ACRIN 6691
Monitoring and Predicting Breast Cancer Neoadjuvant Chemotherapy Response Using Diffuse Optical Spectroscopic Imaging (DOSI)
CRF Set
Part I. The following questions will be asked at Study Registration:

1. Name of institutional person registering this case [1]
2. Was the eligibility check list completed? [2] O 1 No O 2 Yes
3. Is the participant eligible for this study? [3] O 1 No O 2 Yes
4. Date the study-specific consent form was signed (mm-dd-yyyy) (Must be prior to study entry) [4]
8. Date of birth (mm-dd-yyyy) [8]
9. Ethnicity [9] O 1 Hispanic or Latino O 2 Not Hispanic or Latino O 9 Unknown
12. Participant's country of residence (if other, complete Q12a) [12]
   O 1 United States O 3 Other
   O 2 Canada O 9 Unknown
12a. Other country, specify (completed if Q12 is coded “other”) [18]
14. Participant's insurance status [14]
   O 0 Other O 5 Medicaid and Medicare
   O 1 Private Insurance O 6 Military or Veteran's Administration
   O 2 Medicare O 7 Self Pay
   O 3 Medicare and Private Insurance O 8 No means of payment
   O 4 Medicaid O 9 Unknown/Decline to answer
15. Will any component of the participant's care be given at a military or VA facility? [15]
   O 1 No O 2 Yes O 9 Unknown
16. Calendar base date [Date of registration] (mm-dd-yyyy) [16]
17. Race (check all that apply)
Part II. Inclusion Criteria:

24. Is there a diagnosis of invasive breast cancer by clinical breast examination, by standard of care diagnostic imaging, or by initial tissue biopsy (confirmed by the local site pathologist)? [28]
   O 1 No O 2 Yes

25. Date of most recent biopsy ______-____-____ (mm-dd-yyyy) [29]

26. Is the participant determined to be a candidate for primary systemic (neoadjuvant) therapy and for surgical resection of residual primary tumor following completion of neoadjuvant therapy? [30]
   O 1 No O 2 Yes

27. Is the tumor size >2cm, measured on imaging or estimated by physical exam? [31]
   O 1 No O 2 Yes

28. Are there no contraindications for primary chemotherapy? [32]
   O 1 No O 2 Yes

29. Is there planned definitive breast surgery (mastectomy or lumpectomy/breast conservation) following completion of neoadjuvant therapy? [33]
   O 1 No O 2 Yes

30. Is the participant 18 years of age or older? [34]
   O 1 No O 2 Yes

31. Does the participant have an ECOG Performance Status ≤ 2 or a Karnofsky ≥ 60%; (see appendix II of the protocol)? [35]
   O 1 No O 2 Yes

31a. Please provide one score:
   ECOG ________________________ [55]   Karnofsky ________________________ [56]

32. Does the participant have adequate organ and marrow function, as defined at participating institutions? [57]
   O 1 No O 2 Yes

33. If the participant is female, is she post menopausal for a minimum of one year, OR surgically sterile, OR not pregnant, confirmed by a pregnancy test as per institutional SOC, and willing to use adequate contraception (hormonal or barrier method of birth control; abstinence) for the duration of study participation? [44]
   O 1 No O 2 Yes

34. Is the participant able to understand and willing to sign a written informed consent document and a HIPAA authorization in accordance with institutional guidelines? [45]
   O 1 No O 2 Yes
Part III. Exclusion Criteria:

35. Has the participant received previous treatment (chemotherapy, radiation, or surgery) to involved breast; **including hormone therapy?** [46]
   - O 1 No  O 2 Yes

36. Does the participant have uncontrolled intercurrent illness including, but not limited to, ongoing or active infection, symptomatic congestive heart failure, unstable angina pectoris, cardiac arrhythmia, or psychiatric illness/social situations that would limit compliance with study requirements? [47]
   - O 1 No  O 2 Yes

37. Is the participant medically unstable? [48]
   - O 1 No  O 2 Yes

38. Is the participant under age 18? [49]
   - O 1 No  O 2 Yes

39. Is the participant pregnant or nursing? [50]
   - O 1 No  O 2 Yes

40. Has the participant experienced a previous malignancy, other than basal cell or squamous cell carcinoma of the skin or in situ carcinoma of the cervix, from which the patient has been disease free for less than 5 years? [51]
   - O 1 No  O 2 Yes

Comments: ____________________________________________________________

______________________________________________________________________

______________________________________________________________________

______________________________________________________________________

______________________________________________________________________ [52]

______________________________________________________________________ [53]

Initials of person(s) completing this form

Date Form Completed (mm-dd-yyyy) [54]
1. **Date of discovery:** ____/____/____ (mm/dd/yyyy) [1]

2. **Eligibility Status** [2]
   - O 1 Eligible
   - O 2 Ineligible

3. **Administrative reason for status change** [3]
   - O 1 Unwilling / Unable to provide consent
   - O 2 Consent post-registration
   - O 5 Enrolled under expired assurance
   - O 6 Waiver of eligibility criteria granted (complete Q4)
   - O 7 Intergroup criteria not met
   - O 10 Eligibility criteria not met at the time of registration (complete Q4)
   - O 12 Duplicate case registration/randomization (complete Q5)
   - O 88 Other (specify reason below)

   Specify reason: ______________________________________________________________ [4]

4. **Reason for status change** [5]
   - O 1 Age criteria not met
   - O 2 Gender criteria not met
   - O 3 Participant history not allowable per protocol
   - O 5 Cancer Stage Criteria not met
   - O 6 Prior malignancy
   - O 7 Pregnant
   - O 8 Pre-existing medical conditions
   - O 9 Histology not protocol compliant
   - O 10 Disease free entry criteria not met
   - O 12 Patient performance status criteria not met
   - O 19 Adjuvant therapy at study entry
   - O 21 (Non) Surgical Candidate
   - O 22 Medical contraindication
   - O 88 Other (specify reason below)

   Specify reason: ______________________________________________________________ [6]

5. **Duplicate Case #:** ______________________________________________________ [7]

6. **Comments:** ____________________________________________________________ [8, 9]

7. **Initials of person completing the form:** __________________________________ [10]
All Adverse Events (AEs) and Serious Adverse Events (SAEs) as defined in the protocol require routine reporting via web entry of the AE CRF. Only one AE is captured per form. For further instructions in completing the form, please refer to the AE completion instructions. Please note that source documentation (ACRIN AE log, ACRIN AE CRF, printed AE web confirmation, or participant’s chart) must have the investigator’s signature. For AE reporting requirements, please refer to the AE reporting section of the protocol. Contact ACRIN’s AE coordinator for any questions.

### AE Description

AE Short Name (online look-up)

<table>
<thead>
<tr>
<th>Grade</th>
<th>Attribution</th>
<th>Expectedness</th>
<th>Serious AE?</th>
<th>Expedited Report Submitted</th>
<th>Action Taken</th>
<th>Outcome</th>
<th>Date of AE Onset and Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild</td>
<td>Unrelated</td>
<td>Expected</td>
<td>No</td>
<td>None</td>
<td>Recovered</td>
<td>O</td>
<td>(mm-dd-yyyy); mark X</td>
</tr>
<tr>
<td>Moderate</td>
<td>Unlikely</td>
<td>Unexpected</td>
<td>Yes</td>
<td>Medication therapy</td>
<td>Improved</td>
<td>O</td>
<td>if the AE</td>
</tr>
<tr>
<td>Severe</td>
<td>Possible</td>
<td></td>
<td></td>
<td>Procedure</td>
<td>Ongoing</td>
<td>O</td>
<td>is ongoing at the time</td>
</tr>
<tr>
<td>Life threatening or disabling</td>
<td>Probable</td>
<td></td>
<td></td>
<td>Hospitalization</td>
<td>Death</td>
<td>O</td>
<td>of report</td>
</tr>
<tr>
<td>Fatal</td>
<td>Definite</td>
<td></td>
<td></td>
<td>Other</td>
<td>Unknown</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

```
Start date:      
Resolution date: 
Ongoing:         
```

### Comments:

Additional AEs to report?

