. Calcifications	
O Irregular	O None	all that and by
62g. Orientation	O Present (check a	all that apply) ations (> 0.5 mm)
O Parallel to skin	☐ Microcalcifica	,
O Not parallel (includes round)		tions outside mass
	62a Lasian nalnabla	in retrospect during sonography?
62h. Margin	62o. Lesion palpable 0 No	in retrospect during sonography?
O Circumscribed O Not circumscribed (If not circumscribed, choose dominant feature)	O Yes	
☐ Indistinct		
☐ Angular	63. Likelihoo	od of malignancy for
☐ Microlobulated	this lesion (best guess	s from 0-100)
☐ Spiculated	63a. Assessment for	this lesion
	o 1 Negative o 2 Benign (co	mplete Q63b)
62i. Boundary Zone	o 3 Probably B	
O Abrupt Interface	o 4A Low Suspic	
O Echogenic Halo	o 4B Intermediat o 4C Moderately	
62j. Echo Pattern		gestive of Malignancy
O Anechoic	63b. Known benign b	v prior biopsy?
O Hyperechoic	(only complete if	
O Complex cystic	o No (proceed to	Q64)
O Hypoechoic with few tiny cystic areas	o Yes (complete) o < 1 year ago	
O Isoechoic to fat	o 1-2 years ago	
O Mixed hyperechoic and hypoechoic	o > 2 years ago	
O Hypoechoic to fat	64. Recommendation for t	his lesion
62k. Posterior Features	o Routine screening in o Diagnostic follow-up	
O None	o Short-interval follow-up	up in 6 months with US
0 Enhancement	o Intervention and/or Ad	dditional Imaging
O Combined shadowing/enhancement	(detail intervention an □ <b>Intervention</b>	d/or additional imaging)
0 Shadowing	o Aspiration w/cor	re biopsy if solid
62I. Surrounding Tissue	o US-guided core	biopsy
O No effect		d biopsy, guidance by US d biopsy, guidance by Mammo
O Effect (check all that apply)	o Excisional biops	
☐ Duct changes	_	ing (check all that apply)
□ Edema	☐ Comparison to c (lesion seen on	current mammogram is required
☐ Cooper's ligament distortion ☐ Architectural distortion	,	rior mammograms is required
☐ Skin thickening	☐ Additional mamr	nographic projections
☐ Skin retraction	65. Is this lesion assessed	l as probably benign AND
62m. Vascularity (flow)	recommended for inte	
O None	o No (proceed to Q66)	
O Yes (check all that apply)	<ul> <li>Yes (specify dominant o Participant preference</li> </ul>	
☐ Present in lesion	o Cancer present now	~
☐ Present immediately adjacent to lesion	o In this breast	
☐ Increased in surrounding tissue	o In opposite breast o Patient risk factors	
O Not performed	o Vaguely palpable	
	o Follow-up not reason	

o Interval suspicious change o Investigator uncertainty

S	If this is a revised or corrected form, please check box		N Study 6666 LABEL HERE
		Institution	Institution No
		Participant Initials	Case No
☐ Co ☐ Sp ☐ Po ☐ Tis ☐ Pa	lesion evaluation, techniques used (check all the proventional imaging partial compounding grower Doppler under Basic Harmonic Imaging partial compounding was used, what was a o No influence (proceed to Q14) o Influenced (please answer the following que Margin depiction o Better o Same o Worse	its influence? (please answer the follow	ing questions)
	Internal structure depiction o Better o Same o Worse  Posterior feature depiction o Better o Same o Worse		
	Confidence in lesion characterization o Better o Same o Worse		
66b.	Change in likelihood of malignancy with spatial o None o Looks more benign with spatial compounding o Looks more malignant with spatial compounding	al compounding? (complete then proce	eed to Q14, Final Assessment)



	Institution	Institution No
	Participant Initials	Case No
Instructions: Please complete an ID form for each case who assessment other than negative or benign, or recommendation mended that the same <u>Radiologist</u> who performed the <u>survey</u> to breast imaging is recommended at the time of integration reading and additional evaluation on IM form.	n other than for annual follow-up <b>ultrasound</b> completes the <b>ID</b> forr	o. It is strongly recom- to 215-717-0936.
1. RadiologistID	7. First Lesion Description	on
<ul> <li>1a. Same radiologist as survey US? o No o Yes</li> <li>1b. Time point in study of this integration interpretation <ul> <li>Initial screening</li> <li>12 month screening</li> <li>24 month screening</li> </ul> </li> </ul>	o Asymmetry o Calcifications o Architectural dis	circumscribed masses
2. Date of integration interpretation  (mm-dd-yyyy)  3. Date of study mammogram	7b. Is this lesion seed o No (proceed o Yes, and de	to Q7c) tailed on form IA (complete)
(mm-dd-yyyy)  3a. Date of survey ultrasound	o In retrospect  New Lesion	` '
(mm-dd-yyyy)  3b. Was comparison made to prior studies at time of integration interpretation?  o No o Yes (check all that apply)  Mammogram US whole breast Targeted US	Detail lesion Quadrant - o Right bre o Left brea □ Bilateralr □ Axillary ta	Location (check all that apply) east
When both initial studies are reviewed together:	7c. Is this lesion seen	
4. Did any lesion on IA form have a final assessment of BI-RADS 3 or higher, or recommendation for additional evaluation or other than annual follow-up?  O No O Yes (If yes, complete 4a)  4a. If yes, how many lesions?	o No (proceed o Yes and det  Lesion ID  (e.g. UR1, U o Yes, cyst, no o In retrospect  New Lesion	to Q7d) ailed on <b>IS</b> (complete)
<ul> <li>5. Did any lesion on the IS form have a final assessment of BI-RADS 3 or higher, or recommendation for additional evaluation or other than annual follow-up?  O NO O Yes (If yes, complete 5a)</li> <li>5a. If yes, how many lesions?</li> </ul>	Detail lesior O Right brea Clockface Ic (hour and half Distance fro	allocation ast o Left breast  cation: o'clock hour e.g. 7:00 = 0700, 12:30 = 1230)  om the nipple cm
6. When both studies are reviewed together, how many discrete findings are there to be detailed?	of the lesion on b ultrasound?	oth mammography and  % (best guess from 0-100; een on both modalities)
	7e. Combined readin	g likelihood of malignancy for
	this lesion	% (best guess from 0-100)
	lesion is based: o Primarily on n o Primarily on n o On both man	

If this is a revised or corrected form, please check box		Study 6666 LABEL HERE
7. Accomment for this locion	Institution	Institution No
7g. 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 of Malignancy O 5 Highly Suggestive of Malignancy	Participant Initials	Case No
7h. Recommendation for this lesion  O 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  O Aspiration with core biopsy if solid  O 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?  O No (proceed to Q7j) O Yes (check 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		
7j. Are there additional lesion(s) you wish to describe?  O No (proceed to Q8) O Yes (proceed to Q10)		
	Continue	e onto next page

/-					
	ID	If this is a revised or corrected form, please check box		PLACE	N Study 6666 LABEL HERE
			Institution		Institution No
			Participan	t Initials	Case No
8.	Final	Assessment of <u>Right</u> Breast	9. Fina	al Assessment	of <u>Left</u> Breast
	8a.	□ Not on study (proceed to Q9)	9a.	□ Not on stud	y (stop and sign below)
	8b.	% Combined reading likelihood of malignancy for right breast (best guess from 0-100)	9b.	% ( malignancy fo	Combined reading likelihood of or left breast (best guess from 0-100)
	8c.	Assessment for right breast  0	9c.	0 4A Low S 0 4B Interm 0 4C Moder	ve
	8d.	Recommendation for right breast  O 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  O Aspiration with core biopsy if solid  O US-guided core biopsy  O Vacuum-assisted biopsy, guidance by US  O Vacuum-assisted biopsy, guidance by mammography  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	9d.	O Routine scree O Diagnostic foll Short-interval Short-interval O Intervention an (detail interver Interventio O Aspiration O US-guide O Vacuum- O Vacuum- O Excisiona Additiona Additiona Target (lesion Addition Fechn Possib Repeat u Incomp	low-up in 1 year follow-up in 6 months with US follow-up in 6 months with mammography ind/or Additional Imaging intion and/or additional imaging)  on in with core biopsy if solid ad core biopsy, guidance by US assisted biopsy, guidance by mammography al biopsy I Imaging (check all that apply) al evaluation arison to prior mammogram is required and ultrasound a seen on mammography) onal mammographic projections ultrasound ique/interpretation in question bly abnormal mammogram
			Stop. I	Orni Complet	e, sign and date below.
C:	ommer	nts:			
Si	gnature	of Radiologist responsible for the data <sup>1</sup>		Date For	rm Completed (mm-dd-yyyy)
Si	gnature	of person entering data onto web <sup>2</sup>			

	If this is a revised or corrected form, please check box				
0. Additional Lesion Description					
10a.	Lesion Description (dominant feature) O Mass				
	O Multiple bilateral circumscribed masses				
	O Asymmetry O Calcifications				
	O Architectural distortion				
	O Mixed calcifications and mass/density				
10b.	Is this lesion seen on mammography? o No (proceed to Q10c)				
	o No (proceed to Q10c) o Yes, and detailed on form IA (complete)				
	Lesion ID M on form IA				
	(e.g. MR1, MB1, ML1 etc.)				
	O In retrospect (only after reviewing ultrasound)  New Lesion # M (number sequentially				
	where IA left off, e.g. MR2, MB2, MR3, etc.)				
	Detail lesion location				
	Quadrant - Location (check all that apply)				
	o Right breast $\square$ upper o Left breast $\square$ lower				
	☐ Bilateral multiple ☐ inner				
	☐ Axillary tail ☐ outer ☐ Retroareolar ☐ Central				
	Distance from the nipple cm				
10c.	Is this lesion seen on ultrasound?				
100.	o No (proceed to Q10d)				
	o Yes and detailed on <b>IS</b> (complete)				
	Lesion ID U on form IS				
	(e.g. UR1, UB1, UL1 etc.) O Yes, cyst, not detailed on form <b>IS</b>				
	O In retrospect (only after reviewing mammogram)				
	New Lesion # U (number sequentially				
	where IS left off, e.g. UR2, UB2, UR3, etc.)				
	Detail lesion location				
	o Right breast o Left breast  Clockface location: o'clock				
	(hour and half hour e.g. 7:00 = 0700, 12:30 = 1230)				
	Distance from the nipplecm				
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: O Primarily on mammogram				
	O Primarily on mammogram O Primarily on ultrasound				
	O On both mammography and ultrasound				
	O Primarily on risk factors or clinical history				

Institu	tion _		Institution No
Partici	ipant Ir	nitials_	Case No
10g.	Asses	sment	for this lesion
	0	1	Negative
	0	2	Benign
	0	3	Probably Benign
		4A	
	0	4B	Intermediate Suspicion
	0	4C 5	Moderately High Suspicion of Malignancy Highly Suggestive of Malignancy
10h	Reco	mmen	dation for this lesion
			screening in 1 year
			tic follow-up in 1 year
		_	terval follow-up in 6 months with US
			terval follow-up in 6 months with mammography
			tion and/or Additional Imaging
			ntervention and/or additional imaging)
	J	☐ Inter	vention
		O As	piration with core biopsy if solid
			-guided core biopsy
			cuum-assisted biopsy, guidance by US
			cuum-assisted biopsy, guidance by mammography
			cisional biopsy
			tional Imaging (check all that apply)
			ditional evaluation
			Comparison to prior mammogram is required Fargeted ultrasound (lesion seen on mammography)
			Additional mammographic projections
			peat ultrasound
			Fechnique/interpretation in question
			Possibly abnormal
			peat mammogram
			ncomplete
			Motion artifact/other technical problem
10i.	Is this	slesior	n assessed as probably benign AND
	recon	nmend	ed for intervention?
			ed to Q10j)
			ify dominant reason)
	0		pant preference
	0		r present now
			is breast
	_		oposite breast
			risk factors
		_	ly palpable
			-up not reasonable
			I increase (>20% in volume for masses)
	0		I suspicious change
	0		gator uncertainty
10j.			litional lesions you wish to describe?
		**	ed to Q8)
	O Ye	s (proce	eed to Q11)

טו	If this is a revised or corrected form, please check box
1.Addi	tional Lesion Description
11a.	Lesion Description (dominant feature)
	O Mass O Multiple bilateral circumscribed masses
	O Asymmetry
	O Calcifications
	O Architectural distortion
	O Mixed calcifications and mass/density
11b.	Is this lesion seen on mammography?
	<ul><li>No (proceed to Q11c)</li><li>Yes, and detailed on form IA (complete)</li></ul>
	Lesion ID M on form IA
	(e.g. MR1, MB1, ML1 etc.)
	O In retrospect (only after reviewing ultrasound)
	New Lesion # M (number sequentially
	where IA left off, e.g. MR2, MB2, MR3, etc.)  Detail lesion location
	Quadrant - Location (check all that apply)
	o Right breast ☐ upper
	o Left breast □ lower □ Bilateral multiple □ inner
	☐ Axillary tail ☐ outer
	☐ Retroareolar ☐ Central
	Distance from the nipple cm
11c.	Is this lesion seen on ultrasound?
	<ul><li>No (proceed to Q11d)</li><li>Yes and detailed on IS (complete)</li></ul>
	Lesion ID U on form IS
	(e.g. UR1, UB1, UL1 etc.)
	O Yes, cyst, not detailed on form IS
	O In retrospect (only after reviewing mammogram)
	New Lesion # U (number sequentially where IS left off, e.g. UR2, UB2, UR3, etc.)
	Detail lesion location
	o Right breast o Left breast
	Clockface location: o'clock
	(hour and half hour e.g. 7:00 = 0700, 12:30 = 1230)
	Distance from the nipplecm
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:
	O Primarily on mammogram O Primarily on ultrasound
	O On both mammography and ultrasound
	O Primarily on risk factors or clinical history

Institution			Institution No
Participan	t Ini	itials_	Case No
11g. As	ses	sment	for this lesion
J	0	1	Negative
	0	2	Benign
	0	3	Probably Benign
	0	4A	Low Suspicion of Malignancy
	0	4B	Intermediate Suspicion
	0	4C	Moderately High Suspicion of Malignancy
	0	5	Highly Suggestive of Malignancy
11h.Re	con	nmend	ation for this lesion
	0	Routine	screening in 1 year
	0	Diagnos	tic follow-up in 1 year
		Short-in	terval follow-up in 6 months with US
		Short-in	terval follow-up in 6 months with mammography
	0	Interven	tion and/or Additional Imaging
		(detail in	tervention and/or additional imaging)
		□ Inter	vention
		O As	piration with core biopsy if solid
		o US	-guided core biopsy
		O Va	cuum-assisted biopsy, guidance by US
			cuum-assisted biopsy, guidance by mammography
			cisional biopsy
			tional Imaging (check all that apply)
			ditional evaluation
			Comparison to prior mammogram is required
			Fargeted ultrasound (lesion seen on mammography
			Additional mammographic projections
			peat ultrasound
			Гесhnique/interpretation in question
			Possibly abnormal
			peat mammogram
			ncomplete
			Motion artifact/other technical problem
			nassessed as probably benign AND ed for intervention?
0	) No	(procee	ed to Q11j)
			ify dominant reason)
			pant preference
		. '	r present now
	Ü		is breast
			oposite breast
	0		risk factors
			y palpable
		_	
			up not reasonable
	0		I increase (>20% in volume for masses)
	0		I suspicious change gator uncertainty
11:	the		•
_			itional lesions you wish to describe? ed to Q8)
			ed to Q12)
U	, 10	s (proce	GU IU WIZ)

	ID		If this is a revised or corrected form, please check box
12	2. Addi	tion	al Lesion Description
	12a.		sion Description (dominant feature)
		0 N	fultiple bilateral circumscribed masses symmetry
			calcifications
			rchitectural distortion  fixed calcifications and mass/density
	12h	ls ti	his lesion seen on mammography?
	120.	0	No (proceed to Q12c) Yes, and detailed on form IA (complete)
			Lesion ID M on form IA
		0	(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.) <b>Detail lesion location</b>
			Quadrant - Location (check all that apply) o Right breast □ upper
			o Left breast □ lower
			☐ Bilateral multiple ☐ inner ☐ Axillary tail ☐ outer
			☐ Retroareolar ☐ Central  Distance from the nipple ☐ cm
	40-	1- (	
	12c.	0 0	his lesion seen on ultrasound?  No (proceed to Q12d)  Yes and detailed on IS (complete)
			Lesion ID U on form IS
		0	(e.g. UR1, UB1, UL1 etc.) Yes, cyst, not detailed on form <b>IS</b>
		0	In retrospect (only after reviewing mammogram)
			New Lesion # U (number sequentially where IS left off, e.g. UR2, UB2, UR3, etc.)
			Detail lesion location
			O Right breast O Left breast  Clockface location: o'clock
			(hour and half hour e.g. 7:00 = 0700, 12:30 = 1230)
			Distance from the nipplecm
	12d.		w certain are you that there is correspondence he lesion on both mammography and ultrasound?
		not	% (best guess from 0-100; code 998 if seen on both modalities)
	12e.	Coi	mbined reading likelihood of malignancy for
		this	s lesion % (best guess from 0-100)
	12f.		al assessment/recommendation for this ion is based:
		0	Primarily on mammogram
			Primarily on ultrasound On both mammography and ultrasound
		0	

Institu	tion _		Institution No
Partic	ipant	Initials	Case No
12g.			nt for this lesion
	0	1	Negative
	0		Benign Probably Benign
		4A	Low Suspicion of Malignancy
	0	4B	
	_	4C	Moderately High Suspicion of Malignancy
	0	5	Highly Suggestive of Malignancy
12h.	Rec	ommer	ndation for this lesion
	0	Routine	screening in 1 year
	0	Diagnos	tic follow-up in 1 year
			terval follow-up in 6 months with US
			terval follow-up in 6 months with mammography
	0		tion and/or Additional Imaging
		•	ntervention and/or additional imaging)
			vention
			piration with core biopsy if solid
			-guided core biopsy
			cuum-assisted biopsy, guidance by US cuum-assisted biopsy, guidance by mammography
			cisional biopsy
			tional Imaging (check all that apply)
			ditional evaluation
			Comparison to prior mammogram is required
			Targeted ultrasound (lesion seen on mammography)
			Additional mammographic projections
		☐ Re	peat ultrasound
		□.	Technique/interpretation in question
			Possibly abnormal
		☐ Re	peat mammogram
			ncomplete
			Motion artifact/other technical problem
12i.			n assessed as probably benign AND ded for intervention?
			ed to Q12j) ify dominant reason)
			pant preference
			r present now
	·		is breast
			oposite breast
	0		risk factors
			ly palpable
		_	-up not reasonable
			I increase (>20% in volume for masses)
	0		I suspicious change
	0		gator uncertainty
12j.	Are tl	here ad	ditional lesions you wish to describe?
			ed to Q8)
	O Ye	es (proce	eed to Q13)

ID	If this is a revised or corrected form, please check box			
13. Additional Lesion Description				
13a.	Lesion Description (dominant feature)  o Mass			
	O Multiple bilateral circumscribed masses O Asymmetry Calcifications O Architectural distortion O Mixed calcifications and mass/density			
13b.	Is this lesion seen on mammography?  o No (proceed to Q13c) o Yes, and detailed on form IA (complete)  Lesion ID M on form IA (e.g. MR1, MB1, ML1 etc.)			
	o In retrospect (only after reviewing ultrasound)  New Lesion # M (number sequentially where IA left off, e.g. MR2, MB2, MR3, etc.)			
	Detail lesion location  Quadrant - Location (check all that apply)  o Right breast □ upper o Left breast □ lower □ Bilateral multiple □ inner □ Axillary tail □ outer □ Retroareolar □ Central			
	Distance from the nipple cm			
13c.	Is this lesion seen on ultrasound?  o No (proceed to Q13d) o Yes and detailed on IS (complete)  Lesion ID U on form IS			
	(e.g. UR1, UB1, UL1 etc.)  O 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  O Right breast O Left breast  Clockface location: o'clock  (hour and half hour e.g. 7:00 = 0700, 12:30 = 1230)  Distance from the nipple cm			
13d.	How certain are you that there is correspondence of the lesion on both mammography and ultrasound?  We (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:  O Primarily on mammogram O Primarily on ultrasound O On both mammography and ultrasound O Primarily on risk factors or clinical history			

Institu	tion _		Institution No
Partici	ipant	Initials	Case No
13g.			nt for this lesion
	0	1	Negative
	0	2 3	Benign Brobably Bonign
	0	3 4A	Probably Benign Low Suspicion of Malignancy
	0	4A 4B	Intermediate Suspicion
	0	4C	Moderately High Suspicion of Malignancy
	0	5	Highly Suggestive of Malignancy
13h.	Re	ecomm	endation for this lesion
	0	Routine	screening in 1 year
			stic follow-up in 1 year
		Short-in	terval follow-up in 6 months with US
		Short-in	terval follow-up in 6 months with mammography
			ition and/or Additional Imaging
			ntervention and/or additional imaging)
			vention
			piration with core biopsy if solid
			g-guided core biopsy
			cuum-assisted biopsy, guidance by US
			cuum-assisted biopsy, guidance by mammography
			cisional biopsy
			itional Imaging (check all that apply)
			ditional evaluation
			Comparison to prior mammogram is required Targeted ultrasound (lesion seen on mammography)
			Additional mammographic projections
			peat ultrasound
			Technique/interpretation in question
			Possibly abnormal
			peat mammogram
			Incomplete
			Motion artifact/other technical problem
13i.			on assessed as probably benign AND ded for intervention?
	O No	(proce	ed to Q13j)
			k dominant reason)
	0	Partici	pant preference
	0	Cance	r present now
		O In th	nis breast
		O In o	pposite breast
	0	Patient	t risk factors
	0	Vague	ly palpable
	0	Follow	-up not reasonable
	0		Il increase (>20% in volume for masses)
	0		ll suspicious change
	0	Investi	gator uncertainty
13j.	Are tl	nere ad	Iditional lesions you wish to describe?
•			ed to Q8)
			eed to Q14)
	. •	(1-23)	· ,

		If this is a revised or corrected form, please check box
14. Addi	tion	nal Lesion Description
14a.	Les	sion Description (dominant feature)
		Mass
		Multiple bilateral circumscribed masses Asymmetry
		Calcifications
		Architectural distortion
	0 1	Mixed calcifications and mass/density
14b.	ls t	his lesion seen on mammography?
	0	No (proceed to Q14c)
	0	Yes, and detailed on form IA (complete)
		Lesion ID M on form IA
	0	(e.g. MR1, MB1, ML1 etc.) In retrospect (only after reviewing ultrasound)
	Ü	New Lesion # M (number sequentially
		where IA left off, e.g. MR2, MB2, MR3, etc.)
		Detail lesion location
		Quadrant - Location (check all that apply)
		o Right breast □ upper o Left breast □ lower
		☐ Bilateral multiple ☐ inner
		☐ Axillary tail ☐ outer
		□ Retroareolar □ Central
		Distance from the nipple cm
14c.	ls t	his lesion seen on ultrasound?
	0	No (proceed to Q14d)
	0	Yes and detailed on IS (complete)  Lesion ID U on form IS
	0	(e.g. UR1, UB1, UL1 etc.) Yes, cyst, not detailed on form <b>IS</b>
	0	In retrospect (only after reviewing mammogram)
		New Lesion # U (number sequentially
		where IS left off, e.g. UR2, UB2, UR3, etc.)
		Detail lesion location
		o Right breast o Left breast
		Clockface location: o'clock
		(hour and half hour e.g. 7:00 = 0700, 12:30 = 1230)
		Distance from the nipple cm
14d.		w certain are you that there is correspondence the lesion on both mammography and ultrasound?
		(best guess from 0-100; code 998 if
	not	seen on both modalities)
14e.	Со	mbined reading likelihood of malignancy for
	thi	s lesion
14f.	Fin	al assessment/recommendation for this
		ion is based:
		Primarily on mammogram
		Primarily on ultrasound
		O On both mammography and ultrasound O Primarily on risk factors or clinical history
		,

Institution			Institution No
Partic	ipant	Initials	S Case No
14g.	Asse	essme	nt for this lesion
	0	1	Negative
	0	2	Benign
	0	3	Probably Benign
	0	4A	Low Suspicion of Malignancy
	0	4B	Intermediate Suspicion
	0	4C	Moderately High Suspicion of Malignancy
	0	5	Highly Suggestive of Malignancy
14h.	Reco	ommei	ndation for this lesion
			screening in 1 year
		_	stic follow-up in 1 year
			terval follow-up in 6 months with US
			terval follow-up in 6 months with mammography
			ntion and/or Additional Imaging
			ntervention and/or additional imaging)
	l		vention
			piration with core biopsy if solid
			3-guided core biopsy
			cuum-assisted biopsy, guidance by US
			cuum-assisted biopsy, guidance by mammography
	r		cisional biopsy
	l		itional Imaging (check all that apply) ditional evaluation
			Comparison to prior mammogram is required Targeted ultrasound (lesion seen on mammography)
			Additional mammographic projections
			peat ultrasound
			Technique/interpretation in question
			Possibly abnormal
			peatmammogram
			Incomplete
			Motion artifact/other technical problem
14i.			on assessed as probably benign AND
			ded for intervention?
			ed to Q14j)
			ify dominant reason)
			pant preference
	0		r present now
			nis breast
			pposite breast
			t risk factors
			ly palpable
			-up not reasonable
			al increase (>20% in volume for masses)
	0		al suspicious change
	0	investi	gator uncertainty
14j.	Are t	here a	dditional lesions you wish to describe?
	O No	(proce	ed to Q8)
	O Ye	s (proc	eed to Q15)

	ID		If this is a revised or corrected form, please check box					
1	15. Additional Lesion Description							
	15a. Lesion Description (dominant feature)  O Mass							
		0 1	Multiple bilateral circumscribed masses					
			Calcifications					
			Architectural distortion  Mixed calcifications and mass/density					
	15b.	ls t	his lesion seen on mammography?					
		0	No (proceed to Q15c) Yes, and detailed on form IA (complete)					
			Lesion ID M on form IA					
		0	(e.g. MR1, MB1, ML1 etc.) In retrospect (only after reviewing ultrasound)					
		Ū	New Lesion # M (number sequentially					
			where IA left off, e.g. MR2, MB2, MR3, etc.)					
			Detail lesion location Quadrant - Location (check all that apply)					
			o Right breast ☐ upper					
			o Left breast □ lower □ Bilateral multiple □ inner					
			☐ Axillary tail ☐ outer					
			☐ Retroareolar ☐ Central  Distance from the nipple ☐ ☐ cm					
	45-	1- 4	• •					
	15C.	0	his lesion seen on ultrasound?  No (proceed to Q15d)					
		0	Yes and detailed on IS (complete)					
			Lesion ID U on form IS					
		0	(e.g. UR1, UB1, UL1 etc.) Yes, cyst, not detailed on form <b>IS</b>					
		0	In retrospect (only after reviewing mammogram)					
			New Lesion # U (number sequentially					
			where IS left off, e.g. UR2, UB2, UR3, etc.)					
			Detail lesion location					
			O Right breast O Left breast  Clockface location: o'clock					
			(hour and half hour e.g. 7:00 = 0700, 12:30 = 1230)					
			Distance from the nipplecm					
	15d	Но	w certain are you that there is correspondence					
	100.		the lesion on both mammography and ultrasound?					
		not	% (best guess from 0-100; code 998 if seen on both modalities)					
	15e.	Со	mbined reading likelihood of malignancy for					
		this	s lesion % (best guess from 0-100)					
	15f.	Fin	al assessment/recommendation for this					
			ion is based:					
			Primarily on mammogram     Primarily on ultrasound					
			On both mammography and ultrasound					
		C	Primarily on risk factors or clinical history					

Institution			Institution No
Partici	pant	Initials_	Case No
15a.	Ass	essmen	t for this lesion
.09.	0		Negative
	0		Benign
	0	3	Probably Benign
	0	4A	Low Suspicion of Malignancy
	0		Intermediate Suspicion
	0	4C	Moderately High Suspicion of Malignancy
	0	5	Highly Suggestive of Malignancy
15h.	Rec	ommen	dation for this lesion
	0	Routine s	screening in 1 year
			c follow-up in 1 year
		Short-inte	erval follow-up in 6 months with US
		Short-inte	erval follow-up in 6 months with mammography
	0	Interventi	on and/or Additional Imaging
		(detail int	ervention and/or additional imaging)
		□ Interv	ention
			ration with core biopsy if solid
			guided core biopsy
			uum-assisted biopsy, guidance by US
			uum-assisted biopsy, guidance by mammography
		O Exci	sional biopsy
			ional Imaging (check all that apply)
			itional evaluation
			omparison to prior mammogram is required
			argeted ultrasound (lesion seen on mammography)
			dditional mammographic projections
			eat ultrasound
			echnique/interpretation in question ossibly abnormal
			•
			eat mammogram complete
			lotion artifact/other technical problem
15i	le th	ie laciar	n assessed as probably benign AND
131.			ed for intervention?
			d to Q15j)
		**	y dominant reason)
			ant preference
			present now
	Ŭ	O In this	•
			posite breast
	0		risk factors
			palpable
		0 ,	up not reasonable
	0		increase (>20% in volume for masses)
	0		suspicious change
	0		ator uncertainty
15j. <i>i</i>	Are tl	nere ado	litional lesions you wish to describe?
-		(proceed	
			ed to Q16)
			•

If this is a revised or corrected form, please check box	ACRIN Study 6666 PLACE LABEL HEI	RE
	Institution Institution	No
6. Additional Lesion Description	Participant Initials Case No.	
16a. Lesion Description (dominant feature)		
O Mass O Multiple bilateral circumscribed masses	16g. Assessment for this lesion	
O Asymmetry	O 1 Negative	
O Calcifications	O 2 Benign O 3 Probably Benign	
O Architectural distortion	O 4A Low Suspicion of Malignand	NV
O Mixed calcifications and mass/density	O 4B Intermediate Suspicion	, <b>y</b>
46h la thia lasian agan an mammagraphy?	O 4C Moderately High Suspicion o	
16b. Is this lesion seen on mammography?  O No (proceed to Q16c)	O 5 Highly Suggestive of Maligna	ancy
o Yes, and detailed on form IA (complete)	16h. Recommendation for this lesion	
Lesion ID M on form IA	O Routine screening in 1 year	
(e.g. MR1, MB1, ML1 etc.)	O Diagnostic follow-up in 1 year	
o In retrospect (only after reviewing ultrasound)	☐ Short-interval follow-up in 6 months wi	
New Lesion # M (number sequentially	☐ Short-interval follow-up in 6 months wi O Intervention and/or Additional Imaging	th mammography
where IA left off, e.g. MR2, MB2, MR3, etc.)	(detail intervention and/or additional imaging	aging)
Detail lesion location	☐ Intervention	-99/
Quadrant - Location (check all that apply)	O Aspiration with core biopsy if soli	d
o Right breast □ upper o Left breast □ lower	O US-guided core biopsy	
☐ Bilateral multiple ☐ inner	O Vacuum-assisted biopsy, guidanc O Vacuum-assisted biopsy, guidanc	
☐ Axillary tail ☐ outer	O Excisional biopsy	e by mammography
☐ Retroareolar ☐ Central	☐ Additional Imaging (check all the	at apply)
Distance from the nipple cm	☐ Additional evaluation	m in required
16c. Is this lesion seen on ultrasound?	☐ Comparison to prior mammogra ☐ Targeted ultrasound (lesion see	
o No (proceed to Q16d)	☐ Additional mammographic proje	
o Yes and detailed on <b>IS</b> (complete)	☐ Repeat ultrasound	
Lesion ID U on form IS	☐ Technique/interpretation in que	estion
(e.g. UR1, UB1, UL1 etc.)	☐ Possibly abnormal ☐ Repeat mammogram	
O Yes, cyst, not detailed on form IS	□ Incomplete	
O In retrospect (only after reviewing mammogram)  New Lesion # U (number sequentially)	☐ Motion artifact/other technical	oroblem
where IS left off, e.g. UR2, UB2, UR3, etc.)		
Detail lesion location	16i. Is this lesion assessed as probably be	enign AND
o Right breast o Left breast	recommended for intervention? O No (proceed to Final Assessment(s) Q8,	O9)
Clockface location: o'clock	O Yes (specify dominant reason)	Q0)
(hour and half hour e.g. 7:00 = 0700, 12:30 = 1230)	O Participant preference	
Distance from the nipplecm	O Cancer present now	
	O In this breast	
16d. How certain are you that there is correspondence	O In opposite breast O Patient risk factors	
of the lesion on both mammography and ultrasound?	O Vaguely palpable	
w (best guess from 0-100; code 998 if not seen on both modalities)	O Follow-up not reasonable	
not seen on both modalities)	O Interval increase (>20% in volume for	masses)
16e. Combined reading likelihood of malignancy for	O Interval suspicious change O Investigator uncertainty	
this lesion % (best guess from 0-100)	o investigator uncertainty	
tina lealon // (best guess from 0-100)		
16f. Final assessment/recommendation for this	Proceed to Final Assessment(s), Q8, Q9	
lesion is based:		
O Primarily on ultrasound		
<ul><li>O Primarily on ultrasound</li><li>O On both mammography and ultrasound</li></ul>		
O Primarily on risk factors or clinical history		
•		

# ACRIN 6666 Additional Evaluation: Additional Views/Targeted US

or=	revised	or	corrected	form	check	
оох	and fax	to	215-717-09	936.		