Was the AE assessed, reviewed and signed by the investigator?

Date form completed (mm-dd-yyyy)

Investigator’s signature (for external use only)
# ACRIN 6691 Central Pathology Review Discrepancy Form

If this is a revised or corrected form, please ✓ box. 

**Instructions:** Please complete the discrepancy form for any issues found on the IP (Initial Pathology) or SP (Surgical Pathology) forms. This form is to be web-entered. Please include case number and Patient Initials in label section above. All discrepancies will be followed up by Data Management.

<table>
<thead>
<tr>
<th>Item #</th>
<th>Form ID</th>
<th>Breast</th>
<th>Lesion #</th>
<th>Bilateral lesion</th>
<th>Question Description</th>
<th>Issue</th>
<th>Notification of resolution requested</th>
<th>Response corresponds to measured breast</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>O IP</td>
<td>O Left</td>
<td>O 1</td>
<td>O No</td>
<td>O Yes</td>
<td>O No</td>
<td>O Yes</td>
<td>O No</td>
</tr>
<tr>
<td></td>
<td>O SP</td>
<td>O Right</td>
<td>O 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>O Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>O 3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>O Yes</td>
</tr>
<tr>
<td>2</td>
<td>O IP</td>
<td>O Left</td>
<td>O 1</td>
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<td>O Yes</td>
<td>O No</td>
<td>O Yes</td>
<td>O No</td>
</tr>
<tr>
<td></td>
<td>O SP</td>
<td>O Right</td>
<td>O 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>O Yes</td>
</tr>
<tr>
<td></td>
<td></td>
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<td>O 3</td>
<td></td>
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<td>O Yes</td>
<td>O No</td>
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</tr>
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</tr>
<tr>
<td>4</td>
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<td>O Left</td>
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<td>O No</td>
<td>O Yes</td>
<td>O No</td>
<td>O Yes</td>
<td>O No</td>
</tr>
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<td>5</td>
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<td>O Yes</td>
<td>O No</td>
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<tr>
<td></td>
<td>O SP</td>
<td>O Right</td>
<td>O 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>O Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>O 3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>O Yes</td>
</tr>
</tbody>
</table>

("Copyright 2012")
POST-CHEMOTHERAPY SURGERY

1. Date of central pathology review: __________-________-________ (mm-dd-yyyy) [1]

2. Initials of central pathology reviewer: ________________________________ [2]

3. Date of initial pathology: __________-________-________ (mm-dd-yyyy) [3]
   3a. Initial pathology comments: ________________________________________ [4]
   3b. Any discrepancies noted on this form [5]
       O No
       O Yes (Provide details on the central pathology review discrepancy form)

4. Date of surgical pathology: __________-________-________ (mm-dd-yyyy) [6]
   4a. Surgical pathology comments: ________________________________________ [7]
   4b. Any discrepancies noted on this form [8]
       O No
       O Yes (Provide details on the central pathology review discrepancy form)

5. Final pathologic response [9]
   O No response
   O Partial response
     Invasive carcinoma present in breast [10]
     O No
     O Yes
     If yes provide response [11]
     O One or a few tumor nodules
     O Scattered individual and nests of cells in region of most of original tumor
     O Not specified
     Invasion present in lymph node [12]
     O No
     O Yes
     O Complete response [13]
     O DCIS present
     O DCIS absent or not mentioned
   O Indeterminate

5a. Type of response for partial or complete [14]
   O Not described in pathology report
   O Foamy macrophages
   O Fibrosis
   O Lymphocytic infiltrate
   O Other, specify ______________________________________________________ [15]

Initials of person(s) completing form [16] Date form completed (mm-dd-yyyy) [17]
1. Provide reason for study disposition by selecting one of the following:
   - O 1 Protocol defined follow-up completed
   - O 2 Participant lost to follow-up
   - O 3 Participant refused follow-up / withdrew
   - O 4 Death (specify date and cause below)
     Date of death: __________ / __________ / __________ (mm/dd/yyyy)
     Cause of death
     - O 1 Disease Progression
     - O 8 Adverse Event / Side Effects / Complications
     - O 88 Other, specify ________________________________
   - O 5 Adverse Event / Side Effects / Complications
   - O 8 Study terminated by sponsor
   - O 88 Other (specify reason below)
     Specify reason: ________________________________

2. Date of disposition: ______ / ______ / ______ (mm/dd/yyyy)

3. Did the investigator review and sign off on the participant’s disposition?
   - O 1 No
   - O 2 Yes

Comments: ____________________________________________________________

_________________________ / __________ / __________ [17] [18]
Initials of person completing the form Date form completed (mm-dd-yyyy)

To the best of my knowledge, the data collected for the participant are accurate and complete.

Investigator’s signature: ____________________________________________
Part I. Imaging Visit Details

1. Timepoint: [1]
   - Baseline DOSI (Visit 1)
   - Early Therapy DOSI (Visit 2)
   - Mid-therapy DOSI (Visit 3)
   - Post-therapy DOSI (Visit 4)
   - Repeat Baseline DOSI (Visit 1)
   - Repeat Early Therapy DOSI (Visit 2)
   - Repeat Mid-therapy DOSI (Visit 3)
   - Repeat Post-therapy DOSI (Visit 4)

2. Date of Imaging Visit: _____-_____ mm-dd-yyyy [2]

3. Was imaging initiated? [3]
   - No, complete Q3a then skip to Q7
   - Yes, skip to Q4

3a. If imaging was not initiated, please provide reason(s): (check all that apply)
   - Participant refusal [4]
   - Institutional error [5]
   - Participant withdrew from study complete DS form [6]
   - Scheduling problem [7]
   - Unknown [8]

   - No, complete Q4a
   - Yes, skip to Q5

4a. If imaging was not completed, please provide reason(s): (check all that apply)
   - Participant refusal [12]
   - Institutional error [13]
   - Unknown [14]
   - Other, [15] specify: _______________________________ [16]

5. Was the 6691 standardized mapping scheme followed? [17]
   - No
   - Yes

6. Initials of technologist performing DOSI: _________ [18]

Part II. Participant Information

7. Did the participant have any SOC imaging done since the last study visit? [19]
   - No
   - Yes
   - Unknown

NOTE: All SOC imaging reviewed as part of registration and/or Visit 1 should be submitted as part of the Baseline DOSI Visit (Visit 1).

7a. If yes or unknown, check imaging performed:
   - Ultrasound [22] # imaging visits: _______ [23]
   - Other imaging [26] # imaging visits: _______ [27]
   - Specify type(s) of imaging:
     _______________________________ [28]
   - Unknown [29]

8. Any adverse event(s) to report? [32]
   - No
   - Yes (complete AE form)
Part I. Visit Details

1. Date of Visit: [ ] [ ] [ ] mm-dd-yyyy

Part II. Visit Study Procedures

Details of assessments must be recorded in source

2. Study procedures completed and/or assessed as part of visit (check all that apply):
   * Required per protocol for all participants   ** Required for all female participants of childbearing potential
   - [ ] Physical Exam [ ]
   - [ ] Pregnancy Test [ ]
   - [ ] Medical History [ ]
   - [ ] Clinical Test Results [ ]
   - [ ] Pathology Report [ ] from initial biopsy
   - [ ] Diagnostic Imaging reports [ ]
   - [ ] Prognostic Imaging reports [ ]
   - [ ] Medical Records [ ]
   - [ ] Other imaging [ ] specify:
   - [ ] Other imaging [ ] specify:

2a. If any of the protocol required (*) visit procedures were not done provide reason:
   - Participant refusal
   - Time constraints
   - Not clinically indicated per treating physician
   - Other, specify:

Part III. General Participant Information

3. Weight [ ]:
   - [ ] lbs [ ]
   - [ ] kg

4. Height [ ]:
   - [ ] in [ ]
   - [ ] cm

5. Bra cup size (if breasts are different sizes, check larger) [ ]:
   - [ ] A
   - [ ] B
   - [ ] C
   - [ ] D
   - [ ] DD
   - [ ] E
   - [ ] Other, specify:

6. Skin color [ ]:
   - [ ] Light
   - [ ] Medium
   - [ ] Dark

Part IV. Smoking Habits

7. Has participant ever smoked? [ ]
   - [ ] No, continue to Q8
   - [ ] Yes, complete 7a-7c

7a. Age when first started smoking:
   - [ ] Unknown

7b. Packs per day:
   - [ ] Unknown

7c. Does the participant currently smoke? [ ]
   - [ ] No
   - [ ] Yes
Part V. Family Cancer History

8. Is there a family history of breast cancer? [00] O No, continue to Q9
   O Yes, complete 8a-8b

   8a. Number of relatives: ________ [31]
   8b. List 4 closest relatives: use code table

   Family member A, diagnosed at the age of: ________ [32]
   Family member B, diagnosed at the age of: ________ [35]
   Family member C, diagnosed at the age of: ________ [38]
   Family member D, diagnosed at the age of: ________ [41]

   O Yes, complete 9a-9b

   9a. Number of relatives: ________ [45]
   9b. List 4 closest relatives: use code table

   Family member A, diagnosed at the age of: ________ [46]
   Family member B, diagnosed at the age of: ________ [49]
   Family member C, diagnosed at the age of: ________ [52]
   Family member D, diagnosed at the age of: ________ [55]

Part VI. Pregnancy History

10. Number of pregnancies (including miscarriages): ________ [56] If 0, continue to Q11. If 1 or more, complete 10a-10d

   10a. Number of live births: ________ [59]
   10b. Participant age at first birth: ________ years [60]
   10c. Participant age at last birth: ________ years [61]
   10d. Did the participant ever breast-feed? [62] O No
       O Yes, Estimate total duration: _____ months [63]

Part VII. Gynecological History

11. Age at first menses: ________ years [64]
12. Cycle length (approximate): ________ days [65]
13. Regular cycle? [66] O No
    O Yes

14. Does/did participant experience breast tenderness during their period? [67] O None
    O Mild
    O Severe

15. Menopausal status: [68] O Pre
    O Peri
    O Post

Part VIII. Medication History

16. Has participant ever taken oral contraceptives? [69] O No, continue to Q17
    O Yes, complete 16a-16b

   16a. Is participant still taking the oral contraceptive? [70] O No
       O Yes

   16b. Age started on oral contraceptive: ________ years [71]

17. Has the participant ever taken hormonal agents? [72] O No, continue to Q18
    O Yes, complete 17a-17b

   17a. Is participant still taking the agent? [73] O No
       O Yes

   17b. Age started on the hormonal agent: ________ years [74]
18. Has the participant ever taken cancer prevention agents? [76]  ○ No, continue to Q19  ○ Yes, complete 18a-18b

18a. Is participant still taking the agent? [76]  ○ No  ○ Yes

18b. Age started on the agent: ______ years [77]

Part IX. Medical History

19. Has the participant ever had:  

<table>
<thead>
<tr>
<th>Condition</th>
<th>Never</th>
<th>Yes, current</th>
<th>Yes, not currently</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart Disease</td>
<td>[78]</td>
<td>O</td>
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<tr>
<td>Hypertension</td>
<td>[79]</td>
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<td>O</td>
</tr>
<tr>
<td>Stroke</td>
<td>[80]</td>
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<td>O</td>
</tr>
<tr>
<td>Diabetes (Type I or II)</td>
<td>[81]</td>
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<td>O</td>
</tr>
<tr>
<td>Breast infection</td>
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<tr>
<td>High cholesterol</td>
<td>[83]</td>
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<tr>
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<td>Thyroid/ other metabolic</td>
<td>[88]</td>
<td>O</td>
<td>O</td>
</tr>
</tbody>
</table>

Part X. Surgical History

20. Has the participant ever had breast implants? [89]  ○ No, continue to Q21  ○ Yes, complete 20a-20b

20a. Type of implant: ___________________________ [80]

20b. Age at time of procedure: __________ years [91]

21. Has the participant ever had breast reduction? [92]  ○ No, continue to Q22  ○ Yes, complete 21a

21a. Age at time of procedure: __________ years [93]

22. Has the participant had a hysterectomy? [94]  ○ No, continue to Q23  ○ Yes, complete 22a

22a. Age at time of procedure: __________ years [95]

23. Has the participant had an oophorectomy? [96]  ○ No, continue to Q24  ○ Yes, complete 23a

23a. Age at time of procedure: __________ years [97]

24. Has the participant had any major surgery? [98]  ○ No, initial and date form  ○ Yes, complete 24a-24b

24a. Type of surgery: ___________________________ [99]

24b. Date of procedure: _____ - _____ - ________ [100] mm-dd-yyyy

□ Unknown [101]

---

Initials of Person(s) Completing This Form: ________________ [102]  Date Form Completed: __________ - _____ - ________ [103] mm-dd-yyyy
Part I. General Information

1. Procedure:
   - OFNA
   - Core Needle
   - Mammoforme
   - Other, specify _____________________________

2. Institution performing procedure: _____________________________

3. Date of procedure: _____ - _____ - _______  mm-dd-yyyy

4. Total number of lesions:
   - 1, complete Q5, Q6, and part II (skip pt III and IV)
   - 2, complete Q5, Q6, part II, and part III (skip part IV)
   - 3, complete Q5, Q6, part II, III, and IV
   - > 3 complete Q5, Q6, part II, III, and IV