## ACRIN Study 6666 PLACE LABEL HERE

TENCE ENDER 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 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 evaluation.

addition	ion. Description is only required for those lesions requiring additional evaluation based on <b>ID</b> form(s), <b>M3</b> fit nal evaluation. Complete Section II for each lesion that requires description based on the <b>ID</b> form, each <b>M3</b> fi ditional imaging revealed no abnormalities. Complete form <b>M3</b> if the MRI study is repeated as part of addition	nding th	at requires description based on the MX form recommendation, and/or clinical findings even
I. (	GENERAL INFORMATION		8a. Have there been any clinically significant changes
1.	Is this form IM the continuation from additional evaluations reported on another form IM?  o No o Yes		in the right breast since the last annual examination?  o No o Yes (check all clinical changes that apply)  □ Palpable mass (complete location)  Location of abnormality
2.	Did participant return for additional evaluation?  o No (specify reason, STOP and sign form) o Second opinion felt not mandated o Participant refusal o Participant did not return o Unable to be performed and rescheduled o Yes o Completed o Incomplete, will return on (mm-dd-yyyy)  □ Check box if date unknown		o'clock or specify location:  o Axilla o Retroareolar o Unknown  Nipple discharge (detail): o Bloody o Clear spontaneous o Other Other, specify:  Not applicable (not on study) (proceed to Q8b)
3.	Indication for exam(s): (check all that apply)  Routine mammogram abnormal Survey ultrasound abnormal Clinical abnormalities MRI abnormalities CAD abnormalities		8b. Have there been any clinically significant changes in the left breast since the last annual examination?  o No o Yes (check all clinical changes that apply)  □ Palpable mass (complete location)  Location of abnormality
4.	Date study(ies) performed (mm-dd-yyyy) (Report date comparison made if only reporting comparison to prior studies.)		o'clock or specify location:  Axilla  Retroareolar
	<ul> <li>4a. Date of study interpretation</li></ul>		o Unknown  ☐ Nipple discharge (detail): o Bloody o Clear spontaneous o Other ☐ Other, specify: o Not applicable (not on study) (proceed to Q9)
5.	Faction of the second s	9.	Has the patient had any other evaluation of breast(s) since the last annual study exam(s)?  o No (proceed to Q10) o Yes (check all that apply)
6.	Which breast(s) are reported on this form? (check all that apply)  Right Breast Left Breast		□ 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.
7.	How many lesions were recommended for additional evaluation for this breast based on ID form(s)?		□ MRI □ Outside US □ Outside mammogram
	<b>Note:</b> enter "0" if participant here for clinical, MRI or off-study (see instructions) abnormalities only.	10.	Comparison studies other than most recent
	7a. Were any new lesions seen only on additional mammographic evaluation of this breast?[i.e.not reported on IA]  o No (proceed to Q7b) o Yes (detail how many) o Not applicable, not done		annual mammogram and study US?  o Not available (proceed to Section IIA) o Available (complete, check all that apply)  □ Prior mammography □ Prior targeted US □ Right □ Left
	7b. Were any new lesions seen only on additional US evaluation of this breast?[i.e.not reported on IS]  o No (proceed to Q8) o Yes (detail how many) o Not applicable, not done		☐ Prior survey US

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IIV	Fo	or revised or corrected form, check box and fax to 215-717-0936.						
Res	Results (by lesion)							
Pleas Desc	Please complete Mammographic Lesion Description and Sonographic Lesion Description for each lesion to be described based on the ID or MX form, and/or clinical findings even if the additional imaging revealed no abnormalities.							
IIA.	Lesion # from prior MRI: (e.g. GR1, GL1, GL2, etc.) (if not applicable code 998)							
11.	Mamr	mographic Lesion Description						
	11a.	Were additional mammographic views obtained						
		directed to this finding?  o No (specify reason and proceed to Q12) o Not recommended o Participant refused o Not needed after targeted US o Scheduling constraints; participant rescheduled o Other o Yes (check all that apply)  R						
		☐ ☐ Magnification views ☐ ☐ Rolled views						
	441	☐ ☐ Repeat CC or MLO or both						
	11b.	Was lesion seen on additional mammographic view(s)?  o No e.g. resolved on additional views (complete then proceed to Q12) Lesion # from prior mammogram M  (if not applicable code 998) Lesion # from prior ultrasound (if not applicable code 998) o Yes						
	11c.	Was lesion enumerated on any prior						
		study mammogram?  o No and not visible in retrospect (assign next sequential mammogram lesion #)  o No but now visible in retrospect (assign next sequential mammogram lesion #) New lesion # M  o Yes Lesion # from prior mammogram: (e.g. MR1, MB1, ML1, MR2, etc.)						
	11d.	Was lesion enumerated on any prior						
		study ultrasound?  o No o Simple cyst o Not a simple cyst o Yes (complete) Lesion # from ultrasound:  (e.g. UR1, UB1, UL1, UR2, etc.)						
	11e.	Location on Mammography: (check all that apply)						
		<b>Note:</b> for multiple bilateral findings with similar appearances, check "bilateral, multiple" and indicate specific location and size of the largest such finding.						
		oRight breast						
	11f.	Distance from nipplecm by Mammography						
	11g.	Size of lesion by Mammography:						
		(largest diameter) X (largest perpendicular dimension)						
	11h.	Lesion Description Mammography (check all that apply)						

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### PLACE LABEL HERE

Institution		Institution No			
Participa	nt Initials	_ Case No			
	Mass (select worse ma	,			
	o Spiculated  Asymmetry (code type o Focal Asymmetry seen o One view o Both views				
	Coarse typical Milk of calcium Coarse heterog Punctate (<0.5 Amorphous/Inc Pleomorphic Branching/Fine Distribution of calcifi Clustered Multiple cluste Regional Linear Segmental Diffuse scatte In mass or as Architectural Distortion	ications (check all that apply) ly benign n geneous s mm, uniformly round) distinct elinear cations (check all that apply) rs (same morphology)			
12. Sono	graphic Lesion Desc	•			
12a.	to this lesion?  o No (specify reason a o Not recommende o Participant refuse o Not needed after	d additional mammographic views raints; participant rescheduled			
12b.	Was lesion seen on  o No (complete then proc Lesion # from pric (if not applicable of Lesion # from pric (if not applicable of o Yes	per mammogram M  code 998)  or ultrasound U			
12c.	Was lesion enumera	ated on any prior study ultrasound?			
	o No (complete) o Simple cyst (proc o Not a simple cyst (assign next sequ o Not a simple cyst				
		1, UR2, etc.) rated on any study mammogram			
		al views obtained today)?			
	o No o Yes (complete)				
	Lesion # from mamr number: M	nogram or additional view			

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

<b>II</b>	For revised or co	ACRIN 666 prrected form, check box an	-	ACRIN Study 6666 PLACE LABEL HERE				
				Institution	Institu	ution No		
12d.			? hour	Participant Inition  Depth from center of (to nearest)	skin to lesion	No		
	o <b>R</b> o <b>L</b>	o' cl	ock cm		cm			
12e.	Lesion Size							
	<u>Largest</u> <u>Horizontal</u> <u>Meas (mm) D1</u>	Measured Plane o Trv	Vertical A-P meas (mm) D2	Horizontal pendicular Meas (mm) D3	Second Measured Plane V O Trv	olume D1XD2XD3 ÷ 2		
	mm	o Sag n o Rad	mm X	mm	o Sag o Rad	mm³		
12f.	Special Case (e	o Arad o Oblique see choices below)			o Arad o Perpendicular Obliqu	Note: Volume is programmed to be calculated on line; however, as verification, please		
40-	o Complicated ( For complex of Homoger	cystic masses code "no nous low-level echoes oris level aternal echoes bilateral complicated cyeral solid oval, circumsor skin crocysts ass	e this term for "complex cyso" for Q12f, proceed to Q1	2g and indicate "con	nplex cystic" at 12k).	calculate volume based on horizontal, vertical and perpendicular measurements as a validation.		
12g.	Shape 0 Oval 0 Two or three ge 0 Round 0 Irregular	entle lobulations						
12h.	Orientation O Parallel to skin O Not parallel (incl	ludes round)						
12i.	Margin  O Circumscribed  O Not circumscribe  Indistinct  Angular  Microlobula  Spiculated		d, choose dominant feature	<del>)</del>				
12j.	Boundary Zone O Abrupt Interface O Echogenic Halo	9						

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### **ACRIN 6666** For revised or corrected form, check box and fax to 215-717-0936. 12k. Echo Pattern O Anechoic O Hyperechoic O Complex cystic O Hypoechoic with few tiny cystic areas O Isoechoic to fat O Mixed hyperechoic and hypoechoic O Hypoechoic to fat 12I. **Posterior Features** O None O Enhancement O Combined shadowing/enhancement O Shadowing 12m. Surrounding Tissue O No effect O Effect (check all that apply) □ Duct changes □ Edema ☐ Cooper's ligament distortion ☐ Architectural distortion ☐ Skin thickening ☐ Skin retraction 12n. Vascularity (flow) O None O Yes (check all that apply) ☐ Present in lesion ☐ Present immediately adjacent to lesion ☐ Increased in surrounding tissue O Not performed 12o. Calcifications on ultrasound O None O Present (check all that apply) ☐ Macrocalcifications (> 0.5 mm) ☐ Microcalcifications in mass ☐ Microcalcifications outside mass 12p. Was lesion palpable in retrospect during sonography? O No O Yes, in retrospect O Yes, participant presented with lump 13. Is this lesion at the site of prior biopsy? o No (proceed to Q14) o Yes (If yes, select procedure)

- o Core/vacuum biopsy site with clip
- o Core/vacuum biopsy site without marker
- 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

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Institution No.	

Institution	Institution No
Participant Initials	Case No.

#### Section III.

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

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

#### 14b. Assessment for this lesion

- Negative
- 0 2 Benign
- Probably Benign 0
- 4A Low Suspicion of Malignancy 0
- 4B Intermediate Suspicion 0
- 0 4C Moderately High Suspicion
- 0 5 Highly Suggestive of Malignancy

#### 14c. Recommendation(s) for this lesion

- o Routine screening in 1 year
- o 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
- o Intervention and/or Additional Imaging (detail intervention and/or additional imaging)

#### ☐ Intervention

- o Aspiration with core biopsy if solid
- o US-guided core biopsy
- o Vacuum-assisted biopsy, guidance by US
- o Vacuum-assisted biopsy, guidance by mammo
- o Excisional biopsy
- o 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?

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

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

- O No (proceed to Q16)
- O Yes (proceed to Section IIB)

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For revised or corrected form, check box and fax to 215-717-0	6. PLACE LABEL HERE
	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)	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 les present, even if that lesion did not undergo additional evaluation.	
16a % Likelihood of malignancy for this breast (best guess from 0-100)	17a. Likelihood of malignancy for this breast (best guess from 0-100)
16b. Assessment for this breast 0 1 Negative 0 2 Benign 0 3 Probably Benign 0 4A Low Suspicion of Malignancy 0 4B Intermediate Suspicion 0 4C Moderately High Suspicion 0 5 Highly Suggestive of Malignancy  16c. Recommendation for this breast 0 Routine screening in 1 year 0 Diagnostic follow-up in 1 year 0 Diagnostic follow-up in 6 months with US 0 Short-interval follow-up in 6 months with MRI 0 Intervention and/or Additional Imaging (detail intervention and/or additional imaging) 1 Intervention 0 Aspiration with core biopsy if solid 0 US-guided core biopsy 0 Vacuum-assisted biopsy, guidance by US 0 Vacuum-assisted biopsy, guidance by MRI 1 Additional Imaging 1 Additional Imaging 1 Additional Imaging 1 Additional evaluation 1 Comparison to prior mammogram is requi 1 Targeted ultrasound 1 (lesion seen on mammography) 1 Additional mammographic projections 1 Repeat ultrasound 1 Technique/interpretation in question 1 Possibly abnormal 1 Repeat mammogram 1 Incomplete 1 Motion artifact/other technical problem	□ Short-interval follow-up in 6 months with MRI o Intervention and/or Additional Imaging (detail intervention and/or additional imaging) □ Intervention o Aspiration with core biopsy if solid o US-guided core biopsy o Vacuum-assisted biopsy, guidance by US o Vacuum-assisted biopsy, guidance by mammograpy o Excisional biopsy o Vacuum-assisted biopsy, guided by MRI □ Additional Imaging □ Additional evaluation
	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>	

IM
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	IVI	For revised or corrected form, check box and fax to 215-717-0936.				
II.	I. 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.					
		B. Lesion # from prior MRI: G (e.g. GR1, GL1, GL2, etc.) (if not applicable code 998)				
	18. Ma	ammographic Lesion Description				
	18	a. Were additional mammographic views obtained				
		directed to this finding?				
		<ul> <li>No (specify reason and proceed to Q19)</li> <li>Not recommended</li> </ul>				
		o Participant refused o Not needed after targeted US				
		o Scheduling constraints; participant rescheduled				
		o Other o Yes (check all that apply)				
		<u>R</u> <u>L</u>				
		True lateral				
		☐ ☐ Laterally exaggerated CC☐ ☐ Magnification views				
		☐ ☐ Rolled views				
	18	□ □ Repeat CC or MLO or both  b. Was lesion seen on additional				
	10	mammographic view(s)?				
		o No e.g. resolved on additional views (complete then proceed to Q19)				
		Lesion # from prior mammogram M (if not applicable code 998)				
		Lesion # from prior ultrasound				
		(if not applicable code 998) o Yes				
	18	c. Was lesion enumerated on any prior				
		study mammogram?				
		<ul> <li>No and not visible in retrospect (assign next sequential mammogram lesion #)</li> </ul>				
		o No but now visible in retrospect				
		(assign next sequential mammogram lesion #)  New lesion #   M				
		o Yes				
		Lesion # from prior mammogram: M (e.g. MR1, MB1, ML1, MR2, etc.)				
	18	d. Was lesion enumerated on any prior study				
		ultrasound?				
		o No o Simple cyst				
		o Not a simple cyst o Yes (complete)				
		Lesion # from ultrasound:				
	18	(e.g. UR1, UB1, UL1, UR2, etc.)  Be. Location on Mammography: (check all that apply)				
	10	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 Upper				
		oLeft breast				
		☐ Axillary tail ☐ Outer ☐ Retroareolar ☐ Central				
	18	f. Distance from nipple cm by Mammography				
	18	g. Size of lesion by Mammography:				
		mm <b>X</b> mm				
		(largest diameter) (largest perpendicular dimension)				
	18	th. Lesion Description Mammography (check all that apply)				

Institutio	n Institution No
Participa	nt Initials Case No
19. Sono	graphic Lesion Description
<b>19a.</b>	Was ultrasound performed again directed to this lesion?  o No (specify reason and proceed to Q20) o Not recommended o Participant refused o Not needed after additional mammographic views o Scheduling constraints; participant rescheduled o Other o Yes (check all that apply)  ☐ Targeted only ☐ Whole breast
19b.	Was lesion seen on this Ultrasound?  o No (complete then proceed to Q20)  Lesion # from prior mammogram  (if not applicable code 998)  Lesion # from prior ultrasound  U
	(if not applicable code 998) o Yes
19c.	Was lesion enumerated on any prior study ultrasound  o 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 #  U  o Yes (complete)  Lesion # from prior ultrasound:
	(e.g. UR1, UB1, UL1, UR2, etc.)  Was lesion enumerated on any study mammogram
	(including additional views obtained today)?  o No
	o Yes (complete) Lesion # from mammogram or additional view number:   (e.g. MR1, MB1, ML1, MR2, etc.)

<b>IM</b>	ACRIN 6666 For revised or corrected form, check box and fax to 215-717-0936.	ACRIN Study 6666 PLACE LABEL HER
		Institution Institution N Participant Initials Case No
	Check if this "lesion" is multiple bilateral circumscribed masses.  Describe largest mass in Q19d and Q19e then proceed to Q19f.  Clockface (report on 1/2 hour) (report on hour and 1/2 hour e.g. 7:00=0700, 12:30=1230)  OROL  o' clock cm	Depth from skin to center of lesion (to nearest 0.5 cm)
196.	Lesion Size  Largest Horizontal Meas (mm) D1  Measured Plane  O Trv  O Sag O Rad O Arad O Oblique	Horizontal Second pendicular Meas Measured Plane O Trv O Sag O Rad O Arad O Perpendicular Oblique Grar lated
19f.	Special Case (see choices below)  O No O Yes (detail below then proceed to Q19o) o Complicated Cyst (Note: Do not use this term for "complex cy For complex cystic masses code "no" for Q19f, proceed to Q1 Homogenous low-level echoes Homogenous low-level echoes Homogenous low-level echoes Multiple bilateral complicated cysts in company of simple o 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 O Other, specify	19g and indicate "complex cystic" at 19k).
19g.	Shape 0 Oval 0 Two or three gentle lobulations 0 Round 0 Irregular	
19h.	Orientation O Parallel to skin O Not parallel (includes round)	
19i.	Margin O Circumscribed	

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

L HERE nstitution No.

> $\text{mm}^3$ Note: Volume is programmed to be calculated on line; however, as verification, please calculate volume based on horizontal, vertical and perpendicular measurements as a valida-

tion.

Volume D1XD2XD3 : 2

19j.

 $\ \square \ \ Indistinct$ ☐ Angular ☐ Microlobulated  $\square$  Spiculated

**Boundary Zone** O Abrupt Interface O Echogenic Halo

<u>IVI</u>	For revised or corrected form, check box and fax to 215-717-0936.
19	9k. Echo Pattern O Anechoic
	O Hyperechoic O Complex cystic O Hypoechoic with few tiny cystic areas O Isoechoic to fat O Mixed hyperechoic and hypoechoic O Hypoechoic to fat
19	Ol. Posterior Features O None O Enhancement O Combined shadowing/enhancement O Shadowing
19	Om. Surrounding Tissue  O No effect  O Effect (check all that apply)  Duct changes Edema Cooper's ligament distortion Architectural distortion Skin thickening Skin retraction
19	On. Vascularity (flow)  O None  O Yes (check all that apply)  Present in lesion  Present immediately adjacent to lesion  Increased in surrounding tissue O Not performed
19	O None O Present (check all that apply)  Macrocalcifications (> 0.5 mm)  Microcalcifications in mass  Microcalcifications outside mass
19	Op. Was lesion palpable in retrospect during sonography?  O No O Yes, in retrospect O Yes, participant presented with lump
20. Is	this lesion at the site of prior biopsy?  o No (proceed to Q21) o Yes (If yes, select procedure) o Core/vacuum biopsy site with clip o Core/vacuum biopsy site without marker o Surgical biopsy site (select diagnosis) o Benign o Atypical/high-risk lesion o Cancer site o Unknown

ACRIN Study 6666
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Institution	Institution No
Participant Initials	Case No.

#### Section III.

21.	Assessment/Recommendations	(b	y lesion)	)
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#### 21b. Assessment for this lesion

- 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

#### 21c. Recommendation(s) for this lesion

- o Routine screening in 1 year
- o Diagnostic follow-up in 1 year
- $\square$  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
- o Intervention and/or Additional Imaging (detail intervention and/or additional imaging)

#### □ Intervention

- o Aspiration with core biopsy if solid
- o US-guided core biopsy
- o Vacuum-assisted biopsy, guidance by US
- o Vacuum-assisted biopsy, guidance by mammo
- o Excisional biopsy
- o Vacuum-assisted biopsy, guided by MRI

#### □ Additional Imaging

- ☐ Targeted ultrasound (lesion seen on mammography)
- $\hfill\square$  Comparison to prior mammogram is required
- ☐ Additional mammographic projections

### 21d. Is this lesion assessed as probably benign AND recommended for intervention?

- o No (proceed to Q22)
- o Yes (specify dominant reason)
  - o Participant preference
  - o Cancer present now
    - o In this breast
    - o In opposite breast
  - o Patient risks factors
  - o Vaguely palpable
  - o Follow-up not reasonable
  - o Interval increase (>20% in volume for masses)
  - o Interval suspicious change
  - o Investigator uncertainty

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

- O No (proceed to Q16)
- O Yes (proceed to Section IIC)

o Biopsy details unknown

o Not applicable, multiple bilateral circumscribed masses

o FNAB

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IMI _	ACRIN 6666		
	or revised or corrected form, check box and fax to 215-717-0936.		
	(by lesion)		
Description fo	lete Mammographic Lesion Description and Sonographic Lesion or each lesion to be described based on the ID or MX form, and/or clinical if the additional imaging revealed no abnormalities.		
	n # from prior MRI: G (e.g. GR1, GL1, GL2, etc.) applicable code 998)		
23. Mamr	mographic Lesion Description		
23a.	Were additional mammographic views obtained		
	directed to this finding?  o No (specify reason and proceed to Q24) o Not recommended o Participant refused o Not needed after targeted US o Scheduling constraints; participant rescheduled o Other o Yes (check all that apply) R L		
	□       Spot compression         □       True lateral         □       Laterally exaggerated CC         □       Magnification views         □       Rolled views         □       Repeat CC or MLO or both		
23b.			
	mammographic view(s)? o 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		
	(if not applicable code 998) o Yes		
23c.			
	Lesion # from prior mammogram: M (e.g. MR1, MB1, ML1, MR2, etc.)		
23d.	Was lesion enumerated on any prior study ultrasound?  o No  o Simple cyst  o Not a simple cyst  o Yes (complete) Lesion # from ultrasound:  (e.g. UR1, UB1, UL1, UR2, etc.)		
23e.	Location on Mammography: (check all that apply)		
	<b>Note:</b> for multiple bilateral findings with similar appearances, check "bilateral, multiple" and indicate specific location and size of the largest such finding.		
	o Right breast		
23f.	Distance from nipple cm by Mammography		
23g.	Size of lesion by Mammography:		
	(largest diameter) Mm (largest perpendicular dimension)		
23h.	Lesion Description Mammography (check all that apply)		

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Institutio	n Institution No
Participa	nt Initials Case No
	Mass (select worse margin feature present)
	Asymmetry (code type of asymmetry) o Focal Asymmetry seen on o One view o Both views
	o Global  Calcifications (code morphology and distribution) Morphology of calcifications (check all that apply)  Coarse typically benign Milk of calcium Coarse heterogeneous Punctate (<0.5 mm, uniformly round) Amorphous/Indistinct Pleomorphic Branching/Fine linear Distribution of calcifications (check all that apply) Clustered Multiple clusters (same morphology) Regional Linear Segmental Diffuse scattered In mass or asymmetry Architectural Distortion
24. Sono	graphic Lesion Description
24a.	Was ultrasound performed again directed to this lesion?  o No (specify reason and proceed to Q25) o Not recommended o Participant refused o Not needed after additional mammographic views o Scheduling constraints; participant rescheduled o Other o Yes (check all that apply)  Targeted only Whole breast
24b.	Was lesion seen on this Ultrasound?  o No (complete then proceed to Q25)  Lesion # from prior mammogram  (if not applicable code 998)  Lesion # from prior ultrasound  (if not applicable code 998)  o Yes
24c.	Was lesion enumerated on any prior study ultrasound  o No (complete) o Simple cyst (proceed to Q25) o Not a simple cyst and not visible in retrospect (assign next sequential sonogram lesion #) o Not a simple cyst and now visible in retrospect (assign next sequential sonogram lesion #) New lesion # U  o Yes (complete) Lesion # from prior ultrasound: (e.g. UR1, UB1, UL1, UR2, etc.)  Was lesion enumerated on any study mammogram (including additional views obtained today)? o No o Yes (complete)
	Lesion # from mammogram or additional view number: M

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

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		Institution		tion No
24d.	□ Check if this "lesion" is multiple bilateral circumscribed masses.  Describe largest mass in Q24d and Q24e then proceed to Q24f.  Clockface Breast (report on 1/2 hour)  (report on hour and 1/2 hour e.g. 7:00 = 0700, 12:30 = 1230)	Depth from ski center of lesio (to nearest 0.5	<u>on</u>	
	o R o L o' clock cm		cm	
24e.	Lesion Size  Largest Horizontal Measured Plane Wertical A-P Period Plane Measured Plane Measured Plane Measured Plane Measured Plane Measured Plane Measured Plane	<u>Horizontal</u> pendicular Meas <u>M</u>	<u>Second</u> leasured Plane	Volume D1XD2XD3 ÷ 2
	Meas (mm) D1 O Trv meas (mm) D2	(mm) D3 0	) Trv ) Sag	
	o Arad o Oblique	0	o Rad o Perpendicular Oblique	<b>Note:</b> Volume is programmed to be calculated on line; however,
24f.	Special Case (see choices below) O No O Yes (detail below then proceed to Q24o)			as verification, please calculate volume based on horizontal, vertical and perpendicular mea-
	For complex cystic masses code "no" for Q24f, proceed to Q2  Homogenous low-level echoes Fluid debris level Mobile internal echoes Multiple bilateral complicated cysts in company of simple of 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		cystic" at 24k).	
24g.	Shape 0 Oval 0 Two or three gentle lobulations			
	O Round O Irregular			
24h.	Orientation O Parallel to skin O Not parallel (includes round)			
24i.	Margin  O Circumscribed  O Not circumscribed (If not circumscribed, choose dominant feature ☐ Indistinct ☐ Angular ☐ Microlobulated ☐ Spiculated	e)		
24j.	Boundary Zone O Abrupt Interface C Echogenic Halo			

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M		ACRIN 6666 For revised or corrected form, check box and fax to 215-717-0936
	241	<ul> <li>k. Echo Pattern</li> <li>O Anechoic</li> <li>O Hyperechoic</li> <li>O Complex cystic</li> <li>O Hypoechoic with few tiny cystic areas</li> <li>O Isoechoic to fat</li> <li>O Mixed hyperechoic and hypoechoic</li> <li>O Hypoechoic to fat</li> </ul>
	241	<ul> <li>Posterior Features</li> <li>O None</li> <li>O Enhancement</li> <li>O Combined shadowing/enhancement</li> <li>O Shadowing</li> </ul>
	241	<ul> <li>M. Surrounding Tissue</li> <li>O No effect</li> <li>O Effect (check all that apply)</li> <li>Duct changes</li> <li>Edema</li> <li>Cooper's ligament distortion</li> <li>Architectural distortion</li> <li>Skin thickening</li> <li>Skin retraction</li> </ul>
	241	n. Vascularity (flow)  O None  O Yes (check all that apply)  ☐ Present in lesion  ☐ Present immediately adjacent to lesion ☐ Increased in surrounding tissue O Not performed
	240	O. Calcifications on ultrasound O None O Present (check all that apply)  Macrocalcifications (> 0.5 mm)  Microcalcifications in mass  Microcalcifications outside mass
	24	<ul> <li>Was lesion palpable in retrospect during sonography?</li> <li>O No</li> <li>O Yes, in retrospect</li> <li>O Yes, participant presented with lump</li> </ul>
25.	ls t	his lesion at the site of prior biopsy? o No (proceed to Q26)

o Yes (If yes, select procedure)

o Atypical/high-risk lesion

o Biopsy details unknown

o Benign

o FNAB

o Cancer site o Unknown

o Core/vacuum biopsy site with clip

o Core/vacuum biopsy site without marker

o Not applicable, multiple bilateral circumscribed masses

o Surgical biopsy site (select diagnosis)

#### ACRIN Study 6666 PLACE LABEL HERE

Institution	Institution No
Participant Initials	Case No.

#### Section III.

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

this lesion (best guess from 0-100)

#### 26b. Assessment for this lesion

- 0 1 Negative
- 0 2 Benign
- 0 3 Probably Benign
- 4A Low Suspicion of Malignancy 0
- Intermediate Suspicion 0
- Moderately High Suspicion 0
  - Highly Suggestive of Malignancy

### 26c. Recommendation(s) for this lesion

- o Routine screening in 1 year
- o 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
- o Intervention and/or Additional Imaging
  - (detail intervention and/or additional imaging)

#### □ Intervention

- o Aspiration with core biopsy if solid
- o US-guided core biopsy
- o Vacuum-assisted biopsy, guidance by US
- o Vacuum-assisted biopsy, guidance by mammo
- o Excisional biopsy
- o 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?

- o No (proceed to Q27)
- o Yes (specify dominant reason)
  - o Participant preference
  - o Cancer present now
    - o In this breast
    - o In opposite breast
  - o Patient risks factors
  - o Vaguely palpable
  - o Follow-up not reasonable
  - o Interval increase (>20% in volume for masses)
  - o Interval suspicious change
  - o Investigator uncertainty

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

- O No (proceed to Q16)
- O Yes (proceed to Section IID)

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ļ			Fo	r revised or corrected form, check box and fax to 215-717-0936.				
Ш				(by lesion)				
	Des	script	ion fo	olete Mammographic Lesion Description and Sonographic Lesion or each lesion to be described based on the ID or MX form, and/or clinical n if the additional imaging revealed no abnormalities.				
	IID			n # from prior MRI: <b>G</b> (e.g. GR1, GL1, GL2, etc.) applicable code 998)				
	28	. М	amn	nographic Lesion Description				
		28	Ba.	Were additional mammographic views obtained directed to this finding?  o No (specify reason and proceed to Q29) o Not recommended o Participant refused o Not needed after targeted US o Scheduling constraints; participant rescheduled				
				o Other o Yes (check all that apply)  R L  Spot compression  True lateral  Laterally exaggerated CC  Magnification views Rolled views  Repeat CC or MLO or both				
		28	Bb.	Was lesion seen on additional mammographic view(s)?				
				o 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  (if not applicable code 998)  o Yes				
		28	Bc.	Was lesion enumerated on any prior study mammogram?  o No and not visible in retrospect (assign next sequential mammogram lesion #)  o No but now visible in retrospect (assign next sequential mammogram lesion #)				
				New lesion # M  o Yes Lesion # from prior ultrasound: M (e.g. MR1, MB1, ML1, MR2, etc.)				
		28	Bd.	Was lesion enumerated on any prior study ultrasound?  o No o Simple cyst o Not a simple cyst o Yes (complete) Lesion # from ultrasound: U (e.g. UR1, UB1, UL1, UR2, etc.)				
		28e.	ße.	<b>Location on Mammography:</b> (check all that apply)				
				<b>Note:</b> for multiple bilateral findings with similar appearances, check "bilateral, multiple" and indicate specific location and size of the largest such finding.				
				oRight breast ☐ Upper oLeft breast ☐ Lower ☐ Bilateral, multiple ☐ Inner ☐ Axillary tail ☐ Outer ☐ Retroareolar ☐ Central				
		28	ßf.	Distance from nipplecm by Mammography				
		28	ßg.	Size of lesion by Mammography:				
				(largest diameter) mm X (largest perpendicular dimension)				
		28	ßh.	Lesion Description Mammography				

Institutio	on	Institution No		
Participa	ant Initials	Case No.		
	☐ Coarse typically☐ Milk of calcium☐ Coarse heteroge	of asymmetry) on phology and distribution) ations (check all that apply) benign eneous mm, uniformly round)		
	☐ Pleomorphic ☐ Branching/Fine li Distribution of calcifica ☐ Clustered ☐ Multiple clusters ☐ Regional ☐ Linear ☐ Segmental ☐ Diffuse scattere ☐ In mass or asyr ☐ Architectural Distortion	inear ations (check all that apply) (same morphology)  ad mmetry		
	graphic Lesion Descri	-		
<b>29a.</b>	to this lesion?  o No (specify reason an o Not recommended o Participant refused o Not needed after ac	dditional mammographic views ints; participant rescheduled		
29b.	Was lesion seen on t o No (complete then proced Lesion # from prior (if not applicable co	ed to Q30) mammogram M de 998)		
	Lesion # from prior (if not applicable co o Yes			
<b>29c.</b>	o No (complete) o Simple cyst (proced o Not a simple cyst a (assign next sequel O Not a simple cyst a (assign next sequel New lesion #  U  Ves (complete) Lesion # from prior ult	and not visible in retrospect ntial sonogram lesion #) and now visible in retrospect ntial sonogram lesion #)  arrasound:		
	(including additional o No	UR2, etc.) ted on any study mammogram views obtained today)?		
	o Yes (complete) Lesion # from mammonumber:  (e.g. MR1, MB1, ML1,	ogram or additional view MR2, etc.)		