5. Initials of Person(s) Completing This Form: ______________________

6. Date Form Completed: _____ - _____ - _______  mm-dd-yyyy
### Part II. Lesion 1 Details

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<thead>
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<th>Description</th>
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<td></td>
</tr>
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<tr>
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<tr>
<td>Distance From Nipple</td>
<td>___ ___ ____ mm ☐ Unknown</td>
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<tr>
<td>Distance From Skin (depth)</td>
<td>___ ___ ____ mm ☐ Unknown</td>
</tr>
<tr>
<td>DCIS</td>
<td>☐No ☐Yes, percentage: ____ ____ ____% ☐ Unknown</td>
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<tr>
<td>IDC</td>
<td>☐No ☐Yes, percentage: ____ ____ ____% ☐ Unknown</td>
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<tr>
<td>ILC</td>
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<tr>
<td>Inflammatory</td>
<td>☐No ☐Yes, specify _____________________</td>
</tr>
<tr>
<td>Other</td>
<td>☐No ☐Yes, specify _____________________</td>
</tr>
<tr>
<td>Bloom Richardson Score</td>
<td>03 04 05 06 07 08 09 0 Unknown</td>
</tr>
<tr>
<td>Tubules</td>
<td>01 02 03 0 Unknown</td>
</tr>
<tr>
<td>Nuclear grade</td>
<td>01 02 03 0 Unknown</td>
</tr>
<tr>
<td>Mitosis</td>
<td>01 02 03 0 Unknown</td>
</tr>
<tr>
<td>Skin Involvement</td>
<td>☐No ☐Yes 0 Unknown</td>
</tr>
<tr>
<td>Vascular Invasion</td>
<td>☐No ☐Yes 0 Unknown</td>
</tr>
<tr>
<td>Necrosis</td>
<td>☐No ☐Yes 0 Unknown</td>
</tr>
<tr>
<td>Other Notes</td>
<td>☐No ☐Yes, specify _____________________</td>
</tr>
<tr>
<td>ER Status</td>
<td>☐negative ☐positive, %=____ ____ ____% ☐ Unknown</td>
</tr>
<tr>
<td>Threshold used to determine positivity:</td>
<td></td>
</tr>
<tr>
<td>Allred Score (0-8):</td>
<td></td>
</tr>
<tr>
<td>PR Status</td>
<td>☐negative ☐positive, %=____ ____ ____% ☐ Unknown</td>
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<tr>
<td>Threshold used to determine positivity:</td>
<td></td>
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<tr>
<td>Allred Score (0-8):</td>
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</tr>
<tr>
<td>P53 Status</td>
<td>☐negative ☐positive, %=____ ____ ____% ☐ Unknown</td>
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<tr>
<td>Threshold used to determine positivity:</td>
<td></td>
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<tr>
<td>Allred Score (0-8):</td>
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<tr>
<td>Ki-67</td>
<td>☐negative ☐positive, %=____ ____ ____% ☐ Unknown</td>
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<tr>
<td>Threshold used to determine positivity:</td>
<td></td>
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<tr>
<td>Allred Score (0-8):</td>
<td></td>
</tr>
<tr>
<td>HER2/Neu Status (IHC)</td>
<td>00 01 02 03 0 Unknown</td>
</tr>
<tr>
<td>FISH</td>
<td>0 Amplified 0 Not Amplified 0 Unknown</td>
</tr>
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### Part III. Lesion 2 Details

<table>
<thead>
<tr>
<th>Specimen Accession #</th>
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</thead>
<tbody>
<tr>
<td>Lesion #</td>
<td>____________________</td>
</tr>
<tr>
<td>Breast</td>
<td>○ Right ○ Left</td>
</tr>
<tr>
<td>Lesion Location</td>
<td>○ 12-12:30 ○ 12:30-1 ○ 1-1:30 ○ 1:30-2 ○ 2-2:30 ○ 2:30-3 ○ 3-3:30 ○ 3:30-4 ○ 4-4:30 ○ 4:30-5 ○ 5-5:30 ○ 5:30-6 ○ 6-6:30 ○ 6:30-7 ○ 7-7:30 ○ 7:30-8 ○ 8-8:30 ○ 8:30-9 ○ 9-9:30 ○ 9:30-10 ○ 10-10:30 ○ 10:30-11 ○ 11-11:30 ○ 11:30-12 ○ sub-areolar nipple ○ axillary tail</td>
</tr>
<tr>
<td>Distance From Nipple</td>
<td>____________ mm ○ Unknown</td>
</tr>
<tr>
<td>Distance From Skin (depth)</td>
<td>____________ mm ○ Unknown</td>
</tr>
</tbody>
</table>

### Pathological Diagnosis and Grade

#### Biological Markers

| ER Status | ○ negative ○ positive, %=_________ [101] ○ Unknown |
| PR Status | ○ negative ○ positive, %=_________ [108] ○ Unknown |
| P53 Status | ○ negative ○ positive, %=_________ [115] ○ Unknown |
| Ki-67 | ○ negative ○ positive, %=_________ [120] ○ Unknown |
| HER2/Neu Status (IHC) | ○0 ○1 ○2 ○3 ○ Unknown |
| FISH | ○ Amplified ○ Not Amplified ○ Unknown |

---

*Copyright 2011*
### Part IV. Lesion 3 Details

<table>
<thead>
<tr>
<th>Specimen Accession #</th>
<th>__________________________</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesion #</td>
<td>__________________________</td>
</tr>
</tbody>
</table>

#### Lesion Location
- **Breast**
  - Right
  - Left

<table>
<thead>
<tr>
<th>Distance From Nipple</th>
<th>__ __ __ __ mm</th>
<th>Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>Distance From Skin (depth)</td>
<td>__ __ __ __ mm</td>
<td>Unknown</td>
</tr>
</tbody>
</table>

#### Histological Diagnosis
- **DCIS**
  - No
  - Yes, percentage: __ __ __ __% (Unknown)

- **IDC**
  - No
  - Yes, percentage: __ __ __ __% (Unknown)

- **ILC**
  - No
  - Yes, percentage: __ __ __ __% (Unknown)

- **Inflammatory**
  - No
  - Yes, percentage: __ __ __ __% (Unknown)

- **Other**
  - No
  - Yes, specify _____________________ percentage: __ __ __ __% (Unknown)

#### Pathological Diagnosis and Grade
- **Bloom Richardson Score**
  - 0
  - 1
  - 2
  - 3
  - 4
  - 5
  - 6
  - 7
  - 8
  - 9
  - Unknown

- **Tubules**
  - 0
  - 1
  - 2
  - 3
  - Unknown

- **Nuclear grade**
  - 0
  - 1
  - 2
  - 3
  - Unknown

- **Mitosis**
  - 0
  - 1
  - 2
  - 3
  - Unknown

- **Skin Involvement**
  - No
  - Yes
  - Unknown

- **Lymphatic Invasion**
  - No
  - Yes
  - Unknown

- **Vascular Invasion**
  - No
  - Yes
  - Unknown

- **Necrosis**
  - No
  - Yes
  - Unknown

- **Other Notes**
  - No
  - Yes, specify ______________________

#### Biological Markers
- **ER Status**
  - Negative
  - Positive, % = __ __ __ __% (Unknown)
  - Threshold used to determine positivity: __ __ __ __% (Unknown)
  - Allred Score (0-8): __ __ __ __% (Unknown)

- **PR Status**
  - Negative
  - Positive, % = __ __ __ __% (Unknown)
  - Threshold used to determine positivity: __ __ __ __% (Unknown)
  - Allred Score (0-8): __ __ __ __% (Unknown)

- **P53 Status**
  - Negative
  - Positive, % = __ __ __ __% (Unknown)
  - Threshold used to determine positivity: __ __ __ __% (Unknown)

- **Ki-67**
  - Negative
  - Positive, % = __ __ __ __% (Unknown)
  - Threshold used to determine positivity: __ __ __ __% (Unknown)

- **HER2/Neu Status (IHC)**
  - 0
  - 1
  - 2
  - 3
  - Unknown

- **FISH**
  - Amplified
  - Not Amplified
  - Unknown
ACRIN 6691
Monitoring and Predicting Breast Cancer Response Using Using DOSI
SOC Mammogram Local Interpretation

If this is a revised or corrected form, please ✔ box.

**Part I. Imaging Visit Details**

1. Institution where imaging occurred: ____________________________ [1]

2. Date of Imaging: [2] ______-____-______ (mm-dd-yyyy)

3. Date of Interpretation: [3] ______-____-______ (mm-dd-yyyy)


5. Clinically relevant mass(es) identified? [5]  
   [O] No  
   [O] Yes, total number ______________________ [6]

6. Clinically relevant lesion(s) identified? [7]  
   [O] No, initial and date form  
   [O] Yes, continue to Q7

7. Total number of clinically relevant lesions: [8]  
   [O] 1, complete Part II then initial and date form  
   [O] 2, complete Parts II and III, then initial and date form  
   [O] 3, complete Parts II-IV, then initial and date form  
   [O] >3, complete Parts II-IV, then initial and date form

**Part II. Lesion 1 Description**

<table>
<thead>
<tr>
<th>Study Breast [9]</th>
<th>O Right</th>
<th>O Left</th>
</tr>
</thead>
<tbody>
<tr>
<td>Size of the Lesion</td>
<td>x = ______ mm medial-lateral [12]</td>
<td></td>
</tr>
<tr>
<td></td>
<td>y = ______ mm superior-inferior [13]</td>
<td></td>
</tr>
<tr>
<td></td>
<td>z = ______ mm anterior-posterior [14]</td>
<td></td>
</tr>
<tr>
<td>Lesion Max Dimension [15]</td>
<td>______ m m</td>
<td></td>
</tr>
<tr>
<td>Distance from nipple [16]</td>
<td>______ m m □ Unknown [43]</td>
<td></td>
</tr>
<tr>
<td>Distance from skin [17]</td>
<td>______ m m □ Unknown [44]</td>
<td></td>
</tr>
<tr>
<td>Location [18]</td>
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</tbody>
</table>

"Copyright 2012"
Part III. Lesion 2 Description

<table>
<thead>
<tr>
<th>Study Breast</th>
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</thead>
<tbody>
<tr>
<td>Size of the Lesion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>x = _______ mm medial-lateral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>y = _______ mm superior-inferior</td>
<td></td>
<td></td>
</tr>
<tr>
<td>z = _______ mm anterior-posterior</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lesion Max Dimension</td>
<td></td>
<td></td>
</tr>
<tr>
<td>_______ mm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Distance from nipple</td>
<td></td>
<td></td>
</tr>
<tr>
<td>_______ mm</td>
<td>Unknown</td>
<td></td>
</tr>
<tr>
<td>Distance from skin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>_______ mm</td>
<td>Unknown</td>
<td></td>
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</tbody>
</table>

Location

Part IV. Lesion 3 Description

<table>
<thead>
<tr>
<th>Study Breast</th>
<th>O Right</th>
<th>O Left</th>
</tr>
</thead>
<tbody>
<tr>
<td>Size of the Lesion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>x = _______ mm medial-lateral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>y = _______ mm superior-inferior</td>
<td></td>
<td></td>
</tr>
<tr>
<td>z = _______ mm anterior-posterior</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lesion Max Dimension</td>
<td></td>
<td></td>
</tr>
<tr>
<td>_______ mm</td>
<td></td>
<td></td>
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<tr>
<td>Distance from nipple</td>
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<td></td>
</tr>
<tr>
<td>_______ mm</td>
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<td></td>
</tr>
<tr>
<td>Distance from skin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>_______ mm</td>
<td>Unknown</td>
<td></td>
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</tbody>
</table>

Location
Part I. Imaging Visit Details

1. Institution where imaging occurred: [1]

2. Date of Imaging: [2] - - - - (mm-dd-yyyy)

3. Date of Interpretation: [3] - - - - (mm-dd-yyyy)

4. Reader ID: [4]


   - No, initial and date form
   - Yes, continue to Q8

8. Total Number of Clinically Relevant Lesions: [12]
   - 1, complete Part II then initial and date form
   - 2, complete Parts II and III, then initial and date form
   - 3, complete Parts II-IV, then initial and date form
   - >3, complete Parts II-IV, then initial and date form

Part II. Lesion 1 Description

<table>
<thead>
<tr>
<th>Study Breast</th>
<th>[13] Right</th>
<th>Left</th>
</tr>
</thead>
</table>
| Size of the Lesion | x = ____ mm medial-lateral [16]  
   | z = ____ mm anterior-posterior [16]  
   | y = ____ mm superior-inferior [17] |
| Lesion Max Dimension [19] | ____ mm |
| Distance from nipple [20] | ____ m m [21] Unknown [77] |
| Distance from skin [21] | ____ m m [22] Unknown [78] |
| Location [22] | O Sub-areolar nipple  
   | O Axillary tail |
| T2 appearance [23] to surrounding tissue | Hyperintense  
   | Isointense  
   | Hypointense  
   | Unable to evaluate |
   | Moderate  
   | Marked |
   | Sustained  
   | Washout |
| Series and Image Number of Representative Slices list up to 3 |  
   | Series: _____  
   | Image #: _____ |
   | Series: _____  
   | Image #: _____ |
   | Series: _____  
   | Image #: _____ |
| Has this been independently biopsied? [32] | No  
   | Yes  
   | Unknown |
### Part III. Lesion 2 Description

<table>
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<tr>
<th>Study Breast</th>
<th>O Right</th>
<th>O Left</th>
</tr>
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<tbody>
<tr>
<td>Size of the Lesion</td>
<td>( x = \text{mm} ) medial-lateral</td>
<td>( z = \text{mm} ) anterior-posterior</td>
</tr>
<tr>
<td>Lesion Max Dimension</td>
<td>( y = \text{mm} ) superior-inferior</td>
<td></td>
</tr>
<tr>
<td>Distance from nipple</td>
<td>( m ) m</td>
<td>Unknown</td>
</tr>
<tr>
<td>Distance from skin</td>
<td>( m ) m</td>
<td>Unknown</td>
</tr>
<tr>
<td>Location</td>
<td></td>
<td></td>
</tr>
<tr>
<td>T2 appearance to surrounding tissue</td>
<td>O Hyperintense</td>
<td>O Isointense</td>
</tr>
<tr>
<td>O Hypointense</td>
<td>O Unable to evaluate</td>
<td></td>
</tr>
<tr>
<td>Degree of Enhancement</td>
<td>O Minimal</td>
<td>O Moderate</td>
</tr>
<tr>
<td>Enhancement Pattern</td>
<td>O Gradual</td>
<td>O Sustained</td>
</tr>
<tr>
<td>Series and Image Number of Representative Slices</td>
<td>Series:</td>
<td>Image #</td>
</tr>
<tr>
<td>list up to 3</td>
<td>Series:</td>
<td>Image #</td>
</tr>
<tr>
<td></td>
<td>Series:</td>
<td>Image #</td>
</tr>
<tr>
<td>Has this been independently biopsied?</td>
<td>O No</td>
<td>O Yes</td>
</tr>
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</table>

Continue to next page for part IV and to initial / date
### Part IV. Lesion 3 Description