(check all that apply)

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		Institution	Institu	ıtion No	
29d.	☐ Check if this "lesion" is multiple bilateral circumscribed masses.	Participant Initia	ls Case	Case No.	
	Describe largest mass in Q29d and Q29e then proceed to Q29f.  Clockface Breast (report on 1/2 hour) (report on hour and 1/2 hour e.g. 7:00 = 0700, 12:30 = 1230)				
	o R o L o' clock cm		cm		
29e.	Lesion Size				
	Largest Horizontal Meas (mm) D1  Measured Plane O Trv  Vertical A-P meas (mm) D2	Horizontal pendicular Meas (mm) D3	Second Measured Plane o Trv	Volume D1XD2XD3 - 2	
	o Sag o Rad o Arad o Oblique	mm	o Sag o Rad o Arad o Perpendicular Oblique	Mote: Volume is programmed to be calculated on line; however, as verification, please	
29f.	Special Case (see choices below)  O No  O Yes (detail below then proceed to Q29o)  o Complicated Cyst (Note: Do not use this term for "complex cy For complex cystic masses code "no" for Q29f, proceed to Q2  Homogenous low-level echoes  Hobile internal echoes  Multiple bilateral complicated cysts in company of simple of 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  O Other, specify	9g and indicate "com	nplex cystic" at 29k).	calculate volume based on horizontal, vertical and perpendicular measurements as a validation.	
29g.	Shape 0 Oval 0 Two or three gentle lobulations 0 Round 0 Irregular				
29h.	Orientation O Parallel to skin O Not parallel (includes round)				
<b>29i.</b>	Margin  O Circumscribed  O Not circumscribed (If not circumscribed, choose dominant featur  ☐ Indistinct ☐ Angular ☐ Microlobulated ☐ Spiculated	e)			
29j.	Boundary Zone O Abrupt Interface O Echogenic Halo				

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IV	Fo	or revised or corrected form, check box and fax to 215-717-0936.
	29k.	Echo Pattern  O Anechoic  O Hyperechoic  O Complex cystic  O Hypoechoic with few tiny cystic areas  O Isoechoic to fat  O Mixed hyperechoic and hypoechoic  O Hypoechoic to fat
	291.	Posterior Features  0 None  0 Enhancement  0 Combined shadowing/enhancement  0 Shadowing
	29m.	Surrounding Tissue  O No effect  Effect (check all that apply)  Duct changes Edema Cooper's ligament distortion Architectural distortion Skin thickening Skin retraction
	29n.	Vascularity (flow)  O None  O Yes (check all that apply)  □ Present in lesion  □ Present immediately adjacent to lesion  □ Increased in surrounding tissue  O Not performed
	290.	Calcifications on ultrasound  0 None  0 Present (check all that apply)  □ Macrocalcifications (> 0.5 mm)  □ Microcalcifications in mass  □ Microcalcifications outside mass
	29p.	Was lesion palpable in retrospect during sonography?  O No O Yes, in retrospect O Yes, participant presented with lump
30.	0	s lesion at the site of prior biopsy?  No (proceed to Q31)  Yes (If yes, select procedure) o Core/vacuum biopsy site with clip o Core/vacuum biopsy site without marker o Surgical biopsy site (select diagnosis) o Benign o Atypical/high-risk lesion o Cancer site o Unknown o Biopsy details unknown

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Institution	Institution No
Participant Initials	Case No.

#### Section III. (by lesion)

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

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

#### 31b. Assessment for this lesion

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

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

- o Routine screening in 1 year
- o Diagnostic follow-up in 1 year
- ☐ Short-interval follow-up in 6 months with US
- $\hfill\square$  Short-interval follow-up in 6 months with mammo
- $\hfill\square$  Short-interval follow-up in 6 months with MRI
- o Intervention and/or Additional Imaging (detail intervention and/or additional imaging)

#### ☐ Intervention

- o Aspiration with core biopsy if solid
- o US-guided core biopsy
- o Vacuum-assisted biopsy, guidance by US
- o Vacuum-assisted biopsy, guidance by mammo
- o Excisional biopsy
- o 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?

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

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

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

o FNAB

o Not applicable, multiple bilateral circumscribed masses

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		r revised or corrected form, check box and fax to 215-717-0936.				
Please of Descrip	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.					
		# from prior MRI: <b>G</b> (e.g. GR1, GL1, GL2, etc.) applicable code 998)				
33. M	lamn	nographic Lesion Description				
3	3a.	Were additional mammographic views obtained				
		directed to this finding?  o No (specify reason and proceed to Q34) o Not recommended o Participant refused o Not needed after targeted US o Scheduling constraints; participant rescheduled o Other  o Yes (check all that apply)  R L  Spot compression True lateral Laterally exaggerated CC Magnification views Repeat CC or MLO or both				
33	3b.	Was lesion seen on additional				
		mammographic view(s)? o 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)				
3.	2.0	o Yes				
3.	3c.	Was lesion enumerated on any prior study mammogram?  o No and not visible in retrospect (assign next sequential mammogram lesion #)  o No but now visible in retrospect (assign next sequential mammogram lesion #)  New lesion # M  o Yes Lesion # from prior mammogram:  (e.g. MR1, MB1, ML1, MR2, etc.)				
33	3d.	Was lesion enumerated on any prior study				
		ultrasound?  o No o Simple cyst o Not a simple cyst o Yes (complete) Lesion # from ultrasound:  (e.g. UR1, UB1, UL1, UR2, etc.)				
33	3e.	Location on Mammography: (check all that apply)				
		<b>Note:</b> for multiple bilateral findings with similar appearances, check "bilateral, multiple" and indicate specific location and size of the largest such finding.				
		oRight breast ☐ Upper oLeft breast ☐ Lower ☐ Bilateral, multiple ☐ Inner ☐ Axillary tail ☐ Outer ☐ Retroareolar ☐ Central				
3	3f.	Distance from nipplecm by Mammography				
3	3g.	Size of lesion by Mammography:				
		(largest diameter) X (largest perpendicular dimension)				
3,	3h	Lesion Description Mammography				

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Institutio	n	Institution No
Participa	ant Initials	Case No.
	Mass (select worse margir	. ,
	Asymmetry (code type of o Focal Asymmetry seen on of One view of Both views of Global	
	☐ Coarse typically I ☐ Milk of calcium ☐ Coarse heterogen ☐ Punctate (<0.5 m ☐ Amorphous/Indist ☐ Pleomorphic ☐ Branching/Fine lin	tions (check all that apply) penign eous m, uniformly round) inct ear ions (check all that apply) same morphology)
34. Sono	graphic Lesion Descrip	tion
34a.		proceed to Q35)  ditional mammographic views tts; participant rescheduled
34b.	Was lesion seen on the No (complete then proceed Lesion # from prior reference (if not applicable code Lesion # from prior use (if not applicable code of Yes)	d to Q35) nammogram
34c.	o No (complete) o Simple cyst (proceed o Not a simple cyst ar (assign next sequent o Not a simple cyst ar (assign next sequent New lesion # U  O Yes (complete) Lesion # from prior ultra (e.g. UR1, UB1, UL1, U  Was lesion enumerate	nd not visible in retrospect tial sonogram lesion #) Id now visible in retrospect tial sonogram lesion #)  asound:  U  UR2, etc.) ed on any study mammogram views obtained today)?

(check all that apply)

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

ÍΝ	ACRIN 6666 For revised or corrected form, check box and fax to 215-717-0936.			]	ACRIN Study 660 PLACE LABEL	66 HERE	
				Institution	Inst	itution No	
34d.	34d. ☐ Check if this "lesion" is multiple bilateral circumscribed masses. Describe largest mass in Q34d and Q34e then proceed to Q34f.				ials Cas	Case No.	
	<u>Breast</u>	Clockface (report on 1/2 he (report on hour and 1/ e.g. 7:00 = 0700, 12:30 =	Distance from the nipple // 2 hour	Davids forms	lesion		
	0 <b>R</b> 0 <b>L</b>	o' o	clock	n 🔲	cm		
34e.	Lesion Size <u>Largest</u> <u>Horizontal</u> <u>Meas (mm) D1</u>	Measured Plane	<u>Vertical A-P</u> <u>meas (mm) D2</u>	<u>Horizontal</u> pendicular Meas (mm) D3	Second Measured Plane O Try	<u>Volume D1XD2XD3 ÷ 2</u>	
	mm	o Sag	<b>X</b>	mm	o Sag o Rad o Arad o Perpendicular Obliqu	Note: Volume is programmed to be calculated on line; however, as verification, please	
34f.	O No O Yes (detail below o Complicated ( For complex ( Homoger Mobile in Multiple bilate o Mass in or on c Clustered mic Intraductal mac o Lymph node o Calcifications o Foreign body o Post-surgical o Other, specify	cystic masses code "r nous low-level echoe oris level iternal echoes oilateral complicated oral solid oval, circums skin crocysts ass without a mass	se this term for "complex one" for Q34f, proceed to Ges	34g and indicate "cor	mplex cystic" at 34k).	calculate volume based on horizontal, vertical and perpendicular measurements as a validation.	
34g.	Shape O Oval O Two or three get O Round O Irregular	ntle lobulations					
34h.	Orientation O Parallel to skin O Not parallel (incl	udes round)					
34i.	Margin O Circumscribed O Not circumscribe Indistinct Angular Microlobula Spiculated		ed, choose dominant featu	ıre)			
34j.	Boundary Zone O Abrupt Interface O Echogenic Halo	·					

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M	Fo	ACRIN 6666 or revised or corrected form, check box and fax to 215-717-0936.
;	34k.	Echo Pattern  O Anechoic  O Hyperechoic  O Complex cystic  O Hypoechoic with few tiny cystic areas  O Isoechoic to fat  O Mixed hyperechoic and hypoechoic  O Hypoechoic to fat
;	341.	Posterior Features  O None  O Enhancement  O Combined shadowing/enhancement  O Shadowing
:	34m.	Surrounding Tissue  0 No effect  0 Effect (check all that apply)  Duct changes Edema Cooper's ligament distortion Architectural distortion Skin thickening Skin retraction
;	34n.	Vascularity (flow)  O None  O Yes (check all that apply)  ☐ Present in lesion ☐ Present immediately adjacent to lesion ☐ Increased in surrounding tissue  O Not performed
;	340.	Calcifications on ultrasound  O None  O Present (check all that apply)  ☐ Macrocalcifications (> 0.5 mm)  ☐ Microcalcifications in mass  ☐ Microcalcifications outside mass
;	34p.	Was lesion palpable in retrospect during sonography?  O No O Yes, in retrospect O Yes, participant presented with lump
<b>35.</b>	0	No (proceed to Q36) Yes (If yes, select procedure) O Core/vacuum biopsy site with clip O Core/vacuum biopsy site without marker Surgical biopsy site (select diagnosis) O Benign O Atypical/high-risk lesion

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Institution	Institution No
Participant Initials	Case No.

#### Section III.

36. Assessment/Recommendations (	by	(lesion)
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**│% likelihood of malignancy for** this lesion (best guess from 0-100)

#### 36b. Assessment for this lesion

- 1 Negative
- 0 2 Benign
- Probably Benign 0 3
- Low Suspicion of Malignancy 0 4A
- 4B Intermediate Suspicion 0
- 4C Moderately High Suspicion 0
- 0 5 Highly Suggestive of Malignancy

#### 36c. Recommendation(s) for this lesion

- o Routine screening in 1 year
- o Diagnostic follow-up in 1 year
- ☐ Short-interval follow-up in 6 months with US
- $\hfill\square$  Short-interval follow-up in 6 months with mammo
- ☐ Short-interval follow-up in 6 months with MRI
- o Intervention and/or Additional Imaging (detail intervention and/or additional imaging)

#### □ Intervention

- o Aspiration with core biopsy if solid
- o US-guided core biopsy
- o Vacuum-assisted biopsy, guidance by US
- o Vacuum-assisted biopsy, guidance by mammo
- o Excisional biopsy
- o 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?

- o No (proceed to Q37)
- o Yes (specify dominant reason)
  - o Participant preference
  - o Cancer present now
    - o In this breast
    - o In opposite breast
  - o Patient risks factors
  - o Vaguely palpable
  - o Follow-up not reasonable
  - o Interval increase (>20% in volume for masses)
  - o Interval suspicious change
  - o Investigator uncertainty

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

- O No (proceed to Q16)
- O Yes (proceed to Section IIF)

o Cancer site o Unknown

o FNAB

o Biopsy details unknown

o Not applicable, multiple bilateral circumscribed masses

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	IV	Ш		IN 0000 check box and fax to 215-717-0936.		
			·	CHECK DOX AND TAX TO 2 13-7 17-0930.		
	Results (by lesion) Please complete Mammographic Lesion Description and Sonographic Lesion Description for each lesion to be described based on the ID or MX form, and/or clinical findings even if the additional imaging revealed no abnormalities.					
	IIF.		sion # from prior MRI: G not applicable code 998		tc.)	
	38.	Ma	mmographic Lesion De	escription		
		38	directed to this find o No (specify reason and o Not recommended o Participant refused o Not needed after tal	d proceed to Q39)  rgeted US  nts; participant rescheduled  poly)  ression	t	
			Laterally ex  Magnification Rolled view Repeat CC	aggerated CC on views as or MLO or both		
		38	mammographic vie o No e.g. resolved on addi	ew(s)? itional views (complete then proceed to Q	(39)	
Lesion # from prior mammogram (if not applicable code 998)  Lesion # from prior ultrasound (if not applicable code 998)  o Yes						
	38c. Was lesion enumerated on any prior study mammogram?  o No and not visible in retrospect (assign next sequential mammogram lesion #)  o No but now visible in retrospect (assign next sequential mammogram lesion #)  New lesion # M  o Yes Lesion # from prior mammogram:  (e.g. MR1, MB1, ML1, MR2, etc.)					
	(e.g. MR1, MB1, ML1, MR2, etc.)  38d. Was lesion enumerated on any prior study ultrasound?  o No o Simple cyst o Not a simple cyst o Yes (complete) Lesion # from ultrasound: (e.g. UR1, UB1, UL1, UR2, etc.)					
		38	e. Location on Mamm	ography: (check all that apply	)	
			appearances, check	ilateral findings with similar "bilateral, multiple" and indica I size of the largest such findi		
			o Left breast ☐ ☐ Bilateral, multiple ☐ ☐ Axillary tail ☐	Upper Lower Inner Outer Central		
		38	f. Distance from nippl	e cm by Mammograp	hy	
		38	g. Size of lesion by Ma	nmmography:		
			(largest diameter)	mm (largest perpendicular dimension)		
	38h Lesion Description Mammography					

## ACRIN Study 6666 PLACE LABEL HERE

Institution	Institution No		
Participant Initials			
☐ Mass (select worse n o Circumscribed o Fat-containir o Not fat-conta o Microlobulated o Obscured o Indistinct o Spiculated ☐ Asymmetry (code ty o Focal Asymmetry see o One view o Both views o Global	ng aining pe of asymmetry)		
☐ Calcifications (code r Morphology of cal ☐ Coarse typic ☐ Milk of calcit ☐ Coarse heter ☐ Punctate ( <c amorphous="" branching="" calcit<="" distribution="" f="" of="" pleomorphic="" td="" ☐=""><td>um rogeneous 0.5 mm, uniformly round) Indistinct inelinear cifications (check all that apply) ters (same morphology)  ttered asymmetry</td></c>	um rogeneous 0.5 mm, uniformly round) Indistinct inelinear cifications (check all that apply) ters (same morphology)  ttered asymmetry		
39. Sonographic Lesion Des	•		
to this lesion?  o No (specify reasor o Not recommend o Participant refu o Not needed afte	sed er additional mammographic views straints; participant rescheduled		
o No (complete then Lesion # from (if not applica Lesion # from (if not applica	proceed to Q40) prior mammogram M  prior ultrasound U  ble code 998) ble code 998)		
o No (complete) o Simple cyst (pro o Not a simple cy (assign next set o Not a simple cy (assign next set New lesion # Lesion # from prio (e.g. UR1, UB1, Lesion enume	yst and not visible in retrospect quential sonogram lesion #) yst and now visible in retrospect quential sonogram lesion #)  J  or ultrasound:		
o Yes (complete)			

(check all that apply)

Lesion # from mammogram or additional view number:

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

IM	For revised or corr	ACRIN 6666 rected form, check box and f			ACRIN Study 666 PLACE LABEL 1	HERE
						ution No.
39d.		sion" is multiple bilatera mass in Q39d and Q3 Clockface (report on 1/2 hor (report on hour and 1/2 e.g. 7:00 = 0700, 12:30 = 1	9e then proceed to Q3  Distance frur) the nipple hour (230)	es. 39f. om Depth fro	m skin to f lesion	
39e.	Lesion Size  Largest Horizontal Meas (mm) D1	Measured Plane o Trv o Sag o Rad o Arad o Oblique	meas (mm) D2	Horizontal Perpendicular Meas (mm) D3	Second Measured Plane o Trv o Sag o Rad o Arad o Perpendicular Oblique	Volum  Note: gramm lated c
39f.	O No O Yes (detail below o Complicated of For complex of Homoge Homoge Multiple of Multiple bilate o Mass in or on o Clustered mice o Lymph node o Calcifications o Foreign body o Post-surgical	sternal echoes bilateral complicated cy ral solid oval, circumsci skin crocysts ass without a mass	this term for "complex" for Q39f, proceed to state the company of simulation masses	Q39g and indicate "c	omplex cystic" at 39k).	as ver calcula on hor and pe sureme tion.
39g.	Shape 0 Oval 0 Two or three ge 0 Round 0 Irregular	ntle lobulations				
39h.	Orientation O Parallel to skin O Not parallel (incl	udes round)				
39i.	Margin O Circumscribed O Not circumscribe	ed (If not circumscribed	I, choose dominant fe	ature)		

☐ Indistinct ☐ Angular  $\hfill\square$  Microlobulated ☐ Spiculated

**Boundary Zone** O Abrupt Interface O Echogenic Halo

39j.

Volume D1XD2XD3 - 2

Note: Volume is programmed to be calcu-

lated on line; however, as verification, please calculate volume based on horizontal, vertical and perpendicular measurements as a valida-

 ${\rm mm^3}$ 

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### **ACRIN 6666**

<u>•</u> F	or revised or corrected form, check box and fax to 215-717-0936.
39k.	Echo Pattern
JJK.	O Anechoic
	O Hyperechoic
	O Complex cystic
	O Hypoechoic with few tiny cystic areas
	O Isoechoic to fat
	O Mixed hyperechoic and hypoechoic
	O Hypoechoic to fat
391.	Posterior Features
331.	O None
	O Enhancement
	O Combined shadowing/enhancement
	O Shadowing
	o chadowing
39m.	Surrounding Tissue
	O No effect
	O Effect (check all that apply)
	☐ Duct changes
	☐ Edema ☐ Cooper's ligament distortion
	☐ Architectural distortion
	☐ Skin thickening
	☐ Skin retraction
39n.	Vascularity (flow)
	O None
	O Yes (check all that apply)
	☐ Present in lesion
	☐ Present immediately adjacent to lesion
	☐ Increased in surrounding tissue
	O Not performed
39o.	Calcifications on ultrasound
	O None
	O Present (check all that apply)
	☐ Macrocalcifications (> 0.5 mm)
	☐ Microcalcifications in mass
	☐ Microcalcifications outside mass
39n.	Was lesion palpable in retrospect
oop.	during sonography?
	O No
	O Yes, in retrospect
	O Yes, participant presented with lump
le thi	s lesion at the site of prior biopsy?
	No (proceed to Q41)
	Yes (If yes, select procedure)
	o Core/vacuum biopsy site with clip
	o Core/vacuum biopsy site without marker
	o Surgical biopsy site (select diagnosis) o Benign
	o Atypical/high-risk lesion
	o Cancer site
	o Unknown

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Institution	Institution No
Participant Initials	Case No.

#### Section III.

41. Assess	ment/Recommendations	(by	lesion
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#### 41b. Assessment for this lesion

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

#### 41c. Recommendation(s) for this lesion

- o Routine screening in 1 year
- o Diagnostic follow-up in 1 year
- $\square$  Short-interval follow-up in 6 months with US
- $\square$  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

- o Aspiration with core biopsy if solid
- o US-guided core biopsy
- o Vacuum-assisted biopsy, guidance by US
- o Vacuum-assisted biopsy, guidance by mammo
- o Excisional biopsy
- o 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?

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

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

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

o Biopsy details unknown

o Not applicable, multiple bilateral circumscribed masses

o FNAB

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	IV	Ш	For revised or corrected form, check box and fax to 215-717-0936.				
			·				
	Results (by lesion)						
	Desc	riptic	emplete Mammographic Lesion Description and Sonographic Lesion on for each lesion to be described based on the ID or MX form, and/or clinical even if the additional imaging revealed no abnormalities.				
	IIG.		sion # from prior MRI: <b>G</b> (e.g. GR1, GL1, GL2, etc.) not applicable code 998)				
	43.		mmographic Lesion Description				
		43	a. Were additional mammographic views obtained				
			directed to this finding?				
			<ul> <li>No (specify reason and proceed to Q44)</li> <li>Not recommended</li> </ul>				
			o Participant refused				
			<ul> <li>Not needed after targeted US</li> <li>Scheduling constraints; participant rescheduled</li> </ul>				
			o Other o Yes (check all that apply)				
			R L  ☐ Spot compression				
			☐ ☐ True lateral				
			☐ ☐ Laterally exaggerated CC ☐ ☐ Magnification views				
			☐ ☐ Rolled views ☐ ☐ Repeat CC or MLO or both				
		431					
			mammographic view(s)?				
			o 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) o Yes				
43c. Was lesion enumerated on any prior							
	study mammogram? o No and not visible in retrospect						
(assign next sequential mammogram lesion #)							
o No but now visible in retrospect (assign next sequential mammogram lesion #)							
New lesion # M							
o Yes  Lesion # from prior mammogram:			o Yes Lesion # from prior mammogram:				
			(e.g. MR1, MB1, ML1, MR2, etc.)				
		430	d. Was lesion enumerated on any prior study ultrasound?				
			o No				
			o Simple cyst o Not a simple cyst				
			o Yes (complete) Lesion # from ultrasound:  U				
			(e.g. UR1, UB1, UL1, UR2, etc.)				
		43	3 7 7 (* * * * * * * * * * * * * * * * *				
			<b>Note:</b> for multiple bilateral findings with similar appearances, check "bilateral, multiple" and indicate				
			specific location and size of the largest such finding.				
			o Right breast ☐ Upper o Left breast ☐ Lower				
			☐ Bilateral, multiple ☐ Inner				
			☐ Axillary tail ☐ Outer ☐ Retroareolar ☐ Central				
		431	f. Distance from nipple cm by Mammography				
		43	g. Size of lesion by Mammography:				
			mm <b>X</b> mm				
		401	(largest diameter) (largest perpendicular dimension)				
		431	h. Lesion Description Mammography (check all that apply)				

## ACRIN Study 6666 PLACE LABEL HERE

Institutio	n Institution No
Participa	nt Initials Case No
44 Sono	☐ Architectural Distortion  graphic Lesion Description
44a.	Was ultrasound performed again directed
	to this lesion?  o No (specify reason and proceed to Q45) o Not recommended o Participant refused o Not needed after additional mammographic views o Scheduling constraints; participant rescheduled o Other o Yes (check all that apply)  Targeted only Whole breast
44b.	Was lesion seen on this Ultrasound?  o No (complete then proceed to Q45)
	Lesion # from prior mammogram  (if not applicable code 998)  Lesion # from prior ultrasound  (if not applicable code 998)
44-	o 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)?
	o Yes (complete) Lesion # from mammogram or additional view number:  (e.g. MR1, MB1, ML1, MR2, etc.)

IM	ACRIN 6666 For revised or corrected form, check box and fax to 215-717-0936.	ACRIN Study 6666 PLACE LABEL HERE			
		Institution	Institut	tion No	
		Participant Initia	ls Case N	No	
44d.	☐ Check if this "lesion" is multiple bilateral circumscribed masses.  Describe largest mass in Q44d and Q44e then proceed to Q44	lf.			
	Clockface (report on 1/2 hour)  (report on hour and 1/2 hour e.g. 7:00 = 7, 12:30 = 12.5)  Distance fro the nipple		<u>lesion</u>		
	o R o L o' clock	m 📙	cm		
44e.	Lesion Size				
	<u>Largest</u> <u>Horizontal</u> <u>Meas (mm) D1</u> Measured Plane  O Trv  Vertical A-P meas (mm) D2	Horizontal erpendicular Meas (mm) D3	<u>Second</u> <u>Measured Plane</u> o Trv	Volume D1XD2XD3 ÷ 2	
	o Sag o Rad o Arad o Oblique	mm	o Sag o Rad o Arad o Perpendicular Oblique	mm³  Note: Volume is programmed to be calculated on line; however,	
44g.	Special Case (see choices below)  O No O Yes (detail below then proceed to Q44o) o Complicated Cyst (Note: Do not use this term for "complex of For complex cystic masses code "no" for Q44f, proceed to Geometric Homogenous low-level echoes Homogenous low-level echoes Homogenous low-level echoes Multiple bilateral echoes Multiple bilateral complicated cysts in company of simple of Multiple bilateral solid oval, circumscribed masses o Mass in or on skin o Clustered microcysts o Intraductal mass o Lymph node o Calcifications without a mass o Foreign body o Post-surgical scar o Other, specify  Shape O Oval O Two or three gentle lobulations O Round	Q44g and indicate "cor	mplex cystic" at 44k).	as verification, please calculate volume based on horizontal, vertical and perpendicular measurements as a validation.	
44h.	O Irregular  Orientation O Parallel to skin O Not parallel (includes round)				
44i.	Margin  O Circumscribed  O Not circumscribed (If not circumscribed, choose dominant feat ☐ Indistinct ☐ Angular ☐ Microlobulated ☐ Spiculated	ture)			
44j.	Boundary Zone O Abrupt Interface O Echogenic Halo				

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/		ACRIN 6666 or revised or corrected form, check box and fax to 215-717-093	36.
	441	Echo Pattern  O Anechoic  O Hyperechoic  O Complex cystic  O Hypoechoic with few tiny cystic areas  O Isoechoic to fat  O Mixed hyperechoic and hypoechoic  O Hypoechoic to fat	
	441	Posterior Features 0 None 0 Enhancement 0 Combined shadowing/enhancement 0 Shadowing	
	44r	Surrounding Tissue  O No effect  Effect (check all that apply)  Duct changes  Edema  Cooper's ligament distortion  Architectural distortion  Skin thickening  Skin retraction	
	44r	Vascularity (flow)  0 None  0 Yes (check all that apply)  □ Present in lesion □ Present immediately adjacent to lesion □ Increased in surrounding tissue  0 Not performed	
	440	Calcifications on ultrasound  O None  O Present (check all that apply)  ☐ Macrocalcifications (> 0.5 mm)  ☐ Microcalcifications in mass  ☐ Microcalcifications outside mass	
	44p	Was lesion palpable in retrospect during sonography?  O No O Yes, in retrospect O Yes, participant presented with lump	
	Is t	No (proceed to Q46) Yes (If yes, select procedure) o Core/vacuum biopsy site with clip o Core/vacuum biopsy site without marker o Surgical biopsy site (select diagnosis)	

### 45

- 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

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		•		-		T T

### PLACE LABEL HERE

Institution	Institution No.
Participant Initials	Case No.

#### Section III.

46.	Assessment/Recommendations	(b	y lesion)
	, recoccinional recommission and recommendations	~.	,

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

#### 46b. Assessment for this lesion

- 1 Negative
- 2 Benign 0
- Probably Benign 0
- 4A Low Suspicion of Malignancy 0
- 4B Intermediate Suspicion 0
- 0 Moderately High Suspicion
- 0 5 Highly Suggestive of Malignancy

#### 46c. Recommendation(s) for this lesion

- o Routine screening in 1 year
- o 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
- o Intervention and/or Additional Imaging (detail intervention and/or additional imaging)

#### □ Intervention

- o Aspiration with core biopsy if solid
- o US-guided core biopsy
- o Vacuum-assisted biopsy, guidance by US
- o Vacuum-assisted biopsy, guidance by mammo
- o Excisional biopsy
- o 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?