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<table>
<thead>
<tr>
<th>Size of the Lesion</th>
<th>x = _______ mm medial-lateral</th>
<th>z = _______ mm anterior-posterior</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>y = _______ mm superior-inferior</td>
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<tr>
<th>Lesion Max Dimension</th>
<th>_______ mm</th>
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<table>
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<tr>
<th>Distance from nipple</th>
<th>_______ mm</th>
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</table>

<table>
<thead>
<tr>
<th>Distance from skin</th>
<th>_______ mm</th>
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<table>
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<th>O 1:30-2</th>
<th>O 2:30-3</th>
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<td>O 4:30-5</td>
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<td>O 5:30-6</td>
<td>O 6:30-7</td>
<td>O 7:30-7</td>
<td>O 8:30-8</td>
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<td>O 7:30-8</td>
<td>O 8:30-9</td>
<td>O 9:30-9</td>
<td>O 10-10:30</td>
</tr>
<tr>
<td></td>
<td>O 10:30-11</td>
<td>O 11-11:30</td>
<td>O 11:30-12</td>
<td>O Sub-areolar nipple</td>
</tr>
<tr>
<td></td>
<td>O Axillary tail</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>T2 appearance to surrounding tissue</th>
<th>O Hyperintense</th>
<th>O Isointense</th>
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<tbody>
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<td>O Hypointense</td>
<td>O Unable to evaluate</td>
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<thead>
<tr>
<th>Degree of Enhancement</th>
<th>O Minimal</th>
<th>O Moderate</th>
<th>O Marked</th>
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<table>
<thead>
<tr>
<th>Enhancement Pattern</th>
<th>O Gradual</th>
<th>O Sustained</th>
<th>O Washout</th>
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</table>

<table>
<thead>
<tr>
<th>Series and Image Number of Representative Slices list up to 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Series: _______</td>
</tr>
<tr>
<td>Series: _______</td>
</tr>
<tr>
<td>Series: _______</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Has this been independently biopsied?</th>
<th>O No</th>
<th>O Yes</th>
<th>O Unknown</th>
</tr>
</thead>
</table>

---

Initials of Person(s) Completing This Form: __________

Date form completed: __________ - __________ - __________ (mm-dd-yyyy)

"Copyright 2012"
1. Check the Protocol Deviation Being Reported: (check only one) [1]
   - Inclusion/exclusion criteria not met at time of registration
   - Imaging related deviation (complete 1a or 1b)
   - Study activity performed prior to participant signing study consent form
   - Visit procedures not performed per protocol
   - Case enrolled under expired IRB approval / FWA
   - Visit outside of time frame specified in protocol
   - Other, specify:

1a. DOSI Image Deviation: [3]
   - Scan not performed according to protocol specific guidelines
   - Images lost
   - Imaging not performed
   - Other, specify ___________________________________________ [4]

1b. SOC Image Deviation: [5]
   - Images not submitted
   - Images lost
   - Interpretation not performed
   - Other, specify ___________________________________________ [6]

2. Date the protocol deviation occurred: _____ - _____ - 20____ [7] (mm-dd-yyyy)

2a. Timepoint: [8]
   - Registration visit
   - Baseline DOSI Visit (Visit 1)
   - Early therapy DOSI Visit (Visit 2)
   - Mid therapy DOSI Visit (Visit 3)
   - Post therapy DOSI Visit (Visit 4)
   - Post surgery

3. Date the protocol deviation was discovered: _____ - _____ - 20____ [9] (mm-dd-yyyy)

4. Describe the protocol deviation:
   ____________________________________________________________ [10]

5. What was done to rectify the situation and/or prevent future occurrence:
   ____________________________________________________________ [12]

   ____________________________________________________________ [13]


   Initials of person responsible for data (RA, study staff)

   Investigator Signature

Instructions: In the instance a protocol requirement is not met, record the requested information below. Complete a separate form for each case and for each deviation. Submit this form via the ACRIN website; retain the form in the case study file.
Part I. Post-Chemotherapy Surgery

1. Most extensive primary surgery: [1]
   - Partial mastectomy/lumpectomy/excisional biopsy
   - Mastectomy, NOS

2. Date of most extensive primary surgery: [2] mm-dd-yyyy

3. Was breast conserving surgery performed? [3]
   - No, complete Q3a
   - Yes, continue to Q4

   3a. If no indicate principal reason: [4]
       - Multicentric disease
       - Patient choice / family history
       - Inflammatory disease
       - Diffuse microcalcifications
       - Institutional norm
       - Specific anatomy of primary
       - Other, specify

Part II. Pathology: Assessment of Lymph Nodes

4. Was sentinel node sampling performed? [6]
   - No
   - Yes (complete A-C)
   - Unknown

   A. Number of sentinel nodes examined: [7]
   B. Total number of positive sentinel nodes: [8]
   C. Diameter of largest positive sentinel lymph node: mm [9]

5. Was axillary dissection performed? [10]
   - No
   - Yes (complete A-C)
   - Unknown

   A. Number of lymph nodes examined: [11]
   B. Total number of positive lymph nodes: [12]
   C. Diameter of largest positive axillary lymph node: mm [13]

Part III. Pathology: Disease Staging

6. T stage, pathologic [14]
   - T0
   - T1b
   - T4
   - T4d inflammatory
   - Tis
   - T1c
   - T4a chest wall
   - TX
   - T1mic
   - T2
   - T4b skin
   - T1a
   - T3
   - T4c chest wall and skin

7. N stage, pathologic [15]
   - N0
   - N1bi
   - N2
   - N1bii
   - N3
   - N1biii
   - NX
   - N1b
   - N1biv

8. M stage, pathologic [16]
   - M0
   - M1
   - MX

9. Stage grouping [17]
   - 0
   - IIB
   - IV
   - I
   - IIIA
   - IIIB
   - IIIB

Part IV. Pathology: Assessment of Invasive Tumor

10. Clinically relevant lesions identified? [18]
    - No (initial and date form)
    - Yes (complete A)

    A. Total number of lesions identified: [19]
       - 1, complete Part V, then initial and date form
       - 2, complete Parts V and VI, then initial and date form
       - 3, complete Parts V-VII, then initial and date form
       - >3, complete Parts V-VII, then initial and date form
### Part V. Lesion 1 Details