- o No (proceed to Q47)
- o Yes (specify dominant reason)
  - o Participant preference
  - o Cancer present now
    - o In this breast
    - o In opposite breast
  - o Patient risks factors
  - o Vaguely palpable
  - o Follow-up not reasonable
  - o Interval increase (>20% in volume for masses)
  - o Interval suspicious change
  - o Investigator uncertainty

- O No (proceed to Q16)
- O Yes (proceed to Section IIH)

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	II\/	Ш	ACRIN 6666
Ĺ	1 I V		For revised or corrected form, check box and fax to 215-717-0936.
II.	Re	SII	ts (by lesion)
•••	Plea Desc	se c cripti	omplete Mammographic Lesion Description and Sonographic Lesion on for each lesion to be described based on the ID or MX form, and/or clinical even if the additional imaging revealed no abnormalities.
	IIH.		sion # from prior MRI: <b>G</b> (e.g. GR1, GL1, GL2, etc.) not applicable code 998)
	48.	Ma	ammographic Lesion Description
		48	
			directed to this finding?  o No (specify reason and proceed to Q49) o Not recommended o Participant refused o Not needed after targeted US o Scheduling constraints; participant rescheduled o Other o Yes (check all that apply)  R L  Spot compression True lateral Laterally exaggerated CC Magnification views Repeat CC or MLO or both
		48	b. Was lesion seen on additional
			mammographic view(s)?
			o No e.g. resolved on additional views (complete then proceed to Q49)  Lesion # from prior mammogram (if not applicable code 998)  Lesion # from prior ultrasound (if not applicable code 998)  o Yes
		48	c. Was lesion enumerated on any prior study mammogram?  o No and not visible in retrospect (assign next sequential mammogram lesion #)  o No but now visible in retrospect (assign next sequential mammogram lesion #)  New lesion # M  o Yes Lesion # from prior mammogram:
		48	(e.g. MR1, MB1, ML1, MR2, etc.)
		70	ultrasound?  o No o Simple cyst o Not a simple cyst o Yes (complete) Lesion # from ultrasound:  (e.g. UR1, UB1, UL1, UR2, etc.)
		48	e. Location on Mammography: (check all that apply)
			<b>Note:</b> for multiple bilateral findings with similar appearances, check "bilateral, multiple" and indicate specific location and size of the largest such finding.
			o Right breast
		48	f. Distance from nipple cm by Mammography
		48	
			(largest diameter) X (largest perpendicular dimension)
		48	h. Lesion Description Mammography (check all that apply)

## ACRIN Study 6666 PLACE LABEL HERE

Mass (select worse margi o Circumscribed o Fat-containing o Not fat-containin o Microlobulated o Obscured o Indistinct o Spiculated  Asymmetry (code type of	. ,
o Circumscribed o Fat-containing o Not fat-containin o Microlobulated o Obscured o Indistinct o Spiculated  ☐ Asymmetry (code type of	. ,
Morphology of calcification  ☐ Coarse typically ☐ Milk of calcium ☐ Coarse heteroge	hology and distribution) titions (check all that apply) benign
☐ Amorphous/Indis ☐ Pleomorphic ☐ Branching/Fine lii Distribution of calcifica ☐ Clustered ☐ Multiple clusters ☐ Regional ☐ Linear ☐ Segmental ☐ Diffuse scattere	tinct near titions (check all that apply) (same morphology)
raphic Lesion Descri	otion
to this lesion?	ormed again directed
o Not recommended o Participant refused o Not needed after ac o Scheduling constrai o Other	ditional mammographic views nts; participant rescheduled
Lesion # from prior (if not applicable cool Lesion # from prior	mammogram M de 998) ultrasound U
o No (complete) o Simple cyst (procee o Not a simple cyst a	nd not visible in retrospect tial sonogram lesion #) nd now visible in retrospect tial sonogram lesion #) asound:
	o Global Calcifications (code morpinopology of calcifications (code morpinopology of calcifications) Coarse typically Milk of calcium Coarse heteroger Punctate (<0.5 m Amorphous/Indis Pleomorphic Branching/Fine lir Distribution of calcifications Clustered Multiple clusters Regional Linear Segmental Diffuse scattered In mass or asym Architectural Distortion  raphic Lesion Descrip Was ultrasound performs to this lesion? O No (specify reason and o Not recommended o Participant refused o Not needed after ad o Scheduling constrain o Other O Yes (check all that appended on the composition of the compo

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

IM	ACRIN 6666 For revised or corrected form, check box and fax to 215-717-09:	36.	P	ACRIN Stud	
			Institution		Ins Ca
49d.			Depth from center of (to nearest	<u>lesion</u>	
	o R o L o' clock	cm		cm	
49e.	Lesion Size  Largest Horizontal Meas (mm) D1  Measured Plane o Trv  O Sag o Rad o Arad o Oblique	- Peru	Horizontal pendicular Meas (mm) D3 mm	Second Measured Plan o Trv o Sag o Rad o Arad o Perpendicular	_
49f.	Special Case (see choices below)  O No O Yes (detail below then proceed to Q49o) o Complicated Cyst (Note: Do not use this term for "or For complex cystic masses code "no" for Q49f, proceed to Plant of the Port	ceed to Q4	19g and indicate "co	nplex cystic" at 49k	;).
49g.	Shape 0 Oval 0 Two or three gentle lobulations 0 Round 0 Irregular				
49h.	Orientation O Parallel to skin O Not parallel (includes round)				
49i.	Margin  O Circumscribed  O Not circumscribed (If not circumscribed, choose domin  ☐ Indistinct ☐ Angular ☐ Microlobulated	nant featur	e)		

"Copyright 2007"

 $\ \square \ {\sf Spiculated}$ 

**Boundary Zone** O Abrupt Interface O Echogenic Halo

49j.

666 HERE stitution No. se No. – Volume D1XD2XD3 ÷ 2  $\,\mathrm{mm^3}$ Note: Volume is programmed to be calcuue lated on line; however, as verification, please calculate volume based on horizontal, vertical and perpendicular measurements as a validation.

IM
----

M	Fo	ACRIN 6666  r revised or corrected form, check box and fax to 215-717-0936.
	49k.	Echo Pattern  O Anechoic  O Hyperechoic  O Complex cystic  O Hypoechoic with few tiny cystic areas  O Isoechoic to fat  O Mixed hyperechoic and hypoechoic  O Hypoechoic to fat
	491.	Posterior Features  0 None  0 Enhancement  0 Combined shadowing/enhancement  0 Shadowing
	49m.	Surrounding Tissue  O No effect  Effect (check all that apply)  Duct changes Edema Cooper's ligament distortion Architectural distortion Skin thickening Skin retraction
	49n.	Vascularity (flow)  0 None  0 Yes (check all that apply)  □ Present in lesion □ Present immediately adjacent to lesion □ Increased in surrounding tissue  0 Not performed
	490.	Calcifications on ultrasound  O None  O Present (check all that apply)  ☐ Macrocalcifications (> 0.5 mm)  ☐ Microcalcifications in mass  ☐ Microcalcifications outside mass
	49p.	Was lesion palpable in retrospect during sonography?  O No O Yes, in retrospect O Yes, participant presented with lump
50.	0	No (proceed to Q51) Yes (If yes, select procedure) O Core/vacuum biopsy site with clip Core/vacuum biopsy site without marker Surgical biopsy site (select diagnosis) O Benign O Atypical/high-risk lesion

### ACRIN Study 6666 PLACE LABEL HERE

Institution	Institution No
Participant Initials	Case No.

#### Section III.

51.	Assessment/Recommendations	(b)	(lesion	)

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

#### 51b. Assessment for this lesion

- 1 Negative
- 0 2 Benign

0

- Probably Benign (Q51d required) 0
- 4A Low Suspicion of Malignancy 0
- 4B Intermediate Suspicion 0
- 4C Moderately High Suspicion 0
  - 5 Highly Suggestive of Malignancy

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

- o Routine screening in 1 year
- o Diagnostic follow-up in 1 year
- ☐ Short-interval follow-up in 6 months with US
- $\hfill\square$  Short-interval follow-up in 6 months with mammo
- ☐ Short-interval follow-up in 6 months with MRI
- o Intervention and/or Additional Imaging (detail intervention and/or additional imaging)

#### □ Intervention

- o Aspiration with core biopsy if solid
- o US-guided core biopsy
- o Vacuum-assisted biopsy, guidance by US
- o Vacuum-assisted biopsy, guidance by mammo
- o Excisional biopsy
- o 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?

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

Proceed to Final Assessment(s) Q16, Q17.

o Cancer site o Unknown o Biopsy details unknown

o Not applicable, multiple bilateral circumscribed masses

o FNAB

# 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 No th fo

by the Note: that re	ould remain <u>consistent</u> from the IA or IS form on which the lesion was first reported. Radiologist. If follow-up evaluation is not able to be completed at first return visit, con Description is only required for those lesions requiring short interval follow-up and for equires description. Use IM form to report any additional evaluation prompted by new clin- up MRI was performed, please complete an M4.	nplete a se lesions fo	econd "continuation" form <b>F6</b> when patient returns to complete follow-up. and only on this follow-up evaluation. Complete Section II for each lesion
l. (	Is this form F6 the continuation from additional evaluations reported on another form F6?  o No o Yes	;	Ba. Have there been any clinically significant changes in the right breast since the last annual examination?  o No o Yes (check all clinical changes that apply)  □ Palpable mass (complete location) Location of abnormality
2.	Did participant return for the scheduled follow-up?  o No (specify reason, STOP and sign form) o Second opinion, felt not warranted o Participant refusal o Participant unable to be contacted o Unable to be performed and rescheduled o Yes o Completed o Incomplete, will return on (mm-dd-yyyy) ☐ (Check box if date unknown)		o'clock or specify location:  o Axilla o Retroareolar o Unknown  Nipple discharge (detail): o Bloody o Clear spontaneous o Other Other, specify:  Not applicable (not on study) (proceed to Q8b)
3.	Indication for exam(s): (check all that apply)  ☐ Follow-up mammogram ☐ Follow-up ultrasound ☐ Clinical abnormalities ☐ CAD abnormalities	•	Bb. Have there been any clinically significant changes in the left breast since the last annual examination?  o No o Yes (check all clinical changes that apply)  □ Palpable mass (complete location) Location of abnormality
4.	Date study(ies) performed (mm-dd-yyyy)		o'clock or specify location:
5.	4a. Date of study interpretation (mm-dd-yyyy)  4b. Timepoint in study prompting this short-interval follow-up  o Initial screening o 12 month screening o 24 month screening o Other, specify: months  Radiologist ACRIN ID #		o Axilla o Retroareolar o Unknown □ Nipple discharge (detail): o Bloody o Clear spontaneous o Other □ Other, specify: o Not applicable (not on study) (proceed to Q9)
<b>.</b>	5a. Radiologist performing short-interval follow-up (last, first)		Has the patient had any other evaluation of preast(s) since the last annual study exam(s)?
6.	Which breast(s) are reported on this form? (check all that apply)  Right Breast Left Breast		o Yes (check all that apply)  ☐ Clinical examination ☐ Biopsy, already reported ☐ Biopsy, not already reported Note: Complete BX form if core or FNA done, NL
7.	How many lesions are being followed?		form for surgical biopsy and S1 if cancer found.
	For the right breast? (code 98 if not on study)		☐ MRI with contrast o Right o Left
	For the left breast? (code 98 if not on study)		o Bilateral □ Outside US
	7a. Were any new lesions seen on this follow-up mammogram?  o No (proceed to Q7b) o Yes (detail how many) o Not applicable, not done (proceed to Q7b)		☐ Outside mammogram  Comparison studies other than most recent annual nammogram and study US?  o Not available (proceed to Q11)
	7b. Were any new lesions seen on this follow-up ultrasound?  o No (proceed to Q8a) o Yes (detail how many) o Not applicable, not done (proceed to Q8a)		o Available (complete, check all that apply)  ☐ Prior mammography ☐ Prior targeted US ☐ Right ☐ Left ☐ Prior survey US

F6	ACRIN 6666 For revised or corrected form, check box and fax to 215-717-0936.		PLAC	CRIN Study 6666 E LABEL HERE
l. Resul	ts (by lesion)	_ Institutio	n	Institution No
Please co	mplete Mammographic Lesion Description and Sonographic Lesion in for each lesion being followed and for any new findings on this	Participa	nt Initials	Case No
follow-up	examination.			
	esion # from prior MRI: (e.g.GR1, GL1, GL2, etc.) (f not applicable code 998)		(check all that app	
,	mographic Lesion Description		o Circumso o Fat-co	ribed
11a.	Were mammographic views obtained of this finding on this follow-up evaluation?  o No (specify reason and proceed to Q12) o Not recommended o Participant refused o Not needed after targeted US o Scheduling constraints; participant rescheduled o Other o Yes		o Microlobu o Obscured o Indistinct o Spiculate Asymmetry (co	d ode type of asymmetry) try seen on iew
11b.	Change in this lesion from prior mammogram(s)?  New Gone (complete then proceed to Q12) Lesion # from prior mammogram M  (if not applicable code 998) Lesion # from prior ultrasound (if not applicable code 998)  Decreasing Stable Fluctuating bilateral circumscribed masses Increasing Other suspicious change(s) Increasing and other suspicious change(s)		☐ Calcifications (	e heterogeneous ate (<0.5 mm, uniformly round) shous/Indistinct orphic ning/Fine linear of calcifications (check all that apply) red le clusters (same morphology) nal ental e scattered
11c.	Was lesion enumerated on any prior		☐ In mas	ss or asymmetry istortion
	study mammogram? o No and not visible in retrospect	12. Sono	graphic Lesior	Description
11d.	(assign next sequential mammogram lesion #)  o No but now visible in retrospect (assign next sequential mammogram lesion #)  New lesion # M  o Yes Lesion # from prior mammogram: M (e.g. MR1, MB1, ML1, MR2, etc.)  Was lesion enumerated on any prior study	12a.	this follow-up  o No (specify o Not recor o Participar o Not need o Schedulir o Other o Yes (check ☐ Targeted	reason and proceed to Q13) mmended nt refused ed after additional mammographic views ng constraints; participant rescheduled all that apply) only
	ultrasound?  o No o Simple cyst o Not a simple cyst o Yes (complete) Lesion # from ultrasound:  (e.g. UR1, UB1, UL1, UR2, etc.)	12b.	o New o Gone (comp Lesion # fro	s lesion from prior ultrasound?  elete then proceed to Q13)  m prior mammogram M  sable code 998)
11e.	Location on Mammography: (check all that apply)  Note: for multiple bilateral findings with similar appearances, check "bilateral, multiple" and indicate specific location and size of the largest such finding.  o Right breast Upper Lower		Lesion # fro (if not applic Decreasing Stable Fluctuating I Increasing Other suspic	bilateral circumscribed masses cious change(s) ind other suspicious change(s)
	☐ Bilateral, multiple ☐ Inner ☐ Axillary tail ☐ Outer ☐ Retroareolar ☐ Central	12c.	o No (complet o Simple cy	numerated on any prior study ultrasound?  e) yst (proceed to Q13) ple cyst and not visible in retrospect
11f.	Distance from nipple cm by Mammography		(assign no	ext sequential sonogram lesion #)  ple cyst and now visible in retrospect
11g.	Size of lesion by Mammography:		New lesion  O Yes (complete Lesion # from the second test test)	
		12d.	Was lesion el (including vie o No o Yes (comple	numerated on any study mammogram ews obtained today)?
				m mammogram M MB1, ML1, MR2, etc.)

F6	For revised or corr	ACRIN 6660 rected form, check box and		P	ACRIN Study 6666 LACE LABEL H	TERE
				Institution	Institu	ıtion No
				Participant Initia	ls Case	No
12e.	☐ Check if this "les	ion" is multiple bilateral	I circumscribed masses. [	Describe largest mass	s in Q12e and Q12f then pro	oceed to Q12g.
	<u>Breast</u>	Clockface (report on 1/2 hou (report on hour and 1/2 e.g. 7:00 = 0700, 12:30 = 1	hour	Depth from center of (to nearest	<u>lesion</u>	
	o <b>R</b> o <b>L</b>	o' clo			cm	
12f.	Lesion Size					
	<u>Largest</u> <u>Horizontal</u> <u>Meas (mm) D1</u>	Measured Plane o Trv	<u>Vertical A-P</u> Peri meas (mm) D2	Horizontal pendicular Meas (mm) D3	Second Measured Plane o Trv	Volume D1XD2XD3 ÷ 2
	mm	o Sag o Rad o Arad	mm <b>X</b>	mm	o Sag o Rad o Arad	mm³ Note: Volume is pro-
12g. 12h.	o No o Yes (detail below o Complicated C For complex o Homoger Fluid deb Mobile in Multiple b	cystic masses code "no nous low-level echoes ris level ternal echoes bilateral complicated cyral solid oval, circumsor skin crocysts ass	this term for "complex cy " for Q12g, proceed to Q sts in company of simple ribed masses	12h and indicate "cor	o Perpendicular Oblique	grammed to be calculated on line; however, as verification, please calculate volume based on horizontal, vertical and perpendicular measurements as a validation.
12i.	o Round o Irregular  Orientation o Parallel to skin					
12j.	o Not parallel (included)  Margin o Circumscribed o Not circumscribe	ed (If not circumscribed	, choose dominant featur	e)		
12k.	Boundary Zone o Abrupt Interface o Echogenic Halo					

F6	
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<b>6</b> Fo	ACRIN 6666 r revised or corrected form, check box and fax to 215-717-093
121.	Echo Pattern  O Anechoic  O Hyperechoic  O Complex cystic  O Hypoechoic with few tiny cystic areas  O Isoechoic to fat  O Mixed hyperechoic and hypoechoic  O Hypoechoic to fat
12m.	Posterior Features  0 None  0 Enhancement  0 Combined shadowing/enhancement  0 Shadowing
12n.	Surrounding Tissue  O No effect  Effect (check all that apply)  Duct changes Edema Cooper's ligament distortion Architectural distortion Skin thickening Skin retraction
120.	Vascularity (flow)  O None O Yes (check all that apply)  ☐ Present in lesion ☐ Present immediately adjacent to lesion ☐ Increased in surrounding tissue O Not performed
12p.	Calcifications on ultrasound  O None  O Present (check all that apply)  ☐ Macrocalcifications (> 0.5 mm)

- ☐ Microcalcifications in mass
- ☐ Microcalcifications outside mass

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

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

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

- o No (proceed to Q14)
- o Yes (If yes, select procedure)
  - o Core/vacuum biopsy site with clip
  - o Core/vacuum biopsy site without marker
  - 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

## ACRIN Study 6666

	PLACE LA	AREL HEKE	
Institu	ıtion	Institution No.	
Partic	ipant Initials		
Section	on III.		
14.	Assessment/Recomme	endations	

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

#### 14b. Assessment for this lesion

- 0 1 Negative
- Ω 2 Benign
- Probably Benign 0 3
- 4A Low Suspicion of Malignancy Ω
- 4B Intermediate Suspicion 0
- 4C Moderately High Suspicion 0
- Highly Suggestive of Malignancy 0

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

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

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

- o Return to routine screening
- o Diagnostic follow-up to coincide with next annual exam
- $\square$  Short-interval follow-up in 6 months with US
- ☐ Short-interval follow-up in 6 months with mammography
- ☐ Short-interval follow-up in 6 months with MRI
- o Intervention and/or Additional Imaging (detail intervention and/or additional imaging)

#### □ Intervention

- o Aspiration with core biopsy if solid
- o US-guided core biopsy
- o Vacuum-assisted biopsy, guidance by US
- o Vacuum-assisted biopsy, guidance by mammo
- o Excisional biopsy
- o US-guided biopsy, if US negative, MRI guided biopsy

#### □ Additional Imaging

- ☐ 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?

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

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

F6
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ACRIN 6666
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	ACRII	N Study	666	<b>6</b> 6
PLA	CE 1	LAB	EL.	HER

(sign and date form)  Note: Final assessment should be based on the worst lesion present, even if that lesion did not undergo additional evaluation.  16a.	evaluation of Left Breast evaluation of Left Breast, see IA and IS e form)  essment should be based on the worst lesion that lesion did not undergo additional evaluation.  % Likelihood of malignancy for this est guess from 0-100)  ent for this breast Negative Benign Probably Benign Low Suspicion of Malignancy Intermediate Suspicion Moderately High Suspicion Highly Suggestive of Malignancy endation for this breast or orutine screening tic follow-up to coincide with next annual exam terval follow-up in 6 months with US terval follow-up in 6 months with MRI tion and/or Additional Imaging tervention and/or additional imaging) vention biration with core biopsy if solid -guided core biopsy cuum-assisted biopsy, guidance by US cuum-assisted biopsy, guidance by mammo cisional biopsy
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.	evaluation of Left Breast, see IA and IS te form)  essment should be based on the worst lesion that lesion did not undergo additional evaluation.  """  "Likelihood of malignancy for this test guess from 0-100)  ent for this breast  Negative  Benign  Probably Benign  Low Suspicion of Malignancy Intermediate Suspicion  Moderately High Suspicion  Highly Suggestive of Malignancy  endation for this breast  to routine screening tic follow-up to coincide with next annual exam terval follow-up in 6 months with US terval follow-up in 6 months with mammography terval follow-up in 6 months with MRI tion and/or Additional Imaging tervention and/or additional imaging)  vention  Diration with core biopsy if solid  -guided core biopsy cuum-assisted biopsy, guidance by US cuum-assisted biopsy, guidance by mammo cisional biopsy
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.	evaluation of Left Breast, see IA and IS te form)  essment should be based on the worst lesion that lesion did not undergo additional evaluation.  """  "Likelihood of malignancy for this test guess from 0-100)  ent for this breast  Negative  Benign  Probably Benign  Low Suspicion of Malignancy Intermediate Suspicion  Moderately High Suspicion  Highly Suggestive of Malignancy  endation for this breast  to routine screening tic follow-up to coincide with next annual exam terval follow-up in 6 months with US terval follow-up in 6 months with mammography terval follow-up in 6 months with MRI tion and/or Additional Imaging tervention and/or additional imaging)  vention  Diration with core biopsy if solid  -guided core biopsy cuum-assisted biopsy, guidance by US cuum-assisted biopsy, guidance by mammo cisional biopsy
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  0 1 Negative 0 2 Benign 0 3 Probably Benign 0 4A Low Suspicion of Malignancy 0 4B Intermediate Suspicion 0 5 Highly Suggestive of Malignancy 16c. Recommendation for this breast 0 Return to routine screening 0 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 MRI 0 Intervention and/or Additional Imaging (detail intervention and/or additional imaging)   Intervention   O Aspiration with core biopsy if solid   O Vacuum-assisted biopsy, guidance by US   O Vacuum-assisted biopsy   O Vacuum-a	" " " " " " " " " " " " " " " " " " "
16b. Assessment for this breast  0 1 Negative 0 2 Benign 0 3 Probably Benign 0 4A Low Suspicion of Malignancy 0 4B Intermediate Suspicion 0 4C Moderately High Suspicion 0 5 Highly Suggestive of Malignancy 16c. Recommendation for this breast 0 Return to routine screening 0 Diagnostic follow-up to coincide with next annual exam 0 Short-interval follow-up in 6 months with US 0 Short-interval follow-up in 6 months with MRI 0 Intervention and/or Additional Imaging (detail intervention and/or additional imaging) (detail intervention and/or additional imaging) 0 US-guided core biopsy 0 Vacuum-assisted biopsy, guidance by US 0 Vacuum-assisted biopsy, guidance by mammo 0 US-guided biopsy, if US negative, MRI guided biopsy 0 Additional Imaging 0 Additional evaluation 0 Comparison to prior mammography) 0 Additional mammographic projections	Negative Benign Probably Benign Low Suspicion of Malignancy Intermediate Suspicion Moderately High Suspicion Highly Suggestive of Malignancy Indation for this breast o routine screening tic follow-up to coincide with next annual exam terval follow-up in 6 months with US terval follow-up in 6 months with mammography terval follow-up in 6 months with MRI tion and/or Additional Imaging tervention and/or additional imaging) vention biration with core biopsy if solid -guided core biopsy cuum-assisted biopsy, guidance by US cuum-assisted biopsy, guidance by mammo cisional biopsy
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 o Return to routine screening o Diagnostic follow-up to coincide with next annual exam o Return to routine screening o Diagnostic follow-up in 6 months with US o Intervention Interval follow-up in 6 months with MRI o Intervention and/or Additional Imaging (detail intervention and/or Additional imaging) o US-guided core biopsy o Vacuum-assisted biopsy, guidance by US o Vacuum-assisted biopsy, guidance by US o US-guided biopsy, if US negative, MRI guided biopsy  Additional Imaging o 1 Negative o 2 Benign o 2 Benign o 2 Benign o 3 Probabl o 4A Low St o 4A Low St o 4B Intermediate Suspicion o 4B Intermediate o Diagnostic follow-up in 6 months with US o Diagnostic follow	Negative Benign Probably Benign Low Suspicion of Malignancy Intermediate Suspicion Moderately High Suspicion Highly Suggestive of Malignancy endation for this breast o routine screening tic follow-up to coincide with next annual exam terval follow-up in 6 months with US terval follow-up in 6 months with mammography terval follow-up in 6 months with MRI tion and/or Additional Imaging tervention and/or additional imaging) vention biration with core biopsy if solid -guided core biopsy cuum-assisted biopsy, guidance by US cuum-assisted biopsy, guidance by mammo cisional biopsy
o Diagnostic follow-up to coincide with next annual exam Short-interval follow-up in 6 months with US Short-interval follow-up in 6 months with mammography Short-interval follow-up in 6 months with MRI Short-interval follow-up in 6 months with MRI 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 (lesion seen on mammography) Additional mammographic projections  O Diagnostic follow Short-interval foll	tic follow-up to coincide with next annual exameterval follow-up in 6 months with US terval follow-up in 6 months with mammography terval follow-up in 6 months with MRI tion and/or Additional Imaging tervention and/or additional imaging) tervention and/or additional imaging) vention  Diration with core biopsy if solid -guided core biopsy cuum-assisted biopsy, guidance by US cuum-assisted biopsy, guidance by mammo cisional biopsy
o Vacuum-assisted biopsy, guidance by US o Vacuum-assisted biopsy, guidance by mammo o Excisional biopsy o US-guided biopsy, if US negative, MRI guided biopsy  Additional Imaging Additional evaluation Comparison to prior mammogram is required Targeted ultrasound (lesion seen on mammography) Additional mammographic projections  o Vacuum-assisted biopsy o Us-guided biopsy o US-guided biopsy additional in Additional In Comparison to prior mammogram is required (lesion seen on mammography) (lesion	cuum-assisted biopsy, guidance by US cuum-assisted biopsy, guidance by mammo cisional biopsy
□ Targeted ultrasound       □ Targeted         (lesion seen on mammography)       (lesion         □ Additional mammographic projections       □ Addition	Additional evaluation
☐ Technique/interpretation in question ☐ Techni	☐ Comparison to prior mammogram is required  Fargeted ultrasound (lesion seen on mammography) ☐ Additional mammographic projections  Repeat ultrasound ☐ Technique/interpretation in question
☐ Repeat mammogram ☐ Repeat m ☐ Incomplete ☐ Incomp	☐ Possibly abnormal Repeat mammogram ☐ Incomplete ☐ Motion artifact/other technical problem
·	mplete, sign and date below.

F	6	ACRIN 6666			
II. F	Resul	For revised or corrected form, check box and fax to 215-717-0936  ts (by lesion)	Ins	titutio	n
P	Please co Description	implete Mammographic Lesion Description and Sonographic Lesion on for each lesion being followed and for any new findings on this examination.		rticipa	
	18A.L	Lesion # from prior MRI: (e.g.GR1, GL1, GL2, etc.) if not applicable code 998)		18h.	Les (chec
18.	Mam	mographic Lesion Description			
	18a.	Were mammographic views obtained of this finding on this follow-up evaluation?  o No (specify reason and proceed to Q19) o Not recommended o Participant refused o Not needed after targeted US o Scheduling constraints; participant rescheduled o Other			□ As
	18b.	o Yes  Change in this lesion from prior mammogram(s)?  o New o Gone (complete then proceed to Q19)			□ Ca
		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			☐ Ar
		study mammogram? o No and not visible in retrospect	19.	Sono	grap
		(assign next sequential mammogram lesion #)  o No but now visible in retrospect (assign next sequential mammogram lesion #)  New lesion #   o Yes Lesion # from prior mammogram:   (e.g. MR1, MB1, ML1, MR2, etc.)		19a.	Was this
	18d.	Was lesion enumerated on any prior study ultrasound?			0
		o No o Simple cyst o Not a simple cyst o Yes (complete) Lesion # from ultrasound:  (e.g. UR1, UB1, UL1, UR2, etc.)		19b.	Cha ° °
	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 □ Upper			0 0 0 0
		o Left breast		19c.	Was
	18f.	Distance from nipple cm by Mammography			
	18g.	Size of lesion by Mammography:			
		(largest diameter) (largest perpendicular dimension)			0

ACRIN Study 6666 PLACE LABEL HERE	

ns	titutior	n Institution No
a	rticipa	nt Initials Case No
	18h.	Lesion Description Mammography  (check all that apply)
		☐ Linear ☐ Segmental ☐ Diffuse scattered
		☐ In mass or asymmetry ☐ Architectural Distortion
9.	Sono	graphic Lesion Description
	19a.	Was ultrasound performed of this lesion on this follow-up evaluation?  o No (specify reason and proceed to Q20) o Not recommended o Participant refused o Not needed after additional mammographic views o Scheduling constraints; participant rescheduled o Other o Yes (check all that apply)  Targeted only Whole breast
	19b.	Change in this lesion from prior ultrasound?
		o New o Gone (complete then proceed to Q20)  Lesion # from prior mammogram M  (if not applicable code 998)  Lesion # from prior ultrasound (if not applicable code 998) o Decreasing o Stable oF Fluctuating bilateral circumscribed masses o Increasing o Other suspicious change(s) o Increasing and other suspicious change(s)
	19c.	Was lesion enumerated on any prior study ultrasound? o No (complete)
		o Simple cyst (proceed to Q20) o Not a simple cyst and not visible in retrospect (assign next sequential sonogram lesion #) o Not a simple cyst and now visible in retrospect (assign next sequential sonogram lesion #) New lesion #  O Yes (complete) Lesion # from prior ultrasound:  (e.g. UR1, UB1, UL1, UR2, etc.)
	19d.	Was lesion enumerated on any study mammogram
		(including views obtained today)?  o No o Yes (complete) Lesion # from mammogram (e.g. MR1, MB1, ML1, MR2, etc.)

F6		ACRIN 6666 ed form, check box and fa			PL	ACRIN Study 6666	
				In	stitution	Institu	tion No
				P	articipant Initials	Case	No
19e.	□ Check if this "lesi  Breast  OROL	Clockface (report on 1/2 ho (report on hour and 1 e.g. 7:00 = 0700, 12:30	Distanc Dur) the ni	e from	Ü	lesion	proceed to Q19g.
19f.	Lesion Size  Largest Horizontal Meas (mm) D1	Measured Plane	Vertical A-P		Horizontal pendicular Meas (mm) D3	Second  Measured Plane  O Try	Volume D1XD
	mm	o Sag	<b>K</b> mm	X	mm	o Sag o Rad o Arad o Perpendicular Oblique	Note: Volum grammed to lated on line:
19g.	o Complicated C For complex c	then proceed to Q1 syst ( <b>Note:</b> Do not us systic masses code "r ous low-level echoe	e this term for "com			omplex cystic" at 19l).	as verification calculate volur on horizontal and perpendic surements as tion.

Multiple bilateral complicated cysts in company of simple cysts

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

Volume D1XD2XD3 : 2

 $\,mm^3\,$ 

19h. Shape

o Oval

o Mass in or on skin o Clustered microcysts o Intraductal mass o Lymph node

o Foreign body o Post-surgical scar o Other, specify .

o Two or three gentle lobulations

o Calcifications without a mass

Mobile internal echoes

o Multiple bilateral solid oval, circumscribed masses

o Round

o Irregular

Orientation

o Parallel to skin

o Not parallel (includes round)

19j. Margin

o Circumscribed

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

☐ Indistinct

☐ Angular

☐ Microlobulated

☐ Spiculated

19k. Boundary Zone

o Abrupt Interface

o Echogenic Halo

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				1	

### **ACRIN 6666**

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#### 19I. Echo Pattern

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

#### 19m. Posterior Features

- O None
- O Enhancement
- O Combined shadowing/enhancement
- O Shadowing

#### 19n. Surrounding Tissue

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

#### 19o. Vascularity (flow)

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

#### 19p. Calcifications on ultrasound

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

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

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

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

- o No (proceed to Q21)
- o Yes (If ves. select procedure)
  - o Core/vacuum biopsy site with clip
  - o Core/vacuum biopsy site without marker
  - 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

## ACRIN Study 6666 PLACE LABEL HERE

Institution	Institution No.
Participant Initials	Case No.

#### Section III.

#### 21. Assessment/Recommendations

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

#### 21b. Assessment for this lesion

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

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

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

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

- o Return to routine screening
- o Diagnostic follow-up to coincide with next annual exam
- ☐ Short-interval follow-up in 6 months with US
- ☐ Short-interval follow-up in 6 months with mammography
- ☐ Short-interval follow-up in 6 months with MRI
- Intervention and/or Additional Imaging (detail intervention and/or additional imaging)

#### □ Intervention

- o Aspiration with core biopsy if solid
- o US-guided core biopsy
- o Vacuum-assisted biopsy, guidance by US
- o Vacuum-assisted biopsy, guidance by mammo
- o Excisional biopsy
- o US-guided biopsy, if US negative, MRI guided biopsy

#### ☐ Additional Imaging

- ☐ 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?

- o No (proceed to Q22)
- o Yes (specify dominant reason)
  - o Participant preference
  - o Cancer present now
    - o In this breast
  - o In opposite breasto Patient risks factors
  - o Vaguely palpable
  - o Follow-up not reasonable
  - o Interval increase (>20% in volume for masses)
  - o Interval suspicious change
  - o Investigator uncertainty

- O No (proceed to Q16)
- O Yes (proceed to Q23)

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F	6	ACRIN 6666
•		For revised or corrected form, check box and fax to 215-717-0936.
P D	lease escrip ollow-u	Lits (by lesion) complete Mammographic Lesion Description and Sonographic Lesion tion for each lesion being followed and for any new findings on this up examination.  Lesion # from prior MRI: (e.g.GR1, GL1, GL2, etc.) (if not applicable code 998)
23.	Mai	mmographic Lesion Description
	23a	o Not recommended o Not recommended o Not recommended o Not recommended o Not needed after targeted US o Scheduling constraints; participant rescheduled o Yes
	23b	o. Change in this lesion from prior mammogram(s)?  o New o Gone (complete then proceed to Q24) Lesion # from prior mammogram M  (if not applicable code 998) Lesion # from prior ultrasound (if not applicable code 998) o Decreasing o Stable o Fluctuating bilateral circumscribed masses o Increasing o Other suspicious change(s) o Increasing and other suspicious change(s)
	230	
	230	I. Was lesion enumerated on any prior study ultrasound?  o No o Simple cyst o Not a simple cyst o Yes (complete) Lesion # from ultrasound: (e.g. UR1, UB1, UL1, UR2, etc.)
	23e	e. 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
	23f	. Distance from nipple cm by Mammography
	23g	. Size of lesion by Mammography:

## ACRIN Study 6666 PLACE LABEL HERE

Institution	Institution No.
Participar	nt Initials Case No
23h.	Lesion Description Mammography
	(check all that apply)
04 0	☐ Architectural Distortion
24. Sono	graphic Lesion Description  Was ultrasound performed of this lesion on
	this follow-up evaluation?  No (specify reason and proceed to Q25)  Not recommended  Participant refused  Not needed after additional mammographic views  Scheduling constraints; participant rescheduled  Other  Yes (check all that apply)  Targeted only  Whole breast
24b. Change in this lesion from prior ultrasound?	
	o New o Gone (complete then proceed to Q25)  Lesion # from prior mammogram  (if not applicable code 998)  Lesion # from prior ultrasound  (if not applicable code 998) o Decreasing o Stable o Fluctuating bilateral circumscribed masses o Increasing o Other suspicious change(s) o Increasing and other suspicious change(s)
24c.	Was lesion enumerated on any prior study ultrasound?
	o No (complete) o Simple cyst (proceed to Q25) o Not a simple cyst and not visible in retrospect (assign next sequential sonogram lesion #) o Not a simple cyst and now visible in retrospect (assign next sequential sonogram lesion #) New lesion # U  o Yes (complete) Lesion # from prior ultrasound:  (e.g. UR1, UB1, UL1, UR2, etc.)
24d.	Was lesion enumerated on any study mammogram (including views obtained today)?  o No o Yes (complete) Lesion # from mammogram

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

mm (largest perpendicular dimension)

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### **ACRIN 6666**

## ACRIN Study 6666 PLACE LABEL HERE

U	For revised or corrected form, check box and fax to 215-717-0936. PLACE LABEL HER	${f E}$
	Institution Institution N	lo
	Participant Initials Case No	
24e.	<b>4e.</b> □ Check if this "lesion" is multiple bilateral circumscribed masses. Describe largest mass in Q24e and Q24f then proceed <b>Clockface Distance from Depth from skin to</b>	ed to Q24g.
	Breast (report on 1/2 hour) the nipple center of lesion (to nearest 0.5 cm)	
0.46	OROL o' clock cm	
24f.	Largest	
	Horizontal Measured Plane Vertical A-P Perpendicular Meas Measured Plane Vol	lume D1XD2XD3 ÷
	Meas (mm) D1 O Trv meas (mm) D2 (mm) D3 O Trv O Sag	
	mm o Rad	mm³
		e: Volume is pro-
	late	d on line; however,
24g.	g. Special Case (see choices below)	verification, please culate volume based horizontal, vertical
24h.		perpendicular mea- ements as a valida-
2411.	o Oval o Two or three gentle lobulations o Round o Irregular	
24i.	i. Orientation  o Parallel to skin  o Not parallel (includes round)	
24j.	ightharpoonup Margin	
24k.	4k. Boundary Zone o Abrupt Interface o Echogenic Halo	

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### ACRIN 6666

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#### 241. **Echo Pattern**

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

#### 24m. Posterior Features

- O None
- O Enhancement
- O Combined shadowing/enhancement
- O Shadowing

#### 24n. Surrounding Tissue

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

#### 24o. Vascularity (flow)

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

#### 24p. Calcifications on ultrasound

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

#### 24q. Was lesion palpable in retrospect during sonography?

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

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

- o No (proceed to Q26)
- o Yes (If yes, select procedure)
  - o Core/vacuum biopsy site with clip
  - o Core/vacuum biopsy site without marker
  - 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

#### ACRIN Study 6666 PLACE LABEL HERE

Institution	Institution No
Participant Initials	Case No.

#### Section III.

#### 26. Assessment/Recommendations

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

#### 26b. Assessment for this lesion

- 0 1 Negative
- 0 2 Benign
- Probably Benign 3 0
- 4A Low Suspicion of Malignancy 0
- 4B Intermediate Suspicion 0
- Moderately High Suspicion 0
- Highly Suggestive of Malignancy 0

#### 26c. Known benign by prior biopsy?

- o No (proceed to Q26d)
- o Yes (complete)
  - o < 1 year ago
  - o 1-2 years ago
  - o > 2 years ago

#### 26d. Recommendation(s) for this lesion

- o Return to routine screening
- o Diagnostic follow-up to coincide with next annual exam
- ☐ Short-interval follow-up in 6 months with US
- ☐ Short-interval follow-up in 6 months with mammography
- ☐ Short-interval follow-up in 6 months with MRI
- o Intervention and/or Additional Imaging (detail intervention and/or additional imaging)

#### □ Intervention

- o Aspiration with core biopsy if solid
- o US-guided core biopsy
- o Vacuum-assisted biopsy, guidance by US
- o Vacuum-assisted biopsy, guidance by mammo
- o Excisional biopsy
- o US-guided biopsy, if US negative, MRI guided biopsy

#### □ Additional Imaging

- ☐ 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?

- o No (proceed to Q27)
- o Yes (specify dominant reason)
  - o Participant preference
  - o Cancer present now
  - o In this breast
  - o In opposite breast o Patient risks factors
  - o Vaguely palpable
  - o Follow-up not reasonable
  - o Interval increase (>20% in volume for masses)
  - o Interval suspicious change
  - o Investigator uncertainty

- O No (proceed to Q16)
- O Yes (proceed to Q28)

F6	ACRIN 6666 For revised or corrected form, check box and fax to 215-717-0936.		ACRIN Stu	dy 6666 BEL HERE
I. Resul	ts (by lesion)	Institutio	n	Institution No.
Please co Description	implete Mammographic Lesion Description and Sonographic Lesion of reach lesion being followed and for any new findings on this examination.	Participa	nt Initials	Case No. ———
28A.L	Lesion # from prior MRI: (e.g.GR1, GL1, GL2, etc.)	28h.	Lesion Description Ma (check all that apply) ☐ Mass (select worse margin	
`	mographic Lesion Description		o Circumscribed o Fat-containing	riodialo procenty
28a.	Were mammographic views obtained of this finding on this follow-up evaluation?  o No (specify reason and proceed to Q29) o Not recommended o Participant refused o Not needed after targeted US o Scheduling constraints; participant rescheduled o Other o Yes		o Not fat-containing o Microlobulated o Obscured o Indistinct o Spiculated □ Asymmetry (code type o o Focal Asymmetry seen on o One view o Both views	f asymmetry)
28b.	Change in this lesion from prior mammogram(s)?		o Global  Calcifications (code morph Morphology of calcifica	nology and distribution) tions (check all that apply)
	o New o Gone (complete then proceed to Q29) Lesion # from prior mammogram  (if not applicable code 998) Lesion # from prior ultrasound (if not applicable code 998) o Decreasing o Stable o Fluctuating bilateral circumscribed masses o Increasing o Other suspicious change(s) o Increasing and other suspicious change(s)		☐ Clustered ☐ Multiple clusters ( ☐ Regional ☐ Linear ☐ Segmental ☐ Diffuse scattered	eous m, uniformly round) inct ear ions (check all that apply) same morphology)
28c.		29. Sono	☐ In mass or asym ☐ Architectural Distortion  graphic Lesion Descrip	•
28d.	(assign next sequential mammogram lesion #)  o No but now visible in retrospect (assign next sequential mammogram lesion #)  New lesion # M  o Yes Lesion # from prior mammogram: (e.g. MR1, MB1, ML1, MR2, etc.)	29a.	o Scheduling constrair o Other o Yes (check all that app ☐ Targeted only	on? proceed to Q30)  ditional mammographic views tts; participant rescheduled
	o No o Simple cyst o Not a simple cyst	29b.	☐ Whole breast  Change in this lesion  o New	from prior ultrasound?
	o Yes (complete) Lesion # from ultrasound:  (e.g. UR1, UB1, UL1, UR2, etc.)		o Gone (complete then pr Lesion # from prior ma (if not applicable code s	mmogram
28e.	Location on Mammography: (check all that apply)		Lesion # from prior ultra	asound U
	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 ☐ Upper ☐ Lower		(if not applicable code so Decreasing Stable Fluctuating bilateral circo Increasing Other suspicious chango Increasing and other suspicious chango Increasing chango Increasing and Increasing Chango Inc	cumscribed masses e(s)
	□ Bilateral, multiple □ Inner □ Axillary tail □ Outer □ Retroareolar □ Central	29c.	was lesion enumerate o No (complete) o Simple cyst (proceed	ed on any prior study ultrasound?
28f.	Distance from nipplecm by Mammography		<ul><li>Not a simple cyst ar (assign next sequent</li><li>Not a simple cyst ar</li></ul>	nd not visible in retrospect tial sonogram lesion #) nd now visible in retrospect
28g.	Size of lesion by Mammography:		(assign next sequent New lesion #	tial sonogram lesion #)
	(largest diameter) X (largest perpendicular dimension)		o Yes (complete)  Lesion # from prior ultr.  (e.g. UR1, UB1, UL1, I	
		29d.		ed on any study mammogram

o No o Yes (complete)

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

F6	ACRIN 6666 For revised or corrected form, check box and fax to 215-717-093	6.	ACRIN Study PLACE LABI	6666 EL HERE
		Institution _		Institution No
		Participant	Initials	Case No.
29e.	☐ Check if this "lesion" is multiple bilateral circumscribe		•	29f then proceed to Q29g.
		<u>e nipple</u> <u>ce</u>	oth from skin to enter of lesion nearest 0.5 cm)	
	OR OL o' clock	cm	cm	
29f.	Lesion Size			
	LargestHorizontalMeasured PlaneVertical A-Meas (mm) D1O Trymeas (mm)	Pernendicular	Measured Pla	ne Volume D1XD2XD3 ÷ 2
	o Sag mm o Rad	mm X	o Sag mm o Rad	mm³
	o Arad		o Arad	Note: Volume is pro-
	o Oblique		o Perpendicular	Oblique grammed to be calcu- lated on line; however,
29g.	Special Case (see choices below)  o No o Yes (detail below then proceed to Q29p) o Complicated Cyst (Note: Do not use this term for For complex cystic masses code "no" for Q29g, p  Homogenous low-level echoes Fluid debris level Mobile internal echoes Multiple bilateral complicated cysts in compar o Multiple bilateral solid oval, circumscribed masses o Mass in or on skin o Clustered microcysts	roceed to Q29h and inc		as verification, please calculate volume based on horizontal, vertical and perpendicular measurements as a validation.
	o Intraductal mass o Lymph node o Calcifications without a mass o Foreign body o Post-surgical scar o Other, specify			
29h.	Shape o Oval			

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

#### 29i. Orientation

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

#### 29j. Margin

- o Circumscribed
- o Not circumscribed (If not circumscribed, choose dominant feature)
  - ☐ Indistinct
  - $\square$  Angular
  - ☐ Microlobulated
  - ☐ Spiculated

### 29k. Boundary Zone

- o Abrupt Interface
- o Echogenic Halo

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		ACRIN 6666
F 6		For revised or corrected form, check box and fax to 215-717-0936
	291.	Echo Pattern
		O Anechoic
		O Hyperechoic
		O Complex cystic
		O Hypoechoic with few tiny cystic areas
		O Isoechoic to fat
		O Mixed hyperechoic and hypoechoic
		O Hypoechoic to fat
	29m	. Posterior Features
		O None
		O Enhancement
		O Combined shadowing/enhancement
		O Shadowing
	29n.	Surrounding Tissue
		O No effect
		O Effect (check all that apply)
		☐ Duct changes ☐ Edema
		☐ Cooper's ligament distortion
		☐ Architectural distortion
		☐ Skin thickening
		☐ Skin retraction
	29o.	Vascularity (flow)
		O None
		O Yes (check all that apply)
		☐ Present in lesion
		<ul> <li>☐ Present immediately adjacent to lesion</li> <li>☐ Increased in surrounding tissue</li> </ul>
		O Not performed
	29p.	
		O None
		O Present (check all that apply)
		☐ Macrocalcifications (> 0.5 mm)
		☐ Microcalcifications in mass
		☐ Microcalcifications outside mass
	29q.	
		sonography?
		O No
		O Yes, in retrospect O Yes, participant presented with lump
30.		is lesion at the site of prior biopsy? o No (proceed to Q31)

o Yes (If yes, select procedure)

o Atypical/high-risk lesion

o Biopsy details unknown

o Benign

o Cancer site

o Unknown

o FNAB

o Core/vacuum biopsv site with clip

o Core/vacuum biopsy site without marker

o Not applicable, multiple bilateral circumscribed masses

o Surgical biopsy site (select diagnosis)

#### 31. Assessment/Recommendations **│% likelihood of malignancy for** this lesion (best guess from 0-100) 31b. Assessment for this lesion Negative 0 2 Benign 0 Probably Benign 0 4A Low Suspicion of Malignancy 0 4B Intermediate Suspicion 0 4C Moderately High Suspicion 0 Highly Suggestive of Malignancy 31c. Known benign by prior biopsy? o No (proceed to Q31d) o Yes (complete)

o < 1 year ago o 1-2 years ago o > 2 years ago

ACRIN Study 6666 PLACE LABEL HERE

Institution No.

Case No.

Institution .

Section III.

Participant Initials \_\_\_\_

### □ Intervention o Aspiration with core biopsy if solid

☐ Short-interval follow-up in 6 months with US

☐ Short-interval follow-up in 6 months with MRI o Intervention and/or Additional Imaging (detail intervention and/or additional imaging)

o US-guided core biopsy

31d. Recommendation(s) for this lesion o Return to routine screening

- o Vacuum-assisted biopsy, guidance by US
- o Vacuum-assisted biopsy, guidance by mammo

o Diagnostic follow-up to coincide with next annual exam

☐ Short-interval follow-up in 6 months with mammography

- o Excisional biopsy
- o 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?

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

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

F6	ACRIN 6666 For revised or corrected form, check box and fax to 215-717-0936.		ACRIN Study 6666 PLACE LABEL HERE
l. Resu	Its (by lesion)	Institutio	on Institution No
Descripti	omplete Mammographic Lesion Description and Sonographic Lesion on for each lesion being followed and for any new findings on this examination.	Participa	ant Initials Case No
33A.	Lesion # from prior MRI: (e.g.GR1, GL1, GL2, etc.)	33h.	Lesion Description Mammography (check all that apply)  ☐ Mass (select worse margin feature present)
	nmographic Lesion Description		o Circumscribed o Fat-containing
33a.	Were mammographic views obtained of this finding on this follow-up evaluation?  o No (specify reason and proceed to Q34) o Not recommended o Participant refused o Not needed after targeted US o Scheduling constraints; participant rescheduled o Other o Yes		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
33b.	Change in this lesion from prior mammogram(s)?  New Gone (complete then proceed to Q34) Lesion # from prior mammogram M  (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)		□ 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
33c.	Was lesion enumerated on any prior study mammogram?  No and not visible in retrospect (assign next sequential mammogram lesion #)  No but now visible in retrospect (assign next sequential mammogram lesion #)  New lesion # M  Yes Lesion # from prior mammogram: M (e.g. MR1, MB1, ML1, MR2, etc.)		☐ In mass or asymmetry ☐ Architectural Distortion  Ographic Lesion Description  Was ultrasound performed of this lesion on this follow-up evaluation?  o No (specify reason and proceed to Q35) o Not recommended o Participant refused o Not needed after additional mammographic views o Scheduling constraints; participant rescheduled o Other
33d.	Was lesion enumerated on any prior study ultrasound?  o No o Simple cyst o Not a simple cyst o Yes (complete) Lesion # from ultrasound: (e.g. UR1, UB1, UL1, UR2, etc.)	34b.	o Yes (check all that apply)  Targeted only Whole breast  Change in this lesion from prior ultrasound?  o New o Gone (complete then proceed to Q35)  Lesion # from prior mammogram  (if not applicable code 998)
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	240	Lesion # from prior ultrasound (if not applicable code 998) o Decreasing o Stable o Fluctuating bilateral circumscribed masses o Increasing o Other suspicious change(s) o Increasing and other suspicious change(s)
33f. 33g.	☐ Axillary tail ☐ Outer☐ Retroareolar ☐ Central  Distance from nipple ☐ cm by Mammography	34c.	Was lesion enumerated on any prior study ultrasound'  o No (complete)  o Simple cyst (proceed to Q35)  o Not a simple cyst and not visible in retrospect (assign next sequential sonogram lesion #)  o Not a simple cyst and now visible in retrospect (assign next sequential sonogram lesion #)  New lesion #   o 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)?  o No o Yes (complete)

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

F6	ACRIN 6666 For revised or corrected form, check box and fax to 215-717-0936.	PL	ACRIN Study 6666 ACE LABEL H	ERE
	1	Institution	Institut	ion No
		Participant Initials	Case N	lo
34e.	☐ Check if this "lesion" is multiple bilateral circumscribed masse	es. Describe largest mas	ss in Q34e and Q34f then r	proceed to Q34a.
	Breast Clockface Distance from 1/2 hour (report on hour and 1/2 hour e.g. 7:00 = 0700, 12:30 = 1230)	om Depth fron	n skin to lesion	Ü
	OROL o' clock	cm	] cm	
34f.	Lesion Size			
	<u>Largest</u> <u>Horizontal</u> <u>Measured Plane</u> <u>Vertical A-P</u> <u>Meas (mm) D1</u> <u>meas (mm) D2</u>	<u>Horizontal</u> Perpendicular Meas (mm) D3	Second Measured Plane o Try	Volume D1XD2XD3 ÷ 2
	o Sag o Rad X mm X	mm	o Sag o Rad	mm³
	o Arad		o Arad	Note: Volume is pro-
	o Oblique		o Perpendicular Oblique	grammed to be calcu- lated on line; however,
34g.	o No o Yes (detail below then proceed to Q34p) o Complicated Cyst ( <b>Note:</b> Do not use this term for "complex For complex cystic masses code "no" for Q34g, proceed to		omplex cystic" at 34l).	as verification, please calculate volume based on horizontal, vertical and perpendicular measurements as a validation.
	<ul> <li>☐ Homogenous low-level echoes</li> <li>☐ Fluid debris level</li> <li>☐ Mobile internal echoes</li> <li>☐ Multiple bilateral complicated cysts in company of sim</li> <li>o Multiple bilateral solid oval, circumscribed masses</li> </ul>	nple cysts		
	Mass in or on skin     Clustered microcysts     Intraductal mass     Lymph node			
	o Calcifications without a mass o Foreign body			
	o Post-surgical scar			

### 34h. Shape

- o Oval
- o Two or three gentle lobulations

o Other, specify \_

- o Round
- o Irregular

#### 34i. Orientation

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

### 34j. Margin

- o Circumscribed
- o Not circumscribed (If not circumscribed, choose dominant feature)
  - □ Indistinct
  - □ Angular
  - ☐ Microlobulated
  - $\square$  Spiculated

### 34k. Boundary Zone

- o Abrupt Interface
- o Echogenic Halo

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		0

#### 34l Echo Pattern

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

#### 34m. Posterior Features

- O None
- O Enhancement
- O Combined shadowing/enhancement
- O Shadowing

#### 34n. Surrounding Tissue

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

#### 34o. Vascularity (flow)

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

#### 34p. Calcifications on ultrasound

- 0 None
- O Present (check all that apply)
  - ☐ Macrocalcifications (> 0.5 mm)
  - ☐ Microcalcifications in mass
  - $\hfill\square$  Microcalcifications outside mass

## 34q. Was lesion palpable in retrospect during sonography?

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

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

- o No (proceed to Q36)
- o Yes (If ves. select procedure)
  - o Core/vacuum biopsy site with clip
  - o Core/vacuum biopsy site without marker
  - 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

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Institution	Institution No
Participant Initials	Case No

#### Section III.

#### 36. Assessment/Recommendations

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

#### 36b. 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

#### 36c. Known benign by prior biopsy?

- o No (proceed to Q36d)
- o Yes (complete)
  - o < 1 year ago
  - o 1-2 years ago
- o > 2 years ago

#### 36d. Recommendation(s) for this lesion

- o Return to routine screening
- o Diagnostic follow-up to coincide with next annual exam
- ☐ Short-interval follow-up in 6 months with US
- ☐ Short-interval follow-up in 6 months with mammography
- ☐ Short-interval follow-up in 6 months with MRI
- o Intervention and/or Additional Imaging (detail intervention and/or additional imaging)

#### ☐ Intervention

- o Aspiration with core biopsy if solid
- o US-guided core biopsy
- o Vacuum-assisted biopsy, guidance by US
- o Vacuum-assisted biopsy, guidance by mammo
- o Excisional biopsy
- o US-guided biopsy, if US negative, MRI guided biopsy

#### □ Additional Imaging

- ☐ 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?

- o No (proceed to Q37)
- o Yes (specify dominant reason)
  - o Participant preference
  - o Cancer present now
    - o In this breast
  - o In opposite breast o Patient risks factors
  - o Vaguely palpable
  - o Follow-up not reasonable
  - o Interval increase (>20% in volume for masses)
  - o Interval suspicious change
  - o Investigator uncertainty

- O No (proceed to Q16)
- O Yes (proceed to Q38)

	F6	ACRIN 6666 For revised or corrected form, check box and fax to 215-717-0936.		PLACE	IN Study 6
II.	Resul	ts (by lesion)	Institutio	n	In
	Please co Description	mplete Mammographic Lesion Description and Sonographic Lesion in for each lesion being followed and for any new findings on this examination.	Participa	ant Initials	C
	38A.L	esion # from prior MRI: (e.g.GR1, GL1, GL2, etc.)	38h.	Lesion Descript (check all that apply)  Mass (select wors	)
;	,	mographic Lesion Description		o Circumscrib	ed
		Were mammographic views obtained		o Not fat-co	ontaining
	304.	of this finding on this follow-up evaluation?  o No (specify reason and proceed to Q39) o Not recommended o Participant refused o Not needed after targeted US o Scheduling constraints; participant rescheduled o Other o Yes		o Microlobulate o Obscured o Indistinct o Spiculated  Asymmetry (code o Focal Asymmetry o One view o Both view o Global	type of asyn seen on
	38b.	o New			calcifications ( pically benign
		o Gone (complete then proceed to Q39)  Lesion # from prior mammogram M  (if not applicable code 998)  Lesion # from prior ultrasound (if not applicable code 998)  o Decreasing o Stable o Fluctuating bilateral circumscribed masses o Increasing o Other suspicious change(s) o Increasing and other suspicious change(s)		☐ Milk of cace his coarse his Punctate ☐ Amorpho ☐ Pleomorp ☐ Branching Distribution of ☐ Clusterec	alcium eterogeneous (<0.5 mm, uni us/Indistinct hic g/Fine linear calcifications ( l elusters (same
	38c.	Was lesion enumerated on any prior study mammogram?		☐ In mass ☐ Architectural Disto	or asymmetry ortion
		No and not visible in retrospect (assign next sequential mammogram lesion #)  No but now visible in retrospect (assign next sequential mammogram lesion #)  New lesion #   O Yes Lesion # from prior mammogram: (e.g. MR1, MB1, ML1, MR2, etc.)		was ultrasound this follow-up ev  No (specify rea  Not recomm Participant r  Not needed Scheduling o  Other	d performed valuation? uson and proceed ended refused after additional
	38d.	Was lesion enumerated on any prior study ultrasound?  o No o Simple cyst o Not a simple cyst	39b.	o Yes (check all ☐ Targeted on ☐ Whole breas  Change in this I o New	ly
		o Yes (complete) Lesion # from ultrasound:  (e.g. UR1, UB1, UL1, UR2, etc.)		o Gone (complete Lesion # from p (if not applicable)	orior mammog
	38e.	Location on Mammography: (check all that apply)		Lesion # from p	orior ultrasound
		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 Upper Lower		(if not applicabl o Decreasing o Stable o Fluctuating bila o Increasing o Other suspiciou o Increasing and	iteral circumscius change(s)
		☐ Bilateral, multiple ☐ Inner ☐ Axillary tail ☐ Outer ☐ Retroareolar ☐ Central	39c.	o No (complete) o Simple cyst	
	38f.	Distance from nipplecm by Mammography		o Not a simple	e cyst and not sequential sor
	38g.	Size of lesion by Mammography:			sequential sor
		mm X mm		o Yes (complete)	
		(largest diameter) (largest perpendicular dimension)		Lesion # from p	orior ultrasound

666 L HERE stitution No. ase No. ography re present) nmetry) and distribution) (check all that apply) iformly round) check all that apply) morphology) d of this lesion on ed to Q40) al mammographic views articipant rescheduled prior ultrasound? to Q40) ram [**M**  $_{\sf d}ig|{\sf U}$ ribed masses us change(s) any prior study ultrasound? t40)
t visible in retrospect nogram lesion #)
w visible in retrospect nogram lesion #) d: U (e.g. UR1, UB1, UL1, UR2, etc.) 39d. Was lesion enumerated on any study mammogram (including views obtained today)? o No o Yes (complete)

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

F6	For revised or co	ACRIN 6666 rrected form, check box and fax t
39e.	☐ Check if this	"lesion" is multiple bilateral o
	Breast	Clockface (report on 1/2 hour
		(report on hour and 1/2 he.g. 7:00 = 0700, 12:30 = 12
	o <b>R</b> o <b>L</b>	o' cloc
39f.	Lesion Size	

## ACRIN Study 6666 PLACE LABEL HERE

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Institution	Institution No			
Participant Initials	Case No.			

O	For revised or corrected form, ch	eck box and fax to 215-7	717-0936.	PI	LACE LABEI	HERE
				Institution	In:	stitution No.
				Participant Initials	s Ca	ase No. ———
39e.	☐ Check if this "lesion" is mu	ltiple bilateral circum	scribed masses	. Describe largest ma	ss in Q39e and Q39f th	nen proceed to Q39g.
	Breast (report or	lockface t on 1/2 hour) h hour and 1/2 hour =0700, 12:30 = 1230)	Distance fro the nipple	<u>Depth from</u> <u>center o</u> (to neares	f lesion	
	o <b>R</b> o <b>L</b>	o' clock	c	m	cm	
39f.	Lesion Size					
	Largest Horizontal Meas (mm) D1 O Trv		cal A-P (mm) D2	<u>Horizontal</u> erpendicular Meas (mm) D3	Second Measured Plane o Trv	Volume D1XD2XD3 ÷ 2
	o Sag <b>mm</b> o Rad	X	<b></b>	LLL mm	o Sag o Rad	mm³
	o Arad o Obliq				o Arad o Perpendicular Obliq	Note: Volume is programmed to be calculated on line; however,
39g.	g. Special Case (see choices below)  o No  o Yes (detail below then proceed to Q39p)  o Complicated Cyst (Note: Do not use this term for "complex cystic masses".  For complex cystic masses code "no" for Q39g, proceed to Q39h and indicate "complex cystic" at 39l).  Homogenous low-level echoes  Fluid debris level  Mobile internal echoes  Multiple bilateral complicated cysts in company of simple cysts  Mass in or on skin  Clustered microcysts  Intraductal mass  Lymph node  Calcifications without a mass  Foreign body  Post-surgical scar  O Other, specify					
39h.	Shape o Oval o Two or three gentle lobula o Round o Irregular	tions				
39i.	Orientation o Parallel to skin o Not parallel (includes round	d)				
39j.	Margin o Circumscribed o Not circumscribed (If not o	circumscribed, choos	e dominant feat	ure)		

☐ Angular
☐ Microlobulated
☐ Spiculated

39k. Boundary Zone
o Abrupt Interface
o Echogenic Halo

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### ACRIN 6666

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			3	99

#### I. Echo Pattern

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

#### 39m. Posterior Features

- O None
- O Enhancement
- O Combined shadowing/enhancement
- O Shadowing

#### 39n. Surrounding Tissue

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

#### 39o. Vascularity (flow)

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

#### 39p. Calcifications on ultrasound

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

#### 39q. Was lesion palpable in retrospect during sonography?

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

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

- o No (proceed to Q41)
- o Yes (If yes, select procedure)
  - o Core/vacuum biopsv site with clip
  - o Core/vacuum biopsy site without marker
  - 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

#### ACRIN Study 6666 PLACE LABEL HERE

Institution	Institution No
Participant Initials	Case No.

#### Section III.

#### 41. Assessment/Recommendations

41a.			<b>」% likelihood of malignancy for</b>
	this	lesio	n (best guess from 0-100)

#### 41b. Assessment for this lesion

- Negative
- 0 2 Benign
- Probably Benign 3 0
- 4A Low Suspicion of Malignancy 0
- 4B Intermediate Suspicion 0
- Moderately High Suspicion 0 4C
- Highly Suggestive of Malignancy

#### 41c. Known benign by prior biopsy?

- o No (proceed to Q41d)
- o Yes (complete)
  - o < 1 year ago
  - o 1-2 years ago
  - o > 2 years ago

#### 41d. Recommendation(s) for this lesion

- o Return to routine screening
- o Diagnostic follow-up to coincide with next annual exam
- ☐ Short-interval follow-up in 6 months with US
- ☐ Short-interval follow-up in 6 months with mammography
- $\hfill\Box$  Short-interval follow-up in 6 months with MRI
- o Intervention and/or Additional Imaging
- (detail intervention and/or additional imaging)

#### □ Intervention

- o Aspiration with core biopsy if solid
- o US-guided core biopsy
- o Vacuum-assisted biopsy, guidance by US
- o Vacuum-assisted biopsy, guidance by mammo
- o Excisional biopsy
- o US-guided biopsy, if US negative, MRI guided biopsy

#### □ Additional Imaging

- ☐ 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?