<table>
<thead>
<tr>
<th>Description</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specimen Accession #</td>
<td>[20]</td>
</tr>
<tr>
<td>Lesion #</td>
<td>[21]</td>
</tr>
<tr>
<td>Breast</td>
<td>[22] O Right O Left</td>
</tr>
<tr>
<td>Lesion Location</td>
<td>[23] O 12:30-12:30:30 O 12:30-1:30 O 1:30-2 O 2:30-2:30 O 2:30-3 O 3:30-4 O 3:30-6 O 4:30-4 O 4:30-5 O 5:30-6 O 6:30-7 O 7:30-7 O 7:30-8 O 8:30-9 O 9:30-10 O 10:30-10:30 O 10:30-11 O 11:30 O 11:30-12 O sub-areolar O axillary tail</td>
</tr>
<tr>
<td>Distance from nipple</td>
<td>[24]</td>
</tr>
<tr>
<td>Distance from skin</td>
<td>[25]</td>
</tr>
<tr>
<td>DCIS present</td>
<td>[26] O No, skip to assessment of invasive tumor O Yes O Unknown</td>
</tr>
<tr>
<td>DCIS present with invasive cancer</td>
<td>[27] O No O Yes O Unknown</td>
</tr>
<tr>
<td>Pathologic primary tumor size, if pure DCIS</td>
<td>[28]</td>
</tr>
<tr>
<td>Histologic Type</td>
<td>[29] Check all that apply: O Comedo O Solid O Cribriform O Micropapillary O Other, specify</td>
</tr>
<tr>
<td>Residual invasive carcinoma?</td>
<td>[41] O No, skip to biologic markers O Yes O Unknown</td>
</tr>
<tr>
<td>Max Invasive Tumor Dimension</td>
<td>[42]</td>
</tr>
<tr>
<td>Max Invasive Tumor Dimension, Microscopic</td>
<td>[43]</td>
</tr>
<tr>
<td>Histologic type</td>
<td>[44] O Ductal carcinoma O Mixed ductal / lobular carcinoma O Lobular carcinoma O Other, specify</td>
</tr>
<tr>
<td>Nuclear grade (mark highest grade)</td>
<td>[45] O Grade I (low) O Grade II (intermediate) O Grade III (high)</td>
</tr>
<tr>
<td>Mitotic count</td>
<td>[46] O 1 O 2 O 3 O Indeterminate O Unknown</td>
</tr>
<tr>
<td>Architecture (tubule formation)</td>
<td>[47] O 1 O 2 O 3 O Indeterminate O Unknown</td>
</tr>
<tr>
<td>Combined histologic grade-according to SBR / Elston classification</td>
<td>[48] O Grade I (low) O Grade II (intermediate) O Grade III (high)</td>
</tr>
<tr>
<td>PR Status</td>
<td>[52] O Negative O Positive, % = [53] O Unknown Threshold used to determine positivity: O Allred Score (0-8): [54] O Unknown</td>
</tr>
<tr>
<td>P53 Status</td>
<td>[55] O Negative O Positive, % = [56] O Unknown Threshold used to determine positivity: O Allred Score (0-8): [57] O Unknown</td>
</tr>
<tr>
<td>Ki-67</td>
<td>[58] O Negative O Positive, % = [59] O Unknown Threshold used to determine positivity:</td>
</tr>
<tr>
<td>HER2/Neu Status (IHC)</td>
<td>[60] O 0 O 1 O 2 O 3 O Unknown</td>
</tr>
<tr>
<td>FISH</td>
<td>[61] O Amplified O Not Amplified O Unknown</td>
</tr>
</tbody>
</table>

*Copyright 2011*
### Part VI. Lesion 2 Details

<table>
<thead>
<tr>
<th>Description</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Specimen Accession #</strong></td>
<td>[78]</td>
</tr>
<tr>
<td><strong>Lesion #</strong></td>
<td>[79]</td>
</tr>
<tr>
<td><strong>Breast</strong></td>
<td>[80]</td>
</tr>
<tr>
<td><strong>Lesion Location</strong></td>
<td>[81]</td>
</tr>
<tr>
<td><strong>Distance from nipple</strong></td>
<td>[82]</td>
</tr>
<tr>
<td><strong>Distance from skin</strong></td>
<td>[83]</td>
</tr>
<tr>
<td><strong>DCIS present</strong></td>
<td>[84]</td>
</tr>
<tr>
<td><strong>DCIS present with invasive cancer</strong></td>
<td>[85]</td>
</tr>
<tr>
<td><strong>Pathologic primary tumor size, if pure DCIS</strong></td>
<td>[86]</td>
</tr>
<tr>
<td><strong>Histologic Type</strong></td>
<td>[87]</td>
</tr>
<tr>
<td><strong>Assessment of Invasive Tumor</strong></td>
<td>[88]</td>
</tr>
<tr>
<td><strong>Assessment of DCIS</strong></td>
<td>[89]</td>
</tr>
<tr>
<td><strong>Assessment of Invasive Tumor Dimension</strong></td>
<td>[90]</td>
</tr>
<tr>
<td><strong>Max Invasive Tumor Dimension</strong></td>
<td>[91]</td>
</tr>
<tr>
<td><strong>Histologic type</strong></td>
<td>[92]</td>
</tr>
<tr>
<td><strong>Nuclear grade (mark highest grade)</strong></td>
<td>[93]</td>
</tr>
<tr>
<td><strong>Mitotic count</strong></td>
<td>[94]</td>
</tr>
<tr>
<td><strong>Architecture (tubule formation)</strong></td>
<td>[95]</td>
</tr>
<tr>
<td><strong>Combined histologic grade-according to SBR / Elston classification</strong></td>
<td>[96]</td>
</tr>
<tr>
<td><strong>ER Status</strong></td>
<td>[97]</td>
</tr>
<tr>
<td><strong>PR Status</strong></td>
<td>[98]</td>
</tr>
<tr>
<td><strong>P53 Status</strong></td>
<td>[99]</td>
</tr>
<tr>
<td><strong>Ki-67</strong></td>
<td>[100]</td>
</tr>
<tr>
<td><strong>HER2/Neu Status (IHC)</strong></td>
<td>[101]</td>
</tr>
<tr>
<td><strong>FISH</strong></td>
<td>[102]</td>
</tr>
</tbody>
</table>

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Part VII. Lesion 3 Details

Specimen Accession # [136]  
Lesion # [137]  

Breast [136]  
Lesion Location [139]  
O Right  O Left  
O 12:12:30 O 12:30-1 O 1-1:30 O 1:30-2 O 2-2:30  
O 2:30-3 O 3:30-4 O 4:4:30 O 4:30-5  
O 5:5:30 O 6:6:30 O 7:30-8 O 8:30-9 O 9:30-10  
O 10:10:30 O 10:30-11 O 11:11:30 O 11:30-12  
O sub-areolar O axillary tail

Distance from nipple [140]  
Distance from skin [141]  

DCIS present [142]  
DCIS present with invasive cancer [143]  
Pathologic primary tumor size, if pure DCIS [144]  
O No, skip to assessment of invasive tumor O Yes O Unknown  
O No O Yes O Unknown  
— — — mm O Unknown [145]

Histologic primary tumor size, if pure DCIS [144]  
O Comedo [146] O Clinging [153]  
O Solid [147] O Apocrine [154]  
O Cribriform [148] O Intra-cystic (encysted papillary) [155]  
O Micropapillary [149] O Papillary carcinoma in situ (papillary) [155]  
O Other, Specify [151] O Unknown [152]

Assessment of Invasive Tumor  
Residual invasive carcinoma? [157]  
Max Invasive Tumor Dimension [158]  
Max Invasive Tumor Dimension, Microscopic [159]  
O No, skip to biologic markers O Yes O Unknown  
O No O Yes O Unknown  
— — — mm O Unknown [156]

Histologic type [162]  
O Ductal carcinoma O Mixed ductal / lobular carcinoma  
O Lobular carcinoma O Other, specify — — — — — [163]

Nuclear grade (mark highest grade) [164]  
Mitotic count [165]  
Architecture (tubule formation) [166]  
O Grade I (low) O Grade III (high) O Grade II (intermediate)  
O Yes O Unknown  
O 1 O 2 O 3 O Indeterminate O Unknown  
O 1 O 2 O 3 O Indeterminate O Unknown

Combined histologic grade-according to SBR / Elston classification [167]  
O Grade I (low) O Grade III (high) O Grade II (intermediate)  
O Unknown