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

- O No (proceed to Q16)
- O Yes (proceed to Q43)

F	<del>-</del> 6	ACRIN 6666 For revised or corrected form, check box and fax to 215-717-0936.				
II.	. Results (by lesion)			titutior	n Institution No	
	Please complete Mammographic Lesion Description and Sonographic Lesion Description for each lesion being followed and for any new findings on this follow-up examination.			rticipa	nt Initials Case No	
4	( <b>3. Mam</b>	Lesion # from prior MRI: (e.g.GR1, GL1, GL2, etc.) if not applicable code 998)  mographic Lesion Description  Were mammographic views obtained of this finding on this follow-up evaluation?  o No (specify reason and proceed to Q44)		43h.	Lesion Description Mammography (check all that apply)  ☐ Mass (select worse margin feature present)  O Circumscribed O Fat-containing O Not fat-containing O Microlobulated O Obscured O Indistinct	
		o Not recommended o Participant refused o Not needed after targeted US o Scheduling constraints; participant rescheduled o Other o Yes			o Spiculated  ☐ Asymmetry (code type of asymmetry) o Focal Asymmetry seen on o One view o Both views o Global	
	43b.	Change in this lesion from prior mammogram(s)?  o New o Gone (complete then proceed to Q44)  Lesion # from prior mammogram M  (if not applicable code 998) Lesion # from prior ultrasound (if not applicable code 998) o Decreasing o Stable o Fluctuating bilateral circumscribed masses o Increasing o Other suspicious change(s) o Increasing and other suspicious change(s)			□ 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	
	43c.	Was lesion enumerated on any prior study mammogram?  o No and not visible in retrospect (assign next sequential mammogram lesion #)  o No but now visible in retrospect (assign next sequential mammogram lesion #)  New lesion # M  o Yes Lesion # from prior mammogram: M  (e.g. MR1, MB1, ML1, MR2, etc.)	44.		☐ In mass or asymmetry ☐ Architectural Distortion  graphic Lesion Description  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	
	43d.	Was lesion enumerated on any prior study ultrasound?  o No o Simple cyst o Not a simple cyst o Yes (complete) Lesion # from ultrasound: (e.g. UR1, UB1, UL1, UR2, etc.)		44b.	o Yes (check all that apply) ☐ Targeted only ☐ Whole breast  Change in this lesion from prior ultrasound? o New o Gone (complete then proceed to Q45) Lesion # from prior mammogram	
	43e.	Location on Mammography: (check all that apply)  Note: for multiple bilateral findings with similar appearances, check "bilateral, multiple" and indicate specific location and size of the largest such finding.  o Right breast		44-	(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)	
	43f.	Axillary tail   Outer   Retroareolar   Central    Distance from nipple   cm by Mammography		44c.	Was lesion enumerated on any prior study ultrasound?  o No (complete)  o Simple cyst (proceed to Q45)  o Not a simple cyst and not visible in retrospect (assign next sequential sonogram lesion #)	
	43g.	Size of lesion by Mammography:		11d	o Not a simple cyst and now visible in retrospect (assign next sequential sonogram lesion #)  New lesion # U  o Yes (complete)  Lesion # from prior ultrasound: U  (e.g. UR1, UB1, UL1, UR2, etc.)	
				440.	Was lesion enumerated on any study mammogram (including views obtained today)?  o No o Yes (complete)	

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

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	For revised of corrected form, check box and fax to 215-717-0956.	Institution Ir	nstitution No	
44e. 44f.	Breast (report on 1/2 hour) the n (report on hour and 1/2 hour e.g. 7:00=0700, 12:30=1230)  O R O L  Lesion Size  Largest Horizontal Meas (mm) D1  O Try  when  the n  the n  Vertical A-P  meas (mm) D2	nasses. Describe largest mass in Q44e and Q44e  ce from	f then proceed to Q44g.	
	o Sag mm o Rad o Arad o Oblique	o Sag mm o Rad o Arad o Perpendicular Ob	lated on line; however,	
44g.	Special Case (see choices below)  o No  o Yes (detail below then proceed to Q44p)  o Complicated Cyst (Note: Do not use this term for "complex cystic masses".  For complex cystic masses code "no" for Q44g, proceed to Q44h and indicate "complex cystic" at 44l).  Homogenous low-level echoes  Fluid debris level  Mobile internal echoes  Multiple bilateral complicated cysts in company of simple cysts  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  O Other, specify			
44h.	Shape o Oval o Two or three gentle lobulations o Round o Irregular			
44i.	Orientation o Parallel to skin o Not parallel (includes round)			
44j.	Margin o Circumscribed			

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

☐ Indistinct☐ Angular☐ Microlobulated☐ Spiculated

**44k.** Boundary Zone
o Abrupt Interface
o Echogenic Halo

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U	l l	For revised or corrected form, check box and fax to 215-717-0936.
4	44I.	Echo Pattern
		O Anechoic
		O Hyperechoic
		O Complex cystic
		O Hypoechoic with few tiny cystic areas
		O Isoechoic to fat
		O Mixed hyperechoic and hypoechoic
		O Hypoechoic to fat
4	44m	ı. Posterior Features
		O None
		O Enhancement
		O Combined shadowing/enhancement
		O Shadowing
4	44n.	
		O No effect
		O Effect (check all that apply)
		☐ Duct changes ☐ Edema
		☐ Cooper's ligament distortion
		☐ Architectural distortion
		☐ Skin thickening ☐ Skin retraction
		☐ SKIII Tetraction
4	<b>140</b>	. Vascularity (flow)
		O None
		O Yes (check all that apply)
		☐ Present in lesion
		☐ Present immediately adjacent to lesion
		☐ Increased in surrounding tissue
		O Not performed
4	44p.	. Calcifications on ultrasound O None
		O Present (check all that apply)
		☐ Macrocalcifications (> 0.5 mm)
		☐ Microcalcifications in mass
		☐ Microcalcifications outside mass
		□ IVIICIOCAICIIICALIOTIS OULSIUE IIIASS
4	44q.	. Was lesion palpable in retrospect during sonography?
		O No
		O Yes, in retrospect
		,

O Yes, participant presented with lump

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

- o No (proceed to Q46)
- o Yes (If yes, select procedure)
  - o Core/vacuum biopsy site with clip
  - o Core/vacuum biopsy site without marker
  - 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

ACRIN Study 6666 PLACE LABEL HERE					
Institu	ution .		Institution No.		
Partic	cipant	Initials	_ Case No		
Secti	ion II	l.			
46.	Asse	essment/Recomme	endations		
	46a.	% like this lesion (best of	lihood of malignancy for guess from 0-100)		
	46b.	o 4B Intermedia o 4C Moderately	Benign cion of Malignancy		
	46c.	Known benign by o No (proceed to Qo o Yes (complete) o < 1 year ago o 1-2 years ago o > 2 years ago			
	46d.	□ Short-interval follo □ Short-interval follo □ Short-interval follo □ Intervention and/o (detail intervention □ Intervention □ Aspiration wi □ US-guided co □ Vacuum-assi □ Vacuum-assi □ Excisional bii □ US-guided bi □ Additional Im □ Targeted ultri □ Comparison si	screening up to coincide with next annual exam w-up in 6 months with US w-up in 6 months with mammography w-up in 6 months with MRI r Additional Imaging and/or additional imaging) th core biopsy if solid bre biopsy sted biopsy, guidance by US sted biopsy, guidance by mammo bpsy opsy, if US negative, MRI guided biopsy		
	46e.	Is this lesion asserecommended for o No (proceed to Qo o Yes (specify dom o Participant preform o In this breast o In opposite bo Patient risks fare o Vaguely palpado o Followyn pater	17) inant reason) erence : now reast ctors		

- o Interval increase (>20% in volume for masses)
- o Interval suspicious change
- o Investigator uncertainty

- O No (proceed to Q16)
- O Yes (proceed to Q48)

ACRIN 6666   For revised or corrected form, check box and fax to 215-717-0936.			
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)			
(if not applicable code 998)  48. Mammographic Lesion Description  48a. Were mammographic views obtained of this finding on this follow-up evaluation?  o No (specify reason and proceed to Q49) o Not recommended o Participant refused o Not needed after targeted US o Scheduling constraints; participant rescheduled o Other o Yes  48b. Change in this lesion from prior mammogram(s)? o New o Gone (complete then proceed to Q49)		Please complete Mammographic Lesion Description and Sonographic Lesion Description for each lesion being followed and for any new findings on this	II.
48a. Were mammographic views obtained of this finding on this follow-up evaluation?  o No (specify reason and proceed to Q49) o Not recommended o Participant refused o Not needed after targeted US o Scheduling constraints; participant rescheduled o Other o Yes  48b. Change in this lesion from prior mammogram(s)? o New o Gone (complete then proceed to Q49)			
of this finding on this follow-up evaluation?  o No (specify reason and proceed to Q49) o Not recommended o Participant refused o Not needed after targeted US o Scheduling constraints; participant rescheduled o Other o Yes  48b. Change in this lesion from prior mammogram(s)? o New o Gone (complete then proceed to Q49)		48. Mammographic Lesion Description	4
o New o Gone (complete then proceed to Q49)		of this finding on this follow-up evaluation?  o No (specify reason and proceed to Q49)  o Not recommended o Participant refused o Not needed after targeted US o Scheduling constraints; participant rescheduled o Other	
		o New	
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)		(if not applicable code 998) Lesion # from prior ultrasound (if not applicable code 998)  o Decreasing o Stable o Fluctuating bilateral circumscribed masses o Increasing o Other suspicious change(s)	
48c. Was lesion enumerated on any prior study mammogram?  o No and not visible in retrospect (assign next sequential mammogram lesion #)  o No but now visible in retrospect (assign next sequential mammogram lesion #)  New lesion # M  o Yes Lesion # from prior mammogram:		study mammogram?  o No and not visible in retrospect (assign next sequential mammogram lesion #) o No but now visible in retrospect (assign next sequential mammogram lesion #) New lesion #  M  o Yes	
(e.g. MR1, MB1, ML1, MR2, etc.)  48d. Was lesion enumerated on any prior study		(e.g. MR1, MB1, ML1, MR2, etc.)	
ultrasound?  o No o Simple cyst o Not a simple cyst o Yes (complete) Lesion # from ultrasound:  (e.g. UR1, UB1, UL1, UR2, etc.)		ultrasound?  o No o Simple cyst o Not a simple cyst o Yes (complete) Lesion # from ultrasound:	
48e. Location on Mammography: (check all that apply)		48e. Location on Mammography: (check all that apply)	
Note: for multiple bilateral findings with similar appearances, check "bilateral, multiple" and indicate specific location and size of the largest such finding.  o Right breast		appearances, check "bilateral, multiple" and indica specific location and size of the largest such findir  o Right breast	
48f. Distance from nipple cm by Mammography	y	48f. Distance from nipplecm by Mammograp	
48g. Size of lesion by Mammography:		mm X mm	

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		ACRIN Study 6666
		PLACE LABEL HERE
	itutio	
Par	ticipa	nt Initials Case No
	48h.	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)   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
		graphic Lesion Description
	49a.	Was ultrasound performed of this lesion on this follow-up evaluation?  o No (specify reason and proceed to Q50) o Not recommended o Participant refused o Not needed after additional mammographic views o Scheduling constraints; participant rescheduled o Other o Yes (check all that apply) ☐ Targeted only ☐ Whole breast
	49b.	
		o New o Gone (complete then proceed to Q50) Lesion # from prior mammogram (if not applicable code 998) Lesion # from prior ultrasound (if not applicable code 998) o Decreasing o Stable o Fluctuating bilateral circumscribed masses o Increasing o Other suspicious change(s) o Increasing and other suspicious change(s)
	49c.	Was lesion enumerated on any prior study ultrasound? o No (complete)
		o Simple cyst (proceed to Q50) o Not a simple cyst and not visible in retrospect (assign next sequential sonogram lesion #) o Not a simple cyst and now visible in retrospect (assign next sequential sonogram lesion #) New lesion # U  o Yes (complete) Lesion # from prior ultrasound:
	49d.	(e.g. UR1, UB1, UL1, UR2, etc.)  Was lesion enumerated on any study mammogram
	.54.	(including views obtained today)?

o No o Yes (complete)

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

6	ACRIN 6666 For revised or corrected form, check box and fax to 215-717-0936.	PL	ACRIN Study 6666 ACE LABEL H	IERE
		Institution	Institu	tion No
		Participant Initials	case	No
49e.	☐ Check if this "lesion" is multiple bilateral circumscribed ma	ses. Describe largest ma	ss in Q49e and Q49f then	proceed to Q49g.
	Clockface		f lesion	
49f.	Lesion Size			
	Largest Horizontal Meas (mm) D1  O Trv  O Sag O Rad O Arad O Oblique	Horizontal Perpendicular Meas (mm) D3 mm	Second Measured Plane o Trv o Sag o Rad o Arad o Perpendicular Oblique	Volume D1XD2XD3 - 2  mm³  Note: Volume is programmed to be calculated as lies because
49g.	Special Case (see choices below)  o No o Yes (detail below then proceed to Q49p) o Complicated Cyst (Note: Do not use this term for "complicated Cyst (note: Do not use this term for "complicated Cyst (note: Do not use this term for "complicated Cyst (note: Do not use this term for "complicated Cysts in Company of Solid Overland Individual	I to Q49h and indicate "c	omplex cystic" at 49l).	lated on line; however, as verification, please calculate volume based on horizontal, vertical and perpendicular measurements as a validation.

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

#### 49i. Orientation

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

#### 49j. Margin

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

### 49k. Boundary Zone

- o Abrupt Interface
- o Echogenic Halo

07-26-07 "Copyright 2007" 6666 F6b 25 of 26

	F6	F	ACRIN 6666 or revised or corrected form, check box and fax to 215-717-09
49I. 49m. 49n.		91.	Echo Pattern  O Anechoic  O Hyperechoic  O Complex cystic  O Hypoechoic with few tiny cystic areas  O Isoechoic to fat  O Mixed hyperechoic and hypoechoic  O Hypoechoic to fat
		9m.	Posterior Features  0 None  0 Enhancement  0 Combined shadowing/enhancement  0 Shadowing
		9n.	Surrounding Tissue  O No effect  O Effect (check all that apply)  Duct changes Edema Cooper's ligament distortion Architectural distortion Skin thickening Skin retraction
	4	90.	Vascularity (flow)  0 None  0 Yes (check all that apply)  □ Present in lesion □ Present immediately adjacent to lesion □ Increased in surrounding tissue  0 Not performed
	4	9p.	Calcifications on ultrasound  O None  O Present (check all that apply)  ☐ Macrocalcifications (> 0.5 mm)  ☐ Microcalcifications in mass  ☐ Microcalcifications outside mass
	4	9q.	Was lesion palpable in retrospect during sonography?

O No

O Yes, in retrospect

O Yes, participant presented with lump

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

o No (proceed to Q51)

o Yes (If yes, select procedure)

o Core/vacuum biopsy site with clip

o Core/vacuum biopsy site without marker

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

PLACE L			RIN Study 6666 E LABEL HERE		
Institution Participant Initials			Institution No		
			Case No		
Secti	on II	l.			
51.	Asse	essment/Reco	ommendations		
	51a.	this lesion (b	b likelihood of malignancy for pest guess from 0-100)		
	51b.	o 1 Nega o 2 Benig o 3 Proba o 4A Low o 4B Interr o 4C Mode	gn		
	51c.	Known benig o No (proceed o Yes (comple o < 1 year a o 1-2 years o > 2 years	ete) ago ago		
	51d.	o Return to roo o Diagnostic fo Short-interva Short-interva O Intervention (detail intervent o Aspirati o US-guio o Vacuum o Vacuum o Excision o US-guio Addition Targete	ollow-up to coincide with next annual examul follow-up in 6 months with US all follow-up in 6 months with mammography all follow-up in 6 months with MRI and/or Additional Imaging ention and/or additional imaging) tion on with core biopsy if solid ded core biopsy in-assisted biopsy, guidance by US in-assisted biopsy, guidance by mammo all biopsy ded biopsy, if US negative, MRI guided biopsy ded biopsy, if US negative, MRI guided biopsy		
	51e.	o No (proceed o Yes (specify o Participan o Cancer pr o In this b	resent now		

o Patient risks factors

o Vaguely palpable

o Follow-up not reasonable

o Interval increase (>20% in volume for masses)

o Interval suspicious change

o Investigator uncertainty

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.			
percutaneous biopsies and aspiration erformed as the initial diagnostic procedur	e, form check hox and fax			

Instructions: Form BX is designed to capture results of

the <b>N</b> by th	plete a separate form for <u>each</u> lesion biopsied. If surgery was performed as the initial diagnature of the second section I may be completed by the site RA, Sections II, III and I've Radiologist performing the biopsy. Complete another IM if additional diagnostic imaging is perpendicularly in the planned procedure (not already reported), particularly if no biopsy is performed.	V are	e completed	form check box and fax to 215-717-0936.
GEN	IERALINFORMATION	Cod	de Table for Q	1
	Was any percutaneous procedure performed?	1	Lesion resolv	red (complete IM)
••		2	Participant re	
	o No; If no, specify reason from code table (STOP and sign form)	3	Participant di	
	o Yes (continue)	4		performed and
2	Date of Procedure (mm-dd-yyyy)	'	rescheduled	porterniou aria
2.	(IIIII-da-yyyy)	5		, but unable to be performed;
	2a. Time point in study prompting this biopsy		surgery sche	
	o Initial screening	6	Other	duica
	o 6 month follow-up	7		anted and surgical bioney
	o 12 month screening	'		npted and surgical biopsy
	o 18 month follow-up		performed/so	
	o 24 month screening	8		ars probably benign and
	o 30 month follow-up		follow-up pla	
	o 36 month follow-up	9	Lesion appea	9
	o Other, specify	10	_	appears benign on
	O Other, Specify		pre-biopsy M	RI
<ol> <li>4.</li> <li>5.</li> </ol>	Total number of lesions biopsied (please complete a separate BX form for Pathology Specimen ID# (If no specimen, code xxxx)  5a. Were slides sent for central review and results obtained?  o No (proceed to Q6) o Yes (complete Q5b) o Pending (proceed to Q6)  5b. Did central review change management? o No (proceed to Q6)	Coc 1 B 2 P 3 P 4 R 5 A 6 A 7 A	de Table for Q Benign (other t Papilloma Possible phyllo Badial scar/cor	5b (upgrade/downgrade) han below) odes mplex sclerosing lesion
	<ul> <li>6a. Guidance method: <ul> <li>US</li> <li>Stereotactic prone</li> <li>Stereotactic upright</li> <li>Mammographic</li> <li>MRI</li> <li>No image guidance (e.g. palpable or duct excision)</li> <li>Other, specify</li> </ul> </li> <li>6b. Biopsy of this lesion prompted by (check all that apply)</li> </ul>		vasive Cance	
	<ul> <li>□ Mammogram</li> <li>□ US</li> <li>□ MRI</li> <li>□ Clinical</li> <li>□ Patient concern</li> <li>□ Other, specify</li> </ul>			

Institution	BX	For revised or corrected form check box and fax to 215-717-0936.		ACRIN Study 6666 PLACE LABEL HERE	
DETALSOFERCEQUEE   Participant Initials   Case No.       Case No.   Case No.     Case No.     Case No.     Case No.     Case No.				_	
Lesion # seen on any Mammogram If not applicable, code 998 Lesion # seen on any Utrasound If not applicable, code 998 Finding # seen on MRI and reported on M3 or M4 If not applicable, code 998 Finding # seen on MRI and reported on M3 or M4 If not applicable, code 998 Finding # seen on MRI and reported on M3 or M4 If not applicable, code 998 Finding # seen on MRI and reported on M3 or M4 If not applicable, code 998 Finding # seen on MRI and reported on M3 or M4 If not applicable, code 998 Finding # seen on MRI and reported on M3 or M4 If not applicable, code 998 Finding # seen on MRI and reported on M3 or M4 If not applicable, code 998 Finding # seen on MRI and reported on M3 or M4 If not applicable, code 998 Finding # seen on MRI and reported on M3 or M4 If not applicable, code 998 Finding # seen on MRI and reported on M3 or M4 If not applicable, code 998 Finding # seen on MRI and reported on M3 or M4 If not applicable, code 998 Finding # seen on MRI and reported on M3 or M4 If not applicable, code 998 Finding # seen on MRI and reported on M3 or M4 If not applicable, code 998 Finding # seen on MRI application on any interported on many interported on MRI Calcifications				Participant Initials	
If not applicable, code 998 Lesion is seen on any Ultrasound If not applicable, code 988 Finding if seen on RRI and reported on M3 or M4  [e.g. GR1, GL1, etc.] If not applicable, code 998  Breast  [cockdac or specify Location  [report on hour and 12 hour groot on hour groot on hour groot on hour and 12 hour groot on hour groot g			(0)		
If not applicable, code 998   Finding # seen on MRI and reported on M3 or M4	If no	t applicable, code 998			
Breast Clockface or specify Location Distance from Nipple Size (fargest dimension)    Clockface or specify Location   O axilla   O a	If no	t applicable, code 998			
resport on hour and 1/2 hour   e.g. 7:00-0700, 12:30-12:30)   o acitial   o retroareolar			(e.	,	
e.g. 7:00 -0700, 1:2:00 -1200)  R o L	<u>Breast</u>	(report on bour and 1/2 bour	-	<u>Distance from Nipple</u>	Size (largest dimension)
Architectural distortion	8. Lesi	e.g. 7:00 = 0700, 12:30 = 1230)  o L  on type (check all that apply)  Mass  Asymmetry  o' clock  Focus on MF  Non-mass e	retroareolar central RI nhancement	t on MRI	mm
o No, performed at (facility name then proceed to Section III)  10. Type of proceed to Q10)  10. Type of procedure  10a. US guided aspiration w/g needle  o Lesion resolved (proceed to Q12)  o Lesion did not resolve, core also done (complete Q10b)  o Lesion did not resolve, core not done (complete and proceed to Q12)  Reason  10b. o US-guided core biopsy w/g biopsy gun org vacuum - assisted biopsy  number of passes/specimens  o Stereotactically guided biopsy w/g biopsy gun org vacuum - assisted biopsy  number of passes/specimens  o MRI guided biopsy w/g vacuum - assisted biopsy  number of passes/specimens  10c. Specimen radiograph  o Not performed (proceed to Q10d)  o Performed (proceed to Secimens with calcifications or number of specimens felt to include the lesion)  number of specimens felt to include lesion  10d. Was the lesion felt to be well sampled at the time of procedure?  o No  o Yes  o Unsure  10e. Was a clip placed?  o No  o Yes (complete placement location)  o Felt to be at site  o Within 1 cm of site  o 1-2 cm from lesion  o >2 cm from lesion  11. Any clinically significant complications from the biopsy procedure?  o No  o Yes	_		any imaging	g	
o Yes (proceed to Q10)  10. Type of procedure  10a. US guided aspiration w	9. Was	procedure performed at study site?			
10. Type of procedure  10a. US guided aspiration w/ g needle  o Lesion resolved (proceed to Q12)  o Lesion did not resolve, core also done (complete Q10b)  o Lesion did not resolve, core not done (complete and proceed to Q12)  Reason  10b. o US-guided core biopsy w/g biopsy gun org vacuum - assisted biopsy  number of passes/specimens  o Stereotactically guided biopsy w/g biopsy gun org vacuum - assisted biopsy  number of passes/specimens  o MRI guided biopsy w/g vacuum - assisted biopsy  number of passes/specimens  10c. Specimen radiograph  o Not performed (proceed to Q10d)  o 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?  o No			e then proce	eed to Section III)	
10a. US guided aspiration w		"			
Reason  10b. o US-guided core biopsy w/	10a.	o Lesion resolved (proceed to Q12)	(complete C	010b)	
10b. o US-guided core biopsy w/		o Lesion did not resolve, core not done (d	complete and	d proceed to Q12)	
number of passes/specimens  o Stereotactically guided biopsy w/		Reason	1 1	I	
number of passes/specimens  o MRI guided biopsy w/	10b.		gun or	g vacuum - assisted bio	psy
o MRI guided biopsy w/			biopsy gun	org vacuum - assis	ted biopsy
number of passes/specimens  10c. Specimen radiograph  o Not performed (proceed to Q10d)  o Performed (provide number of specimens with calcifications or number of specimens felt to include the lesion)		· l l j			
10c. Specimen radiograph  o Not performed (proceed to Q10d) o Performed (provide number of specimens with calcifications or number of specimens felt to include the lesion)			assisted biop	osy	
o Not performed (proceed to Q10d) o 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? o No o Yes o Unsure  10e. Was a clip placed? o No o Yes (complete placement location) o Felt to be at site o Within 1 cm of site o 1-2 cm from lesion o >2 cm from lesion  11. Any clinically significant complications from the biopsy procedure? o No o Yes	10c.				
number of specimens felt to include lesion  10d. Was the lesion felt to be well sampled at the time of procedure?  o No o Yes o Unsure  10e. Was a clip placed? o No o Yes (complete placement location) o Felt to be at site o Within 1 cm of site o 1-2 cm from lesion o >2 cm from lesion  11. Any clinically significant complications from the biopsy procedure? o No o Yes		o Not performed (proceed to Q10d)	vith calcificat	tions or number of specimens	s felt to include the lesion)
10d. Was the lesion felt to be well sampled at the time of procedure?  o No o Yes o Unsure  10e. Was a clip placed? o No o Yes (complete placement location) o Felt to be at site o Within 1 cm of site o 1-2 cm from lesion o >2 cm from lesion  11. Any clinically significant complications from the biopsy procedure? o No o Yes		number of specimens with calcification	ons or		
<ul> <li>o No</li> <li>o Yes</li> <li>o Unsure</li> <li>10e. Was a clip placed?</li> <li>o No</li> <li>o Yes (complete placement location)</li> <li>o Felt to be at site</li> <li>o Within 1 cm of site</li> <li>o 1-2 cm from lesion</li> <li>o &gt;2 cm from lesion</li> <li>o No</li> <li>o Yes</li> </ul>		·			
o No o Yes (complete placement location) o Felt to be at site o Within 1 cm of site o 1-2 cm from lesion o >2 cm from lesion  11. Any clinically significant complications from the biopsy procedure? o No o Yes	10d.	o No o Yes	time of pro	cedure?	
o >2 cm from lesion  11. Any clinically significant complications from the biopsy procedure?  o No o Yes	10e.	o No o Yes (complete placement location) o Felt to be at site			
11. Any clinically significant complications from the biopsy procedure?  o No o Yes					
o No o Yes	11. Anv		opsv proced	lure?	
o Yes If yes, specify	0	No	- p- y p- 0000		
	0	Yes If yes, specify			

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For	revised	or	corrected	form	check	
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hox	and fax	to	215-717-0	936.		

### ACRIN Study 6666

#### PLACE LABEL HERE

Institution	Institution No
Participant Initials	Case No.

#### III. PATHOLOGY

#### 12. Fluid analysis

- o No fluid obtained (proceed to Q13)
- Fluid typical of benign cyst fluid and discarded (proceed to Q13)
- o Fluid not sent for cytology (proceed to Q12b)
- o Fluid sent for cytology (proceed to Q12a)

#### **12a.** Cytology (complete and proceed to Q12b)

- o Benign
- o Insufficient sample
- o Atypical/indeterminate
- o Suspicious
- o Malignant

#### **12b.** Culture/gram stain (complete and proceed to Q13)

- o Fluid not sent for this
- o Consistent with abscess
- o No organism/no growth

1	3.	Histo	pathol	oav o	f Core
•	•		Pat	-9, -	

☐ 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

- o No (proceed to Q13b)
- o 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

- o No (proceed to Q13c)
- o 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

- o No (proceed to Q15)
- o Yes (check all that apply)
  - ☐ Invasive (infiltrating) ductal carcinoma

#### **Grade**

- o Grade cannot be assessed/ not reported
- o Low (Grade I)
- o Intermediate (Grade II)
- o High (Grade III)
- o Insufficient specimen

#### Pattern(s)

- □ Tubular
- ☐ Colloid/Mucinous
- □ Medullary
- $\ \square \ Cribriform$
- □ Micropapillary
- □NOS
- ☐ Unknown
- ☐ Other, specify: \_
- ☐ Invasive lobular carcinoma☐ Invasive with mixed ductal/lobular features
- □ Ductal carcinoma in situ (DCIS)

#### **Grade**

- o Grade cannot be assessed/ not reported
- o Low (Grade I)
- o Intermediate (Grade II)
- o High (Grade III)
- o Insufficient specimen

#### **Central necrosis**

- o Present
- o Absent
- o Unknown

#### Number of cores with DCIS

(code 99 if unknown)

- □ check if cancerization of lobules present
- ☐ Other Malignant, specify .

#### 14. Lymphovascular invasion on core?

- o Possible or definite
- o Not reported
- o Not applicable

#### 15. Microcalcifications

- o Not present
- o Not detailed
- o In cancer
- o In benign areas only
- o In benign and malignant areas

BX	

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

### ACRIN Study 6666

### PLACE LAREL HERE

1	I LACE LABEL HERE				
	Institution	_ Institution No			
	Participant Initials	_ Case No			

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ıv	- 14	$\sim$	14/	70		w 1

IV. <u>MANAGEMENT</u>	
16. Are the pathology results concordant with imaging findin	qs?
o No	
o Yes	
o Not sure	
17. Recommendation	
o Return to annual screening	
o 12 month diagnostic follow-up	
o 6 month follow-up due on (mm-yyyy)	
☐ Mammography	
□ US	
□ MRI	
o <b>Re-biopsy</b> with (complete and provide reason)	
o Core	
o Surgery	
Reason for rebiopsy	
o insufficient sample	
o atypical or high risk lesion	
o discordant	
o patient desires excision	
o other	
o Definitive surgery	
o Treatment for cancer, no surgery (complete S1 form)	
18. Do you recommend MRI be performed now?	
o No	
o Yes (complete)	
o Bilateral	
o Right	
o 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 For revised or corrected surgery will be performed, please complete form \$1 also at this time. The NL form should also be used when a palpable mass or duct form check box and fax to 215-717-0936. 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. I. GENERAL INFORMATION Code Table for Q1 1 Lesion resolved/biopsy not indicated 1. Was procedure performed? 2 Participant refusal o No; If no, specify reason from code table (stop and sign form) 3 Participant did not return o Yes 4 Unable to be performed and rescheduled Date of procedure \_\_\_\_ \_\_-\_\_\_(mm-dd-yyyy) 5 Unable to be performed; lesion will be followed 6 Participant not a surgical candidate 2a. Time point in study prompting this surgical biopsy 7 Other o Initial screening o 6 month follow-up o 12 month screening o 18 month follow-up o 24 month screening o 30 month follow-up o 36 month follow-up o Other, specify \_\_\_ Radiologist name Total number of lesions localized on this date (submit a separate NL form for each separate lesion localized) Pathology specimen ID # **Code Table for Q5b** (upgrade/downgrade) 1 Benign (other than below) 5a. Were slides from surgery sent for central review and results obtained? 2 Papilloma o No (proceed to Q6) 3 Possible phyllodes o Yes (complete Q5b) 4 Radial scar/complex sclerosing lesion o Pending (proceed to Q6) 5 ADH 5b. Did central review change management? 6 ALH or LCIS o No (proceed to Q6) 7 Atypical papillary lesion 8 DCIS o Yes (complete) Local result Central result (reference code table) 9 Invasive cancer o Upgrade from o Downgrade from to Guidance method: US Stereotactic prone Stereotactic upright Mammographic O 0 No image guidance (e.g. palpable or duct excision) Other, specify. II. DETAILS OF PROCEDURE 7. Lesion Details (e.g. MR1, MB1, ML1 etc.) Lesion # seen on any Mammogram If not applicable, code 998 (e.g. UR1, UB1, UL1 etc.) Lesion # seen on any Ultrasound 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 Size (largest dimension) **Distance from Nipple Breast** Clockface or specify Location (report on hour and 1/2 hour o axilla e.g. 7:00 = 0700, 12:30 = 1230) o retroareolar o central o' clock mm o R o L OR

<u>_</u>		form, please check box
8.	☐ Ma ☐ As ☐ Ca ☐ Arc ☐ Fo ☐ No	n type (check all that apply) ass ymmetry Ilcifications chitectural distortion cus on MRI In Mass enhancement on MRI It seen on any imaging
9.	o No, ther	performed at study site? performed at (facility name not proceed to Section III) (proceed to Q10)
10.	Targe	t
	10a.	Is this the first procedure to sample this lesion?  o No (please complete BX as appropriate) o Yes (proceed to Q10d)
	10b.	Is there a clip?  o No (proceed to Q10c)  o 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 o Lesion readily visualized o Lesion difficult to visualize
	10d.	Was this a bracketed localization? o No (proceed to Q10e) o Yes, detail number of needles/wires o 2 o 3 o 4 or more
	10e.	Length of longest needle used cm
	10f.	Shortest distance from lesion to wire: (If bracketed, give average distance to wires) o ≤ 0.5 cm o 0.6-1.0 cm o 1.1-2 cm o > 2 cm
	10g.	How was the specimen imaged?  o Mammogram only o US only o Both US and mammo o Neither US nor mammo
	10h.	Assessment of specimen o Includes lesion o Equivocal o Does not include lesion
11.	locali	Inically significant complications from the zation procedure?  No (proceed to Q12)  Yes (check all that apply)  Vasovagal reaction  Needle had to be repositioned  Other, specify:

If this is a revised or corrected

ACRIN Study 6666

_	PLACE LA	BEL HERE
	Institution	Institution No
	Participant Initials	Case No
	III. <u>HISTOPATHOLOGY</u>	
	<b>Note:</b> Please report all releva histopathology: e.g. If the ma but LCIS was also present, p	in diagnosis was fibroadenoma
	12. Benign  o No (proceed to Q13) o Yes (If yes, check all th  Fibroadenoma Fibrosis Fibroadenomatoid Usual ductal hyperpl Duct ectasia Sclerosing adenosis Adenosis Fibrocystic changes Apocrine metaplasia Fat necrosis Papilloma without att Abscess Lymph node Ruptured Cyst/Duct Tubular Adenoma PASH Hypersecretory hype Columnar alteration Other  13. High-risk/atypia o No (proceed to Q14) o Yes (If yes, check all th Complex sclerosing Atypical ductal hyper Atypical lobular hype	at apply) asia  ypia  +/- Inflammation  rplasia without atypia  at apply) lesion/radial scar plasia rplasia rplasia
	☐ Lobular carcinoma ir ☐ Check if ductal e ☐ Atypical papilloma ☐ Columnar alteration ☐ Other	extension
	Li Otrici	

If this is a revised or corrected	ACRIN Study 6666
form, please check box	PLACE LABEL HERE
14. Malignant	Institution Institution No.
o No (proceed to Q16)	
o Yes (check all that apply)	Participant Initials Case No
NOTE: If core or excision malignant and no further treatment surgery for cancer is planned, please complete form \$1 also at this time.    Invasive (infiltrating) ductal carcinoma Grade   O Grade cannot be assessed/ not reported	16. Microcalcifications  o Not present o Not detailed o In cancer o In benign areas only o In benign and malignant areas  IV. MANAGEMENT  17. Are the excisional histopathology results concordant with imaging findings? o No o Yes o Not sure  18. Recommendation o Return to annual screening o 12 month diagnostic follow-up o 6 month follow-up due (mm-yyyy)
	Stop, form complete, sign and date below.
	otop, 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 Therapeutic Surgery Form

# ACRIN Study 6666 PLACE LABEL HERE

TERCE ERBEE 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 congrete form \$1

For revised or corrected form check box and fax to

as the mair	ed. Lymph nodes excised on the same date as the brea breast surgery. If an axillary dissection is performed a separate form <b>S1</b> .		
o No o Yes Prin o o	rticipant known to have distant metastases fro (proceed to Q1a) (detail then proceed to Q1a) hary Cancer was in: Right breast Left breast Both breasts Unknown	m breast cancer?	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
1a. H	las an S1 form previously been submitted for the o No o Yes	nis breast?	
1b. V	Vas therapeutic surgical procedure performed	?	
	o No; If no, specify reason from code table (pro	oceed to Q11)	
2. Date	of treatment surgery (mm-dd-yyyy)		
2a. N	lame of facility where surgery performed		
2b. T	ime point in study when this cancer was detec	ted?	
	o Initial screening o 6 month follow-up o 12 month screening o 18 month follow-up o 24 month screening	o 30 month follow-up o 36 month follow-up o Other, specify o No cancer known preoperativel	ly this breast
3. What	surgery was performed?		
3a. T	umor Excision		
	<ul> <li>o Single lumpectomy</li> <li>o Double lumpectomy</li> <li>o Quadrantectomy/ Wide excision/Segmentectomy</li> <li>o Mastectomy</li> </ul>	o Prophylactic mastectomy o Other, specify o Already performed, reported pro	eviously (on prior S1 form)
S	ymph 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 be on the total the	y (detail)	

If this is a revised or corrected form, please check box	- <b>PL</b> #	ACRIN Study 6666 ACE LABEL HERE
	Institution	Institution No
	Participant Initials_	Case No
Pathology Specimen ID#		
o No (proceed to Q5) o Yes (complete Q4b) o Pending (proceed to Q5)  4b. Did central review change management? o No (proceed to Q5) o Yes (complete) o Upgrade from o Downgrade from to	<b>It</b> (reference code table)	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
		en (i.e. lumpectomy of mastectomy)?
		Size
Breast Clockface or specify Location (report on hour and 1/2 hour e.g. 7:00 = 0700, 12:30 = 1230) o axilla		rgest dimension)  Lesion number (e.g. MR1, UL2, GR1, etc)
O R O L o' clock o central	cm	mm
o Cancer o Atypical/high-risk o Benign o Unsure of correlation with final surgical specimen		during this surgery?
Final Margin Status (check all that apply)  Margins clear  o 10 mm or more  o 4-9 mm  o 1-3 mm  o <1 mm  o Unknown  Margins equivocal  Invasive tumor at margin  DCIS at margin  Not applicable, no cancer found		
Will additional surgery be needed for this breast or axilla (oth o No o Yes (please complete another S1 when performed) o Unknown	er than cosmetic sur	gery)?
	Pathology Specimen ID#  4a. Were slides sent for central review and results obtained on No (proceed to Q5)  o Yes (complete Q4b) o Pending (proceed to Q5)  4b. Did central review change management? o No (proceed to Q5) o Yes (complete) o Upgrade from to o Downgrade from o Check if this lesion ONLY seen on M  Breast Clockface or specify Location (report on hour and 1/2 hour e.g. 7:00=0700, 12:30=1230) OR o retroareolar o central  Provide pathology at this surgery for the lesion describe o Cancer o Atypical/high-risk o Benign o Unsure of correlation with final surgical specimen  5b. Was there another previously enumerated lesion remo o No (proceed to Q6) o Yes (proceed to Q13)  Final Margins Status (check all that apply) Margins clear o 10 mm or more o 4-9 mm o 1-3 mm o Unknown Margins equivocal   Invasive tumor at margin   DCIS at margin the performed)	Pathology Specimen ID#  4a. Were slides sent for central review and results obtained?  • No (proceed to Q5) • Yes (complete Q4b) • Pending (proceed to Q5)  4b. Did central review change management? • No (proceed to Q5) • Yes (complete) • Upgrade from • Downgrade from • OR o. Lesion Location   Check if this lesion QNLY seen on MRI  Breast   Clockface or specify Location   Crom Nipple   Clared from Nip

	31	If this is a revised or corrected form, please check box	ACRIN Study 6666 PLACE LABEL HERE		
			Institution_		
8.		al Histopathology	Participant Initials	Case No	
	8a.	Is cancer present at excision?	r articipant initials	Case No	
		<ul> <li>No (complete Q8b-9d based on core information)</li> </ul>			
		<ul> <li>Felt to have been excised at core</li> </ul>	8g. What is the ER	status?	
		<ul> <li>S/P neoadjuvant chemotherapy</li> </ul>	o Positive		
		<ul> <li>Felt to have been missed by surgeon or pathologist</li> </ul>	o Negative		
		o Prophylactic mastectomy (skip to Q12)	o Not assesse	d	
		<ul> <li>Yes (complete Q8b-9d based on worst applicable</li> </ul>	o Unknown	•	
		information from combination of core and excision)	What is the PR	status?	
			o Positive		
	8b.	Are multiple tumors present?	o Negative		
		o No	o Not assesse	d	
		o Yes	o Unknown	•	
		o Multifocal (< 4 cm apart)		r-2/neu (c-erb2) status?	
		o Multicentric (≥ 4 cm apart)	o Negative	2/110d (0 clb2) oldlas.	
		o Diffuse throughout breast	o 1+		
		o Unknown	0 2 +		
			0 3+		
	8c.	Is invasive cancer present?	o Not assesse	d	
		o No (proceed to Q9)	o Unknown	u	
		o Yes (provide largest diameter)	o ommown		
			9. Is Ductal Carcinoma	a in situ present?	
		mm Largest diameter of invasive component (per pathology report) (code 999 if unknown	o No (proceed to Q		
		or not reported)	o Yes (proceed to 0		
		o Unknown	o Unknown (proceed		
		0 OHKHOWH	(4.2222	- 15 - 2.12,	
	84	Is there lymphovascular invasion?	9a. Grade		
	ou.	o No		nnot be assessed	
		o Yes	o Low (Grad		
		o Unknown	o Intermedia		
		0 OTIKITOWIT	o High (Grad	,	
	8e.	Detail investive concer (check all that apply)	o Insufficient		
	oe.	Detail invasive cancer (check all that apply)	9		
		☐ Invasive ductal carcinoma	9b. Is central necro	osis present?	
		(complete grade and pattern)	o No	processing	
		Grade	o Yes		
		o Grade cannot be assessed	o Unknown		
		o Low (Grade I)			
		o Intermediate (Grade II)	9c Histologic type(s)		
		o High (Grade III)		1 1 1	
		o Insufficient specimen	Number of slides	with DCIS (code 99 if unknown)	
		Pattern(s)	Total accepts (	lides     (sada 00 if unlunaum)	
		☐ Tubular	Total number of s	lides (code 99 if unknown)	
		☐ Colloid/ mucinous	Od Fatanatas Into	dustal component (investor serve	
		☐ Medullary		ductal component (invasive cancer	
		☐ Cribriform		e DCIS is at least 25% of tumor with	
		☐ Micropapillary	additional DCIS	foci outside main tumor mass)	
		□NOS	o No		
		☐ Unknown	o Yes		
		☐ Other, specify	o Unknown		
		☐ Invasive lobular carcinoma			
		☐ Invasive with mixed ductal/lobular features		ally proven cancers in this breast	
		□ Invasive, not of breast origin,		mammography or US preoperatively?	
		(specify and then STOP, sign form)		nd only on second look	
				JS after MRI would be classified as	
	8f.	Were Receptors done?		ammography or US.)	
		o No (proceed to Q9)	o No (detail)		
		o Yes (detail then proceed to Q8g)	Number of additional		
		o From core biopsy	`	code mixed invasive and intraductal as invasive)	
		o From surgical specimen	o Invasive lebular e		
		o Unknown (proceed to Q9)	o Invasive lobular ca		
		*		ed ductal/lobular features	
			o DCISonly	road arain	
			o Invasive, not of br	reast orgin	
			o Unknown	4)	
			o Yes (proceed to Q1		
			o Unknown (proceed t	U QII)	

S1		nis is a revised or corrected	ACRIN Stu PLACE LAI	-
			Institution	
1. <u>TNM</u> :	Stage		Participant Initials	_ Case No
	Has stag	ging already been reported on another S1? occeed to Q11c)		
11b.	o No (pro	results of this surgery change the staging of this occed to Q12) roceed to Q11c)	cancer?	
	o TX  o T0  o Tis  o T1  o T2  o T3  o T4	Primary Tumor) Primary Tumor cannot be assessed Reason No evidence of primary tumor Ductal carcinoma in situ Tumor 2 cm or less in greatest dimension o T1 mic Microinvasive tumor, ≤ 0.1 cm in greatest dia o T1a Invasive tumor, 0.1 < x ≤ 0.5 cm in greatest di o T1b Invasive tumor, 0.5 < x ≤ 1.0 cm in greatest di o T1c Invasive tumor, 1.0 < x ≤ 2.0 cm in greatest di nvasive tumor, 2.0 < x ≤ 5.0 cm in greatest diameter Invasive tumor, > 5 cm in greatest diameter Tumor of any size with: o Direct extension to chest wall, T4a o Direct extension to skin with edema (including peau d' o nodules confined to the same breast, T4b o Both skin and chest wall extension, T4c o Dermal lymphatics involved, inflammatory cancer, T4d  (Regional Lymph Nodes) Regional lymph node metastasis o pN0 No regional lymph node metastasis histologic	diameter diameter diameter orange) or ulceration of skin of the breas by removed)	
	o N1	o pN0(i-) o pN0 (i+) No regional lymph node metastasis histologic o pN1 mi o pN1a o pN1a o pN1b Metastasis in 1 to 3 axillary lymph nodes o pN1b Metastasis in 1 to 3 axillary lymph nodes o pN1c Metastasis in 1 to 3 axillary lymph nodes o pN1c Metastasis in 1 to 3 axillary lymph nodes with mot clinically apparent(5) o pN1c Metastases in 1 to 3 axillary lymph nodes and sentinel lymph node dissection but not clinically metastases in ipsilateral axillary lymph nodes fixed or main the absence of clinically evident axillary lymph node metastasis o pN2 Metastasis in ipsilateral axillary lymph nodes for N2b Metastasis in ipsilateral axillary lymph node metastasis o pN2 Metastasis in 4-9 axillary lymph nodes (at least opposed) Metastasis in 4-9 axillary lymph nodes (at least opposed)	cally, negative IHC ly, positive IHC cluster greater than 0.2 greater than 2.0 mm)  nicroscopic disease detected by sentine d in internal mammary lymph nodes with ally apparent <sup>(5, 6)</sup> titted, or in clinically apparent <sup>(1)</sup> ipsilateral netastasis fixed to one another (matted) or to other all internal mammary nodes and in the clinically apparent <sup>(1)</sup> internal mammary set one tumor deposit greater than 2.0 m	el lymph node dissection but th microscopic disease detected by al internal mammary nodes er structures the absence of clinically evident the absence of the
	o N3	o pN2b Metastasis in clinically apparent(1) internal mar Metastasis in ipsilateral infraclavicular lymph node(s) with ipsilateral internal mammary lymph node(s) and in the pre metastasis in ipsilateral supraclavicular lymph node(s) with Metastasis in ipsilateral infraclavicular lymph node N3c Metastasis in ipsilateral internal mammary lymph node internal mammary lymph nodes in the presen lymph nodes with clinically negative microscosupraclavicular lymph nodes o pN3a Metastasis in 10 or more axillary lymph nodes infraclavicular lymph nodes o pN3b Metastasis in 10 or more axillary lymph nodes infraclavicular lymph nodes o pN3b Metastasis in clinically apparent(1) ipsilateral in axillary lymph nodes; or in more than 3 axillar mammary lymph nodes with microscopic dise not clinically apparent(5) o pN3c Metastasis in ipsilateral supraclavicular lymph	or without axillary lymph node involved esence of clinically evident axillary lymph nor without axillary or internal mamma node(s) and axillary lymph node(s) and axillary lymph node(s) node(s) and axillary lymph node(s) es, or in infraclavicular lymph nodes, or ice of 1 or more positive axillary lymph popic metastasis in internal mammary lymph is (at least one tumor deposit greater that the property lymph nodes and in internal mammary lymph nodes and internal mammary lymph no	ment, or in clinically apparent <sup>(1)</sup> oh node metastasis; or ary lymph node involvement in clinically apparent <sup>(1)</sup> ipsilateral nodes; or in more than 3 axillary mph nodes; or in ipsilateral an 2.0 mm), or metastasis to the presence of 1 or more positive ary lymph nodes and in internal
11e.	M Stage o MX o M0 o M1	Presence of distant metastasis cannot be assessed No evidence of distant metastasis Distant metastasis (includes metastasis to ipsilateral suprae	clavicular lymph node(s)	

If this is a revised or corrected form, please check box		Study 6666 LABEL HERE
	Institution	Institution No
	Participant Initials	Case No
<u>Foot Notes</u>		
<ol> <li>Clinically apparent is defined as detected by imaging studies (ex Classification is based on axillary lymph node dissection with or solely on sentinel lymph node dissection without subsequent axi e.g., pN0 (i+) (sn).</li> <li>Isolated tumor cells (ITC) are defined as single tumor cell or sma immunohistochemical (IHC) or molecular methods but which ma metastatic activity (e.g., proliferation or stromal reaction.)</li> <li>RT-PCR: reverse transcriptase/polymerase chain reaction.</li> <li>Not clinically apparent is defined as not detected by imaging studies. If associated with greater than 3 positive axillary lymph nodes, the increased tumor burden.</li> <li>T1 includes T1mic</li> </ol>	without sentinel lymph node llary lymph node dissection is all cell clusters not greater that y be verified on H&E stains. I dies (excluding lymphoscintigr	dissection. Classification based designated (sn) for "sentinel node," n 0.2 mm, usually detected only by TCs do not usually show evidence of aphy) or by clinical examination.
12. Will another form S1 be completed for this breast at this time  o No o Yes	(e.g. double lumpectomy)?	
Comments:		
STOP: Sign and date form		
Signature of person responsible for the data	Date	Form Completed (mm-dd-yyyy)
Signature of person entering data on web		

S	1	If this is a revised or corrected form, please check box			ACRIN Study PLACE LABI	
	•			Institution	I LACE LADI	Institution No
				Participant Ini	tials	Case No
13.	Detail	additional enumerated lesion this	specimen	( <b>,</b>		
	13a.	$\underline{\textbf{Lesion Location}}  \Box \text{ Check if this}$	lesion ONLY seen	on MRI		
	<u>Brea</u>	(report on hour and 1/2 hour		<u>Distance</u> rom Nipple	<u>Size</u> (largest dimension	Lesion number (e.g. MR1, UL2, GR1, etc)
	o R o		o axilla OR o retroareolar o central	cm	LLL mı	m
		Provide pathology at this surgery o Cancer o Atypical/high-risk o Benign o Unsure of correlation with final		ribed above		
	13b.	Was there another previously enu o No (proceed to Q6) o Yes (proceed to Q14)	umerated lesion rer	moved from this br	east during this surg	gery?
14.	Detail	additional enumerated lesion this	specimen			
	14a.	<b>Lesion Location</b> □ Check if this	lesion ONLY seen		Ci	
	Brea	Clockface or specify (report on hour and 1/2 hour e.g. 7:00 = 0700, 12:30 = 1230)	o axilla	<u>Distance</u> from Nipple	Size (largest dimension	Lesion number (e.g. MR1, UL2, GR1, etc)
	o R o	L o' clock	OR o retroareolar o central	cm	mı mı	m
	14b.	Provide pathology at this surgery o Cancer o Atypical/high-risk o Benign o Unsure of correlation with final  Was there another previously enu o No (proceed to Q6) o Yes (proceed to Q15)	surgical specimen		east during this surg	gery?
15.	Detail	additional enumerated lesion this	specimen			
	15a.	<u>Lesion Location</u> ☐ Check if this	lesion <u>ONLY</u> seen	on MRI		
	<u>Brea</u>	(report on hour and 1/2 hour e.g. 7:00 = 0700, 12:30 = 1230)		Distance from Nipple	Size (largest dimension	(e.g. MR1, UL2, GR1, etc)
		Provide pathology at this surgery o Cancer o Atypical/high-risk o Benign o Unsure of correlation with final		ribed above		
Pr	oce	ed to Q6				

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	ACRIN Study 666 PLACE LABEL H	
	Institution Institution	No
	Participant Initials Case No.	
ne s	study breast and submitted to the ACR. Interpr	etation is
ion nha t br	when identifying findings so that consistency and ancement on study; in addition a separate for reast. Reports are dated MM/DD/YYYY. Meast to be numbered: use comments.	ong forms orm is to
	Data recorded represent (A separate form must be confinding. Note: Code GR1 for breast, GL1 for the first lesion	ompleted for <u>each</u> the first lesion in right
	II. FINDING	
	<ul> <li>6a. Signal on T2 for this finding</li> <li>o Purely cystic/fluid</li> <li>o Moderately hyperintense (at least</li> <li>o Slightly hyperintense</li> <li>o Hypointense or not seen</li> </ul>	partially solid)
r	6b. Finding type (study breast) <ul> <li>o Focus/foci ≤ 5 mm (proceed to Q6</li> <li>o Mass (answer Q7 then skip to Q9</li> <li>o Non mass enhancement (skip to Q6</li> <li>o Scar (skip to Q10)</li> </ul>	)
	6c. If focus/foci (detail then proceed to o Solitary If Solitary, largest diamete o 2-3 o ≥ 4	,
	7. Mass size encompassed by Gd en (record three dimensions)	hancement
	med-lat mm sup-inf	
	7a. Mass Shape o Round o Oval o Lobulated o Irregular	
	7b. Mass Margin o Smooth o Irregular o Spiculated	
	7c. Mass Internal Enhancement o Homogeneous o Heterogeneous o Rim enhancement o Dark internal septation(s) o Enhanced internal septation(s) o Central internal enhancement	
	7d. Fat containing o No o Yes	
	7e. Mass Degree of Enhancement o Minimal o Moderate	

initiai	WKI	Assessment	Fori

If thi	s is a	a revised or corrected form, plea	ase $\sqrt{\text{box.}}$
done is ma be c	e blin ainta omp	CTIONS: This form is completed of the 24 month mammogram and US sined. A separate form is completed for EACH breast even if no ted in mm. Nonenhancing cysts an	<ol> <li>Please pay particular attention</li> <li>leted for each finding or en</li> <li>finding is identified in that</li> </ol>
I. G	ENE	ERALINFORMATION	
	1a.	Breast reported on this form o Right Breast o Left Breast	
	1b.	Is this form M3 a continuation for this breast? o No, proceed to Q2 o Yes, proceed to Q5	of another M3
2.	0	s 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 behavior recommendation is other or No or Yes	
3.	Dat	e of MRI Scan	
	_	<b>-</b> (mm-do	d-yyyy)
	3a.	Participant's last menstrual p	
		If < 1 month ago. Note: Code applicable or unknown	
	3b.	Date of MRI Interpretation	
		(mr	n-dd-yyyy)
	3с.	Reader ID#	
		Radiologist Name	(Last, First)
	3d.	Background tissue enhancen o None/minimal o Moderate, patchy o Moderate, uniform o Marked	nent
	3e.	Significant artifacts for this b o No (proceed to Q4) o Yes (check all that apply then	proceed to Q4)
4.		Total number of finding (If zero (0), skip to Q12) (No reported as one lesion if all	ote: Multiple foci can be

- o Moderate o Marked

M3 Revision		RIN Study 6666 E LABEL HERE
8. Type of non-mass enhancement	Institution	Institution No
o Focal area	Participant Initials	Case No
o Linear		
o Ductal o Segmental		
o Regional	10a. Maximum d	istance of Finding From the Nipple
o Multiple regions		
o Diffuse	r	nm
8a. Largest diameter mm	10b. Location of	Finding
8a. Largest diameter Land mm		agram, check each region
8b. Non-Mass enhancement symmetry o Not applicable	in which the finding	g is visible.
o Symmetric o Asymmetric		
8c. Non-Mass enhancement internal characteristics	Cranio-Caudal	Medio-Lateral
o Homogeneous	Right / Left	\RT / \IT /
o Heterogeneous	Lateral	
o Stippled/punctate o Clumped	R1 R4 L4 L1	RB RE LE LB
o Reticular/dendritic	1 R2 R5 L5 L2	CON RC RF LF LC LA
		V VRD LLDV
III. ASSOCIATED FINDINGS	R3 R6 L6 L3	RG LG
A		7 -
<ul><li>Associated findings (finding noted in Q5)</li><li>No (skip to Q10)</li></ul>		0 DT D.T
o Yes (complete Q9A and continue)		.0 □ RT □ LT .1 □ RA □ LA
5 · · · · · (· · · · · · · · · · · · · ·		2
9a. Characterization of Associated findings		.3   RC   LC
(Check all that apply)		.4 □ RD □ LD
☐ Nipple retraction or inversion	□ R5 □ l	.5 🗌 RE 🗌 LE
Skin retraction	□ R6 □ l	_6 □ RF □ LF
☐ Pre-contrast high duct signal		☐ RG ☐ LG
☐ Skin thickening☐ Skin invasion	V KINETIO OLIDVE	ACCECCATENT
Edema	V. KINETIC CURVE	ASSESSMENT
Lymphadenopathy	11. CAD used for thi	slesion
Pectoralis muscle invasion	o No	0.100.101.1
☐ Chest wall invasion	o Yes, for kinetic	
☐ Hematoma / blood☐ Abnormal signal void	o Lesion only de	etected after CAD
(absence of signal due to artifact)	11a. Initial enha	acomont phase
Cyst(s)	o Not applic	
U Other, specify	o Slow	
V. Finding Location (location of finding noted in Q5	o Medium o Rapid	
	44h Deleved on	hanaanant uhaaa
10. Location of finding	11b. Delayed en	nancement pnase utes or after curve begins to change)
o Nipple	o Not applic	
o Central Region o UIQ	o Persisten	
o LIQ	o Plateau o Washout	
o UOQ	- Traditout	
o LOQ		
o Axillary Tail o Breast, NOS		
o Subareolar		
o Multiple scattered areas		
o Other, Specify		

M3 Revision	I	RIN Study 6666 E LABEL HERE
		Institution No
		Case No
VI. OVERALL ASSESSMENT OF FINDING Questions 12 and 13 record recommendations specific Note: If no lesion recorded in Q5, code assessments an	to the finding # reported in Q5	j.
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 biop o MRI guided biopsy directly o Other, specify; o Additional Imaging	IRI in months nts)	
COMMENTS:		
		_
Signature of person responsible for the data <sup>1</sup>	_ Date form com	pleted <sup>3</sup> (mm-dd-yyyy)
Signature of person entering data onto the web <sup>2</sup>	_	

# MRI Short Interval

ACRIN	Study	6666
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### PLACE LABEL HERE

	IVI4	ont Form	
L	Assessin	ent Form	Institution Institution No
f th	nis is a revised or corrected f	orm, please $\sqrt{\text{box.}}$	Participant Initials Case No
oart finc ide	ticular attention when identifying ding or enhancement on stu	g findings so that consistency among for dy; in addition a separate form is t are dated MM/DD/YYYY. Measurement	f the study breast and submitted to the ACR. Please pay ms is maintained. A separate form is completed for each be completed for EACH breast even if no finding is are reported in mm. Nonenhancing cysts and nonenhancing
I. G	GENERAL INFORMATION	V	
	1a. Breast reported on the o Right Breast o Left Breast	nis form	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)
	1b. Is this form M4 a cont for this breast? o No, proceed to Q2 o Yes, proceed to Q5		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.)
2.	was an MRI done?  o No; If no, specify reaso code table (stop and sign form) o Yes (complete Q2a an continue with form)	2 Patient unable to tolerate 3 Scanner failure 4 Injection failure	II. FINDING  6a. Signal on T2 for this finding  o Purely cystic/fluid o Moderately hyperintense (at least partially solid) o Slightly hyperintense o Hypointense or not seen
	2a. Follow-up MRI timepo o 3 months o 6 months o Other, specify	(Note: Immediate/repeat MRI needs to be reported on form M3)	<ul> <li>6b. Finding type (study breast)</li> <li>o Focus/foci ≤ 5 mm (proceed to Q6c)</li> <li>o Mass (answer Q7 then skip to Q9)</li> <li>o Non mass enhancement (skip to Q8)</li> <li>o Scar (skip to Q10)</li> </ul>
		s in the breast reported in Q1a for on is other than routine follow-up?	6c. If focus/foci (detail then proceed to Q10)  o Solitary If Solitary, largest diameter in mm o 2-3 o ≥ 4
3.	Date of MRI Scan	_(mm-dd-yyyy)	7. Mass size encompassed by Gd enhancement (record three dimensions)
	3a. Participant's last mei	nstrual period	mm mm mm
		(mm-dd-yyyy)	med-lat × sup-inf ant-post
	If < 1 month ago. Not applicable or unknow	e: Code 12-12-2100 if not /n	7a. Mass Shape o Round o Oval
	3b. Date of MRI Interpreta	ation	o Lobulated
		(mm-dd-yyyy)	o Irregular 7b. Mass Margin
	3c. Reader ID#		o Smooth o Irregular o Spiculated
	Radiologist Name	(Last, First)	7c. Mass Internal Enhancement o Homogeneous
	3d. Background tissue e  o None/minimal  o Moderate, patchy o Moderate, uniform	nhancement	o Heterogeneous o Rimenhancement o Dark internal septation(s) o Enhanced internal septation(s) o Central internal enhancement
			7d. Fat Containing  o No o Yes  7e. Mass Degree of Enhancement
	☐ Motion ☐ Large breast, at ☐ Inhomogeneous ☐ Clips/sutures ☐ Other, specify _	fat suppression	o Minimal o Moderate o Marked  * * * proceed to question 9 * * *

	M4 Revision		Study 6666 ABEL HERE
_		Institution	Institution No
8.	Type of non-mass enhancement  o Focal area	Participant Initials	
	o Linear		
	o Ductal		
	o Segmental	10a. Maximum distar	nce of Finding From the Nipple
	o Regional o Multiple regions		
	o Diffuse	mm	
	1 1 1	10b. Location of Find	ing
	8a. Largest diameter mm	Referencing the diagra	m, check each region
	8b. Non-Mass enhancement symmetry	in which the finding is	visible.
	o Not applicable		
	o Symmetric o Asymmetric	Cranio-Caudal	Medio-Lateral
	0 Asymmetric	Right / Left	Right (RT/LT) Left
	8c. Non-Mass enhancement internal characteristics	Lateral	Axilla
	o Homogeneous o Heterogeneous	R1 R4 L4 L1	RB RE LE LB
	o Stippled/punctate	(RO R2 R5 L5 L2 L0)	(M RC RF LF LC LA)
	o Clumped o Reticular/dendritic	R3 L3	RD RG LG LD
		R6 L6	
Ш	ASSOCIATED FINDINGS	Cranio-Caudal	Medio-Lateral
0	Accepiated findings (finding noted in OE)		
9.	Associated findings (finding noted in Q5) o No (skip to Q10)	☐ R0 ☐ L0	□ RT □ LT
	o Yes (complete Q9A and continue)	☐ R1 ☐ L1	□ RA □ LA
	On Characterization of Associated findings	□ R2 □ L2 □ R3 □ L3	☐ RB ☐ LB ☐ RC ☐ LC
	9a. Characterization of Associated findings (Check all that apply)	□ R4 □ L4	
		□ R5 □ L5	☐ RE ☐ LE
	☐ Nipple retraction or inversion☐ Skin retraction	□ R6 □ L6	☐ RF ☐ LF
	Pre-contrast high duct signal		☐ RG ☐ LG
	Skin thickening	V. KINETIC CURVE ASS	SESSMENT
	☐ Skin invasion☐ Edema		
	Lymphadenopathy	11. CAD used for this les	sion
	Pectoralis muscle invasion	o No o Yes, for kinetics or	alv
	☐ Chest wall invasion☐ Hematoma / blood	o Lesion only detected	
	Abnormal signal void	44. 191.	
	(absence of signal due to artifact)  Cyst(s)	11a. Initial enhancen o Not applicable	nent phase
	Other, specify	o Slow	
		o Medium o Rapid	
١V	. Finding Location (location of finding noted in Q5)	·	
10	. Location of finding	11b. Delayed enhand	cement phase or after curve begins to change)
	o Nipple	o Not applicable	or after curve begins to change,
	o Central Region	o Persistent o Plateau	
	o UIQ o LIQ	o Washout	
	o UOQ		
	o LOQ		
	o Axillary Tail o Breast, NOS		
	o Subareolar		
	o Multiple scattered areas		
	o Other, Specify		

Revision		RIN Study 6666 E LABEL HERE
		Institution No
		Case No
	Participant initials	Case No.
VI. OVERALL ASSESSMENT OF FINDING Questions 12 and 13 record recommendations specific Note: If no lesion recorded in Q5, code assessments.  12. Assessment  12. Assessment  13. Negative, no abnormal enhancement  15. 2 Benign  16. 3 Probably Benign finding  16. 4A Low Suspicion of Malignancy  17. 4B Intermediate Suspicion of Malignancy  18. 4C Moderately High Suspicion of Malignancy  18. 4C Moderately High Suspicion of Malignancy  19. 5 Highly Suggestive of Malignancy  10. 5 Highly Suggestive of Malignancy  10. 8 Recommendation for this lesion  10. 8 Recommendation for this lesion  10. 9 Routine follow-up with MRI in months  10. 9 US-guided biopsy; if US negative, MRI-guided bio MRI guided biopsy directly  10. Other, specify;  10. Additional Imaging  11. Additional mammographic views  12. Ultrasound targeted to finding  13. 0 If US negative, routine follow-up  14. 0 If US negative, short-interval follow-up with	ic to the finding # reported in Q5 and recommendation for this bro	
Repeat MRI due to o Technical problem or motion (detail in commo 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 com	pleted <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

MRI-US-Mammo Integration	Institution	Institution No
,	Participant Initials	Case No
If this is a revised or corrected form, please √box.		
<b>nstructions:</b> After completing an M3 form for each breast (or M4 if th JS and MRI together.	is is a short interval follow-up MR	RI), please review current mammogram,
I. Radiologist ID		
1a. Radiologist Name(Last, First)		
2. Date of Integration Interpretation:	_	
2a. Date of Mammogram mm-dd-yyyy		
2b. Date of US		
mm-dd-yyyy		
2c. Date of MRI mm-dd-yyyy		
When all approach broads important is reviewed to get here.		
3. When all current breast imaging is reviewed together: Are there any findings seen ONLY on MRI:		
3a. Requiring additional evaluation?		
o None		
o Right breast only		
o Left breast only o Both breasts		
3b. Requiring short interval follow-up?		
o None		
o Right breast only o Left breast only		
o Both breasts		
3c. Requiring biopsy?		
o None		
o Right breast only		
o Left breast only o Both breasts		
<ol> <li>Are any findings considered benign or probably benign by U</li> <li>No</li> </ol>	S that require biopsy based or	n MRI?
o Yes		
5. Are any findings considered benign or probably benign by M	ammography that require bio	psy based on MRI?
o No		
o Yes		

|--|--|

	MX		ACRIN Study 6666 PLACE LABEL HERE				
			Institution	ı	Institution No		
6.		g together all breast imaging on this participant, issessment by breast:	Participa	nt Initials_	Case No		
	Final	Assessment of Right Breast	7. Final	Assessm	ent of <u>Left</u> Breast		
	6a.	□ Not on study (proceed to Q7)	7a.	□ Not on	study (stop and sign below)		
	6b.	% Combined reading likelihood of malignancy for right breast (best guess from 0-100)	7b.	malignan	% Combined reading likelihood of cy for left breast (best guess from 0-100)		
	6c.	Assessment for right breast	7c.		ent for left breast		
		O 1 Negative O 2 Benign			legative		
		O 3 Probably Benign			enign trobably Benign		
		O 4A Low Suspicion of Malignancy			ow Suspicion of Malignancy		
		O 4B Intermediate Suspicion		O 4B Ir	ntermediate Suspicion		
		O 4C Moderately High Suspicion			Moderately High Suspicion		
		O 5 Highly Suggestive of Malignancy			lighly Suggestive of Malignancy		
	6d.	Recommendation for right breast Follow-up	7d.	Follow-			
		O Routine screening in 1 year			e screening in 1 year		
		O Diagnostic follow-up in 1 year  ☐ Short-interval follow-up in 6 months with US			ostic follow-up in 1 year interval follow-up in 6 months with US		
		☐ Short-interval follow-up in 6 months with mammography			interval follow-up in 6 months with mammography		
		☐ Short-interval follow-up MRI in 6 months			interval follow-up MRI in 6 months		
		O Intervention and/or Additional Imaging			ention and/or Additional Imaging		
		(detail intervention and/or additional imaging)		,	intervention and/or additional imaging)		
		☐ Intervention			ervention		
		O Aspiration with core biopsy if solid O US-guided core biopsy			spiration with core biopsy if solid		
		O Vacuum-assisted biopsy, guidance by US			acuum-assisted biopsy, guidance by US		
		O Vacuum-assisted biopsy, guidance			acuum-assisted biopsy, guidance		
		by mammography			y mammography		
		O Excisional biopsy			xcisional biopsy		
		O MRI-guided vacuum assisted biopsy if not US biopsy			IRI-guided vacuum assisted biopsy if ot US biopsy		
		☐ Additional Imaging (check all that apply)		□ Add	ditional Imaging (check all that apply)		
		<ul> <li>☐ Additional evaluation</li> <li>☐ Comparison to prior mammogram is required</li> </ul>			dditional evaluation  Comparison to prior mammogram is required		
		☐ Targeted ultrasound (lesion seen			Targeted ultrasound (lesion seen		
		on mammography)		_	on mammography)		
		☐ Ultrasound targeted to MRI abnormality			Ultrasound targeted to MRI abnormality		
		☐ Additional mammographic projections			Additional mammographic projections		
		☐ Repeat ultrasound ☐ Technique/interpretation in question			epeat ultrasound  Technique/interpretation in question		
		☐ Possibly abnormal			Possibly abnormal		
		☐ Repeat mammogram			Lepeatmammogram		
		☐ Incomplete			Incomplete		
		☐ Motion artifact/other technical problem			Motion artifact/other technical problem		
		☐ RepeatMRI			lepeatMRI		
		O Motion artifact or other technical problem			Motion artifact or other technical problem		
		O Incomplete			Incomplete		
		O Abnormalities likely due to phase in cycle			Abnormalities likely due to phase in cycle		
C	OMMEN	TS:					
	ignature	of person responsible for the data	1	Date form c	ompleted (mm-dd-yyyy)		
J	ignature	or person responsible for the data					
S	ignature	of person entering data onto the web					

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# ACRIN 6666 Screening Breast US Follow-up Assessment Form

Institution Institution No
Participant Initials Case No
initial on study mammography and ultrasound d. e.g. imaging, biopsy, surgery and/or non-protocol dis designed primarily to capture imaging and biopsy ms that have not previously been reported. hual exam, complete form F6 instead of F1, for
5c. Have there been any clinically significant changes in the right breast since the last annual examination?
o No or breast not on study o Yes (check all clinical changes that apply) □ Palpable mass (complete location) Location of abnormality
o'clock or specify location:  o Axilla o Retroareolar o Unknown  Nipple discharge (detail): o Bloody
o Clear spontaneous o Other □ Other, specify:  5d. Have there been any clinically significant changes
in the left breast since the last annual examination?  o No or breast not on study o Yes (check all clinical changes that apply)  Palpable mass (complete location) Location of abnormality  o'clock or specify location: o Axilla o Retroareolar o Unknown
<ul><li>☐ Nipple discharge (detail):</li><li>o Bloody</li><li>o Clear spontaneous</li><li>o Other</li></ul>
Other, specify:  6. Current use of hormones?  o No (proceed to Q7) o Yes (complete Q6a)  6a. Specify hormone(s)  7. Has any interval breast imaging been performed since last visit? (consider only items not previously reported on forms IM, F6, etc., per instructions.) o No (proceed to Section III) o Yes (complete Q7a)  7a. Check all breast imaging performed since last visit:

F1
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### **ACRIN 6666**

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

### 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.

- o Right (Complete Qs 8a, 8b and 9)
- o Left (Complete Qs 8a, 8b and 10)
- o Both (Complete Qs 8a-10a)

8a.	Date	of	most	recent	mammogram		
					3	mm	уууу

8b.	Specity	pasis	tor	aecision	to	optain	tne	wammogran
	Recomn	nended	by:					
	□ C	:	-:+-					

Screening	site

☐ MD who referred you for scre	eening
--------------------------------	--------

☐ Another physician

(identify type of physician)

- ☐ Internist
- □ Surgeon
- ☐ Ob/Gyn
- ☐ Other or unknown
- ☐ Family Member
- ☐ Someone else

(specify relationship of this person to you)

#### 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

- 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
- 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

- 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
- Assessment unknown or incomplete (unable to obtain reported assessment, done at another imaging facility, BIRADS 0, or partial report)

### ACRIN Study 6666 PLACE LABEL HERE

Ins	stitution		Institution No.					
Pa	rticipant Initi	als	_ Case No					
11.	Ultrasound (If no ultrasound performed proceed to Q14)							
	was perform NOTE: Interva on form o Righ o Left	ned in the past	udy site should be repus appropriate. 1a, 11b and 12) a, 11b and 13)					
	11a. Da	te of most rece	ent ultrasound	уууу				
	Re	commended by: Screening site MD who referred Another physicial (identify type of Internist Surgeon Ob/Gyn Other or und Family Member Someone else	physician)					
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

- Negative
- Ω 2 Benign

0

- Probably Benian 0
- 4A Low Suspicion of Malignancy
- Intermediate Suspicion 0
- Moderately High Suspicion
- o 5 Highly Suggestive of Malignancy
  - Assessment unknown or incomplete (unable to obtain reported assessment, done at another imaging facility, BIRADS 0, or partial report)

#### **Ultrasound Assessment of Left Breast** 13.

If No evaluation of Left Breast performed, proceed to Q14 If outside study codes "4, suspicious", code as 4B

#### 13a. Assessment for left breast

- Negative 0 1
- 0 2 Benign
- Probably Benign 0 3
- o 4A Low Suspicion of Malignancy
- Intermediate Suspicion o 4B
- Moderately High Suspicion 4C 0
- 0 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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#### **ACRIN 6666**

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

#### 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?

- o Right (Complete Qs 14a, 14b, and 15)
- o Left (Complete Qs 14a, 14b and 16)
- o Both (Complete Qs 14a-16a)

14a.	Date	of	most	recent	breast	MRI		
							mm	ууу

#### 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

- o 1 Negative
- 0 2 Benian
- o 3 Probably Benign
- 4A Low Suspicion of Malignancy 0
- Intermediate Suspicion
- Moderately High Suspicion o 4C
- 0 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

- o 1 Negative
- 0 2 Benign
- Probably Benign 0 3
- 4A Low Suspicion of Malignancy Ω
- Intermediate Suspicion
- o 4C Moderately High Suspicion
- 0 5 Highly Suggestive of Malignancy
- Assessment unknown or incomplete (unable to obtain reported assessment, done at another imaging facility, BIRADS 0, or partial report)

### ACRIN Study 6666 PLACE LABEL HERE

Institution			Institution No					
Participant Initials		3	Case No					
17.		Other Breast Imaging (If no other breast imaging performed proceed to section III)						
	performed NOTE: Use for sonog o Rig o Lef	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  o Right (Complete Qs 17a, 17b, 17c and 18) o Left (Complete Qs 17a, 17b, 17c and 19) o Both (Complete Qs 17a-19a)						
		cify type	ent other imaging					
	Recci   S   S	ommended by: Screening site MD who referre Another physic identify type of Internist Surgeon Ob/Gyn Other or u Family Member Someone else	f physician)	3				
18.			ent of Right Brea Breast performed,					

#### 18.

If outside study codes as "4, suspicious", code as 4B 18a. Assessment for right breast

- 0 1 Negative
- 2 Benign 0
- Probably Benign 0 3
- 0 4 A Low Suspicion of Malignancy
- o 4B Intermediate Suspicion
- Moderately High Suspicion 0
- Highly Suggestive of Malignancy 0 5
- 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

- Negative 0 1
- 0 2 Benign
- Probably Benign 0 3
- o 4A Low Suspicion of Malignancy
- 4B Intermediate Suspicion
- 4C Moderately High Suspicion 0
- Highly Suggestive of Malignancy 0
  - Assessment unknown or incomplete (unable to obtain reported assessment, done at another imaging facility, BIRADS 0, or partial report)

### **ACRIN 6666**

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

#### Section III. Intervention

- 20. Were there any cyst aspirations, biopsies or surgeries on the study breast(s) in the past 11 months?
  - o No (Proceed to Q21)
  - o Yes, not previously reported (Complete Q20a)
  - o Yes, previously reported (Proceed to Q21)
  - o Unknown (Proceed to Q21)

NOTE: If yes and the procedures have not previously been reported, complete Q20a and Form(s) BX, NL, and S1 as appropriate.

20a. Specify intervention and date (list all that apply below)

If an intervention is on both breasts, list each breast on a separate line.

#### Intervention Code Table (Q20a)

- 1 Cyst Aspiration
- 2 FNAB (complete **BX**)
- 3 Core Needle Biopsy (complete BX)
- 4 Excisional Biopsy (complete NL)
- 5 Lumpectomy (complete **S1**)
- 6 Sentinel Lymph Node (complete S1)
- 7 Axillary Lymph Node Dissection (complete **S1**)
- 8 Mastectomy (complete **S1**)
- 10 Other, specify (in details)
- 99 Specifics Unknown

ntervention	Date (mm-yyyy)	Details	R	L	N/A
	<del>-</del>		0	0	0
			0	0	0
	<del>-</del>		0	0	0
			0	0	0
	_		0	0	Ο

## ACRIN Study 6666 PLACE LABEL HERE

Institution	Institution No.
Participant Initials	Case No.

#### Section IV. Summary/Treatment

- 21. Was a breast cancer diagnosed in the past 11 months?
  - o No (Complete Q21a)
  - o Yes, not already reported (Proceed to Q21b and complete BX and S1 forms)
  - Yes, already reported on BX and/or, NL and S1 (Proceed to Q22)
  - o Unknown (Proceed to Q22)
  - 21a. Most reliable source regarding *Negative* breast cancer status for this participant. (complete then proceed to Q22)
    - o Participant herself says she has not been diagnosed with breast cancer
    - o No findings reported in participant's medical chart
    - o Participant's Primary Care Physician (PCP) (no abnormality found at last clinical exam)
    - o Report of clinical exam
    - o Other Physician
      - (no abnormality found at last clinical exam)
    - o Relative or friend stated that participant has not been diagnosed with breast cancer
    - o Participant is not listed on the cancer registry for the area in which she lives
    - o Hospital billing department reports no charges for breast cancer treatment

0	Other.	specify	

- 21b. Most reliable source regarding *Positive* breast cancer status for this participant.
  - o Pathology report
  - o Cancer diagnosis is reported in participant's medical chart
  - o Participant's Primary Care Physician (PCP) reports breast cancer
  - o Participant herself says she has been diagnosed with breast cancer
  - o Death certificate in municipality of last known address that lists cause of death as breast cancer
  - o Relative or friend states that participant has been diagnosed with breast cancer
  - o Participant is listed on the cancer registry for the area in which she lives
  - o Hospital billing department reports charges for breast cancer treatment
  - o Other, specify \_\_\_\_\_

#### 21c. Site of breast cancer

- o Right
- o Left
- o Bilateral

F1	AC For revised or corrected form	RIN 6666		17-09	36.		CRIN Study	6666 EL HERE
c c	study e Q22a) 3) ng or ne	ew sir		Initials		Institution No		
2	22a. Specify treatment If an intervention on a separate line.  Intervention Code 1 Radiation Ther	is on both b						
	2 Systemic Cher 3 Other hormone 9 Other, specify 99 Specifics Unki	notherapy manipulation (in details) nown						
Interventi	on Date (mm-yyyy)	Details	R		N/A			
	i <del>-</del>		0	0	0			
			0	0	0			
			0	0	0			
			0	0	0			
pas Ult c	s patient enrolled into st 11 months other that rasound in High Risk to No (Stop and sign form of Yes (Complete Q23a) of Unknown (Stop and signature). Provide name of the statement of the state	an the Screenii Women Trial? ) n form)	ng Bre	ast	the			

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

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

Comments: \_\_\_\_

Date Form Completed (mm-dd-yyyy)

# F2 ACRIN 6666 Post 36 Month Follow-up Form

ACRIN Study 6666

## PLACE LABEL HERE

Ъ		1			Institution	Institution No
lf th	his is a re	vised (	or corre	ected form, please $\sqrt{\text{box.}}$	Participant Initials	Case No
				n is designed to capture the results of s to be completed by the RA or a study		
1.	What ty	pe of	imagir	ng was performed of study breasts at	the 36 month time point? (c	check all that apply)
		Stand	dard-vi	ew mammography, date:	(mm-dd-yyyy)	
		Addit	ional r	nammographic views, date:	(mm-dd-yyyy)	
		Whol	e brea	st ultrasound, date:	_ (mm-dd-yyyy)	
		Targe	eted ul	trasound, date: (m	nm-dd-yyyy)	
		0	Right	t		
		0	Left			
		0	Both	breasts		
		Conti	rast-en	hanced MRI, date:	_ (mm-dd-yyyy)	
		0	Right	t		
		0	Left			
		0	Both	breasts		
		None	<del>)</del>			
		Unkn	iown			
2.	Was the	ere a s	uspici	ous abnormality (BI-RADS 4 or 5) ider	ntified in any study breast(s	) at the 36 month time point?
	0	No (5	STOP a	and sign form)		
	0	Yes,	detail v	which breast (check all that apply):		
			Right	t, suspicious by (check all that apply):		
				Mammography		
				US		
				MRI		
				Clinically		
				Unknown		
			Left,	suspicious by (check all that apply):		
				Mammography		
				US		
				MRI		
				Clinically		
				Unknown		

O Unknown (STOP and sign form)

# F2 ACRIN 6666 Post 36 Month Follow-up Form

ACRIN Study 6666

## PLACE LABEL HERE

/			Institution	Institution No
lf t	his is a re	evised or corrected form, please $\sqrt{\text{box.}}$	Participant Initials	Case No
3.	Does t	he suspicious abnormality correspond to a findi	ng previously reported?	)
	0	No (create a new lesion number on the BX form to rep		
	0	Yes, detail lesion number: (e.g. UR3, ML2	2, GR1, etc.)	
4.	Will any	biopsies be performed on any study breast(s) at this	s time?	
	0	No, detail reason:	(STOP and s	ign form)
	0	Yes, detail which breast (check all that apply):	`	,
		☐ Right (please complete a BX form for each biop	osy)	
		☐ Left (please complete a BX form for each biops	y)	
	0	Unknown (STOP and sign form)		
Co	mments	:		
_				
_				
Sig	nature o	f person responsible for the data		Date Form Completed (mm-dd-yyyy)
Sig	nature o	f person entering data on web		
		-		



ACRIN Study	Case #
PLACE	E 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, <u>SAEs meeting the criteria for expedited reporting</u>, 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.

		CTCAE Grade	Attribution		AdEERS Submitted for SAEs	Action Taken	Outcome	Date of AE Onset and Resolution
AE Description	AE Short Name CTCAE v3.0	1 = Mild 2 = Moderate 3 = Severe 4 = Life threatening	1 = Unrelated 2 = Unlikely 3 = Possible 4 = Probable	= Expected = Unexpected	1 = No 2 = Yes	1 = None 2 = Medication Therapy 3 = Procedure 4 = Hospitalization	1 = Recovered 2 = Improved 3 = Ongoing 4 = Death	(mm-dd-yyyy); check box "on-going" if the AE is on-going at the time of report
		or disabling 5 = Fatal	5 = Definite	2 =		5 = Other	5 = Unknown	☑ On-going
								Start date:
1								Resolution date:
								☐ On-going
								Start date:
2								Resolution date:
								☐ On-going
								Start date:
3								Resolution date:
								☐ On-going
Comments - for each comment, identify the AE number from above (#1-3):								
If there are more than 3 AEs for a v check this box and use another for								
< <page of<="" td=""><td></td><td>r Signature</td><td></td><td></td><td></td><td>Date</td><td>Form Comple</td><td>eted (mm-dd-yyyy)</td></page>		r Signature				Date	Form Comple	eted (mm-dd-yyyy)

"copyright 2005" AE 01-18-05 1 of 1

# Screening Breast US Protocol Variation Form

ACRIN Study	6666 Case#
PLACE LA	BEL HERE
Institution	Institution No
Participant's Initials	_ Case No

If this is a revised or corrected form, please  $\sqrt{\text{box}}$ .

INSTRUCTIONS: In the instance a protocol requirement is not met please record the necessary information below. Complete a

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   Excision not performed   Excision not performed   Participant withcrew main (US) study consent, provide documentation. Date of withdrawal:	four	nd upo	orm for each case and for each event. Fax a copy to ACRIN Headquarters @ (215) 717-0936. If the protocol variation is n data or image review by headquarters staff, a copy of the headquarters generated PR form will be faxed to the site RA. of form in the case study file.
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  Excision not performed  Participant withdrew main (US) study consent, provide documentation. Date of withdrawal:	1.	Chec	ck The Protocol Event Being Reported: (report only one per form)
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:			Ineligible participant registered to main (US) study
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:			Duplicate case registration
Imaging not performed per randomization sequence   Same radiologist interpreted both images   Recommended biopsy not performed   Excision not performed   Excision not performed   Participant withdrew main (US) study consent, provide documentation. Date of withdrawal:			Site not currently qualified to accrue participants
Same radiologist interpreted both images Recommended biopsy not performed Excision not performed Participant withdrew main (US) study consent, provide documentation. Date of withdrawal:			Randomization > 2 business days after consent
Recommended biopsy not performed  Excision not performed  Participant withdrew main (US) study consent, provide documentation. Date of withdrawal:			
Excision not performed Participant withdrew main (US) study consent, provide documentation. Date of withdrawal:			
Participant withdrew main (US) study consent, provide documentation. Date of withdrawal:			
o No further contact or follow-up per participant o No further contact, follow-up or permission to use data per participant    Mammogram not performed per protocol specified time point   o Initial   o 12 months   o 24 months   Survey US not performed per protocol specified time point   o Initial   o 12 months   o 24 months   o 12 months   o 24 months   o 12 months   o 24 months   o 12 months   o 13 months   o 14 months			
□ Mammogram not performed per protocol specified time point         ○ 12 months         ○ 24 months         □ Survey US not performed per protocol specified time point         ○ Initial         ○ 12 months         ○ 24 months         □ Survey US or Mammogram interpretation done by radiologist not approved as a qualified investigator in protocol 6666         ○ Initial         ○ 12 months         ○ 24 months         □ Recommended targeted US not done - enter date of imaging study that recommended US         — - — - (mm-dd-yyyy)         □ Recommended additional mammography views not done - enter date of imaging study that recommended these         — - — - (mm-dd-yyyy)         □ Lesion # changed. Previously reported lesion # at time point: o Initial o 12 months         ○ 12 months       o 12 months         ○ 12 months       o 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 oundergo contrast-enhanced breast MR to evaluate the			o No further contact or follow-up per participant
o Initial o 12 months o 24 months o 24 months  Survey US or Mammogram interpretation done by radiologist not approved as a qualified investigator in protocol 6666 o Initial o 12 months o 24 months o 24 months  Recommended targeted US not done - enter date of imaging study that recommended US			Mammogram not performed per protocol specified time point o Initial o 12 months
o Initial o 12 months o 24 months o 24 months  Recommended targeted US not done - enter date of imaging study that recommended US			o Initial o 12 months
Recommended additional mammography views not done - enter date of imaging study that recommended these			o Initial o 12 months
Recommended additional mammography views not done - enter date of imaging study that recommended these			Recommended targeted US not done - enter date of imaging study that recommended US
Recommended additional mammography views not done - enter date of imaging study that recommended these			(mm-dd-vvvv)
		П	
Lesion # changed. Previously reported lesion # at time point: o Initial o 12 months  • Is now lesion # at time point: o Initial o 12 months  o 12 months  o 24 months  O 24 months  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			
• Is now lesion # at time point: o Initial o 24 months o 12 months o 12 months o 24 months  O 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			
<ul> <li>Is now lesion # at time point: o Initial o 24 months o 12 months o 24 months</li> <li>Annual follow-up mammogram performed at outside facility.</li> <li>CAD used on study mammogram</li> <li>Bilateral mastectomies</li> <li>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.</li> <li>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</li> </ul>		Ш	
<ul> <li>□ CAD used on study mammogram</li> <li>□ Bilateral mastectomies</li> <li>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.</li> <li>□ 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</li> </ul>		•	Is now lesion # at time point: o Initial o 24 months o 12 months
<ul> <li>□ Bilateral mastectomies</li> <li>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.</li> <li>□ 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</li> </ul>			Annual follow-up mammogram performed at outside facility.
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			CAD used on study mammogram
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			Bilateral mastectomies
during the trial period, it is then acceptable for the participant to undergo contrast-enhanced breast MR to evaluate the			
			during the trial period, it is then acceptable for the participant to undergo contrast-enhanced breast MR to evaluate the

P	R	Breast US # 6666	Institution	Case #	Revision
		o No further contact o	r follow-up per participa follow-up or permission	n to use data per participant	(mm-dd-yyyy)
			I more than 8 weeks at	by radiologist not approved as a qualifie fter 24 month study ultrasound and n A	• •
		Other, specify:			
2.	Desc	cribe The Protocol Event R	eported Above		
lma	aging:	(Internal Reporting, findin	gs found upon data rev	riew).	
3.	Devi	ations			
		None			
		Breast density insufficier	nt		
		Incorrect US transducer	utilized		
		No images documenting	flow		
		Images without spatial of			
		Images with spatial com		d	
		Mammogram image qua	-		
		US image quality insuffic			
		MRI image quality insuffi			
		Imaging not done within			
		Mammogram images los	t, unable to archive, dat	te of exam	. (mm-dd-yyyy)
		US images lost, unable to	o archive, date of exam	(mm-dd-	уууу)
		Fewer than the required r	number of mammogram	images received, date of exam	(mm-dd-yyyy)
		Fewer than the required	number of US images re	eceived, date of exam	(mm-dd-yyyy)
4.	Com	ments			
				Date form completed	(mm-dd-yyyy)
Perso	on res	ponsible for data			
	HQ	Use Only			
HQ	Rese	arch Associate		Date form completed	(mm-dd-yyyy)

# Clinical Image Quality Form

## **ACRIN Study 6666**

Case #	
Site#_	

<b>INSTRUCTIONS:</b> 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	7d. Are lesion(s) imaged without spatial compounding
2.	DATE OF STUDY	O 1 No
3.	DATE IMAGES REVIEWED	O 2 Yes
		7e. Are lesion(s) imaged with power Doppler?
4.	IF IMAGES ARE RESUBMISSION, DATES OF PREVIOUS REVIEW(S) AND OUTCOME(S)	O 1 No
	4a. 1st review date	O 2 Yes
	Acceptable	8. ARE IMAGES PROPERLY LABELED?
	O 1 No	O 1 No, Detail
	O 2 Yes	O 2 Yes
		O 3 Yes except survey images only indicate
	4b. 2 <sup>nd</sup> review date	quadrant
	Acceptable	quaurani
	O 1 No	9. ARE IMAGES PRESENT FROM EACH QUADRANT?
	O 2 Yes	Right Breast
5.	US SYSTEM UNDER REVIEW:	O 1 No
٥.	O Philips/ATL Model	O 2 Yes
	O Siemens/Acuson Model	O 3 Not on study
	O GE Model	Left Breast
		O 1 No
	O Toshiba Model	
	O Other specify	O 2 Yes
		O 3 Not on study
<u>IM</u>	AGE QUALITY	10. OVERALL US IMAGE QUALITY
6	DOES IMAGING MEET PROTOCOL SPECIFICATIONS?	O Unacceptable (proceed to Q10a)
0.		O Minor deficiences, but acceptable
		(proceed to Q10a)
	O 2 Yes	O Acceptable (proceed to Q11)
7.	ARE THERE FINDINGS ON THIS STUDY?	O Good (proceed to Q11)
	O 1 No (proceed to Q8)	O Good (proceed to QTT)
	O 2 Yes	10a. Image size or field of view
		☐ Too shallow
	7a. Simple cyst only:	☐ Too deep
	O 1 No	☐ Meets Standards
	O 2 Yes	
	7h Ang laging other than south) as	10b. Focal Zones
	7b. Are lesions other than cyst(s) or scar(s) present?	☐ Too anterior
	O 1 No	Too posterior
	O 2 Yes	☐ Too many
	O 2 165	☐ Meets Standards
	7c. Are lesion(s) imaged with spatial	
	compounding	10c. Gain
	O 1 No	☐ Too Low
	O 2 Yes	Too high
		☐ Meets Standards

/		
QC		ACRIN Study 6666
	<b></b>	Case #
1	Od. Transducer frequency  Too Low	Site #
	☐ Too low ☐ Too high	<u> </u>
	☐ Meets Standards	
	Weets Standards	
1	0e. Artifacts present?	
	ONO	
	O Yes	
	Details:	
1	0f. Other	
	SPATIAL COMPOUNDING USED?	
(Ch	neck all that apply:)  Survey Images	
	Images of lesion(s)	
	None of the images	
_		
12. OV	ERALL MAMMOGRAM IMAGE QUALITY	
C	Unacceptable, Detail:	
C		
C		
C	Good	
1	2a. Does mammographic density meet protocol?  O 1 No, Detail	
	O 2 Yes	
	O 3 Borderline	
ACTIO	NS	
13. RE	 VIEWER HAS CONTACTED P.I. OF ORIGINATING SI	TE:
C		
C	2 Yes	
1	3a. Name of the P.I contacted	
1	<b>3b.</b> Phone date E-ma	ail date
14. IF	F CLINICAL IMAGE UNACCEPTABLE OR BELOW AV	
	Remedial plan by site	
	Resubmission O No O Yes	
15. C	COMMENTS:	
16 5	NONATURE OF REVIEWER.	
	SIGNATURE OF REVIEWER:	
		Et
	DATE ENTERED	
10. D	// \   = =	

ACRIN 6666
Image Transmittal Form

# ACRIN Study 6666 PLACE LABEL HERE

- I I I I I I I I I I I I I I I I I I I	31111	I LACE LA	ADEL HERE
		Institution	Institution No
		Participant Initials	— Case No
nstructions: This form to be complete	ed by ACRIN HQ imaging	associate as needed.	
1. Site number [1]			
2. Case number [2]			
3. Breast			
☐ Right <sub>[3]</sub> ☐ Left <sub>[4]</sub>			
4. Image available [5]			
O No, if no provide reason not O Yes	available		<sub>[6]</sub> STOP and sign form
5. Type of images			
☐ Additional mammographic vi	ews [7] Date:	mm-dd-yyyy <sub>[8]</sub>	
☐ Ultrasound [9]	Date:	mm-dd-yyyy <sub>[10]</sub>	
$\square$ MRI <sub>[11]</sub>	Date:	mm-dd-yyyy <sub>[12]</sub>	
☐ Images from biopsy (detail in	n Q6) <sub>[13]</sub> Date:	mm-dd-yyyy <sub>[14]</sub>	
6. Images from biopsy guidance			
US guided [15]	_		
FNAB <sub>[16]</sub>	Date:		
☐ Core biopsy [18]	Date:		
☐ Needle localization [20]	Date:	mm-dd-yyyy <sub>[21]</sub>	
Stereotactically guided [22]	Б.,		
☐ Core biopsy [23]	Date:		
☐ Needle localization [25]	Date:	mm-dd-yyyy <sub>[26]</sub>	
MRI-guided [27]	Data	mm dd ynny	
☐ Core biopsy [28]	Date:		
☐ Needle localization [30]	Date:	1- 1	
☐ Mammographically-guided needle localization [32]		Date:mm	n-dd-yyyy <sub>[33]</sub>
Other, [34] specify	[35]	Date: mm	n-dd-yyyy <sub>[36]</sub>
Initials of imaging Associate completing	[37] g form	——————————————————————————————————————	form completed (mm-dd-yyyy)

ACRIN 6666
Image Transmittal Form

# ACRIN Study 6666 PLACE LABEL HERE

- I I I I I I I I I I I I I I I I I I I	31111	I LACE LA	ADEL HERE
		Institution	Institution No
		Participant Initials	— Case No
nstructions: This form to be complete	ed by ACRIN HQ imaging	associate as needed.	
1. Site number [1]			
2. Case number [2]			
3. Breast			
☐ Right <sub>[3]</sub> ☐ Left <sub>[4]</sub>			
4. Image available [5]			
O No, if no provide reason not O Yes	available		<sub>[6]</sub> STOP and sign form
5. Type of images			
☐ Additional mammographic vi	ews [7] Date:	mm-dd-yyyy <sub>[8]</sub>	
☐ Ultrasound [9]	Date:	mm-dd-yyyy <sub>[10]</sub>	
$\square$ MRI <sub>[11]</sub>	Date:	mm-dd-yyyy <sub>[12]</sub>	
☐ Images from biopsy (detail in	n Q6) <sub>[13]</sub> Date:	mm-dd-yyyy <sub>[14]</sub>	
6. Images from biopsy guidance			
US guided [15]	_		
FNAB <sub>[16]</sub>	Date:		
☐ Core biopsy [18]	Date:		
☐ Needle localization [20]	Date:	mm-dd-yyyy <sub>[21]</sub>	
Stereotactically guided [22]	Б.,		
☐ Core biopsy [23]	Date:		
☐ Needle localization [25]	Date:	mm-dd-yyyy <sub>[26]</sub>	
MRI-guided [27]	Data	mm dd ynny	
☐ Core biopsy [28]	Date:		
☐ Needle localization [30]	Date:	1- 1	
☐ Mammographically-guided needle localization [32]		Date:mm	n-dd-yyyy <sub>[33]</sub>
Other, [34] specify	[35]	Date: mm	n-dd-yyyy <sub>[36]</sub>
Initials of imaging Associate completing	[37] g form	——————————————————————————————————————	form completed (mm-dd-yyyy)