ER Status [168]  
PR Status [175]  
P53 Status [182]  
Ki-67 [187]  
HER2/Neu Status (IHC) [152]  
FISH [193]  
O Negative O Positive, % = ———— [169] O Unknown [170]  
O Unknown O Positive, % = ———— [171] O Unknown [172]  
O Negative O Positive, % = ———— [173] O Unknown [174]  
O Unknown O Positive, % = ———— [175] O Unknown [176]  
O Negative O Positive, % = ———— [177] O Unknown [178]  
O Unknown O Positive, % = ———— [179] O Unknown [180]  
O Negative O Positive, % = ———— [181] O Unknown [182]  
O Unknown O Positive, % = ———— [183] O Unknown [184]  
O Negative O Positive, % = ———— [184] O Unknown [185]  
O Unknown O Positive, % = ———— [186] O Unknown [187]  
O Negative O Positive, % = ———— [188] O Unknown [189]  
O Unknown O Positive, % = ———— [190] O Unknown [191]  
O 0 O 1 O 2 O 3 O Unknown

Initials of person completing form [194]  
Date Form Completed (mm-dd-yyyy) [195]

"Copyright 2011"
<table>
<thead>
<tr>
<th>Row #</th>
<th>Chemotherapy Agent Code</th>
<th>Start Date of Interruption mm-dd-yyyy</th>
<th>Stop Date of Interruption mm-dd-yyyy</th>
<th>Indicate the cycle this chemotherapy/dose was interrupted</th>
<th>Primary Reason for Modification</th>
<th>Type of Modification</th>
<th>Additional interruptions?</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>Code: [22] If other, specify ___________________________</td>
<td>[24] Ongoing[26]</td>
<td>O 0 2 0 3 0 4</td>
<td>Code: [28]</td>
<td>Code: [29] O No O Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Code: [32] If other, specify ___________________________</td>
<td>[34] Ongoing[36]</td>
<td>O 0 2 0 3 0 4</td>
<td>Code: [38]</td>
<td>Code: [39] O No O Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Code: [52] If other, specify ___________________________</td>
<td>[54] Ongoing[56]</td>
<td>O 0 2 0 3 0 4</td>
<td>Code: [58]</td>
<td>Code: [59] O No O Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Code: [62] If other, specify ___________________________</td>
<td>[64] Ongoing[66]</td>
<td>O 0 2 0 3 0 4</td>
<td>Code: [68]</td>
<td>Code: [69] O No O Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Code: [72] If other, specify ___________________________</td>
<td>[74] Ongoing[76]</td>
<td>O 0 2 0 3 0 4</td>
<td>Code: [78]</td>
<td>Code: [79] O No O Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Code: [82] If other, specify ___________________________</td>
<td>[84] Ongoing[86]</td>
<td>O 0 2 0 3 0 4</td>
<td>Code: [88]</td>
<td>Code: [89] O No O Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Code: [92] If other, specify ___________________________</td>
<td>[94] Ongoing[96]</td>
<td>O 0 2 0 3 0 4</td>
<td>Code: [98]</td>
<td>Code: [99] O No O Yes</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*If there are additional interruptions to report, provide on supplemental TI form*

Initials of Person(s) Completing This Form ___________________________ [101] Date form completed _______ - _______ - _______ (mm-dd-yyyy) [102]
**ACRIN Study 6691**

**Monitoring and Predicting Breast Cancer Response Using DOSI**

**Chemotherapy Treatment Plan**

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

1. Estimated early therapy range: 

   - [1] to 

   - [2] (mm-dd-yyyy) (mm-dd-yyyy)

2. Estimated mid-point therapy range: 

   - [3] to 

   - [4] (mm-dd-yyyy) (mm-dd-yyyy)

If the dose and/or regimen for an agent is different across cycles, list the drug once for each unique cycle (ex., if the dose is different for cycles 1 and 4 vs 2 and 3, list the agent twice)

<table>
<thead>
<tr>
<th>Drug Number</th>
<th>Chemotherapy Agent Codes</th>
<th>Planned Dose</th>
<th>Regimen</th>
<th>Indicate the cycle(s) this chemotherapy will be given</th>
<th>Planned Start Date</th>
<th>Planned End Date</th>
<th>Additional Treatment Rows to Record?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1= Docetaxel</td>
<td>O mg/kg [8]</td>
<td>O weekly [11]</td>
<td>[13] [16] [19]</td>
<td>[4] [14] [17] [20]</td>
<td>[21] [22]</td>
<td>O No [23]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>O mg</td>
<td>O Bi-weekly</td>
<td></td>
<td></td>
<td></td>
<td>O Yes go on to next row</td>
</tr>
<tr>
<td></td>
<td></td>
<td>O Other [10]</td>
<td>Other, specify [12]</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>2= Doxorubicin</td>
<td>O mg/kg [28]</td>
<td>O weekly [30]</td>
<td>[32] [35] [38]</td>
<td>[4] [33] [36] [39]</td>
<td>[40] [41]</td>
<td>O No [42]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>O mg</td>
<td>O Bi-weekly</td>
<td></td>
<td></td>
<td></td>
<td>O Yes go on to next row</td>
</tr>
<tr>
<td></td>
<td></td>
<td>O Other [26]</td>
<td>Other, specify [31]</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>3= Cyclophosphamide</td>
<td>O mg/kg [47]</td>
<td>O weekly [40]</td>
<td>[51] [54] [57]</td>
<td>[4] [52] [55] [58]</td>
<td>[59] [60]</td>
<td>O No [61]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>O mg</td>
<td>O Bi-weekly</td>
<td></td>
<td></td>
<td></td>
<td>O Yes go on to next row</td>
</tr>
<tr>
<td></td>
<td></td>
<td>O Other [45]</td>
<td>Other, specify [50]</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>4= Paclitaxel</td>
<td>O mg/kg [66]</td>
<td>O weekly [68]</td>
<td>[70] [73] [76]</td>
<td>[4] [71] [74] [77]</td>
<td>[78] [79]</td>
<td>O No [80]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>O mg</td>
<td>O Bi-weekly</td>
<td></td>
<td></td>
<td></td>
<td>O Yes go on to next row</td>
</tr>
<tr>
<td></td>
<td></td>
<td>O Other [64]</td>
<td>Other, specify [69]</td>
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</tr>
<tr>
<td>5</td>
<td>5= Fluorouracil</td>
<td>O mg/kg [85]</td>
<td>O weekly [87]</td>
<td>[86] [92] [95]</td>
<td>[4] [90] [93] [96]</td>
<td>[97] [98]</td>
<td>O No [99]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>O mg</td>
<td>O Bi-weekly</td>
<td></td>
<td></td>
<td></td>
<td>O Yes complete supplemental TP form</td>
</tr>
<tr>
<td></td>
<td></td>
<td>O Other [83]</td>
<td>Other, specify [88]</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Initials of Person(s) Completing This Form

Date form completed

---

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**ACRIN 6691**

**Monitoring and Predicting Breast Cancer Response Using DOSI**

**Chemotherapy Treatment**

If this is a revised or corrected form, please ✓ box.

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

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

If the dose and/or regimen for an agent is different across cycles, list drug once for each unique cycle. If the drug was given at a modified dose within a cycle, list the drug once for each unique dose given (ex., if a drug was given daily through the first cycle and the dose was reduced days 5-10 and increased days 15-20, the drug should be listed 3 times - once for each different dose given).

<table>
<thead>
<tr>
<th>Drug Number</th>
<th>Chemotherapy Agent Codes</th>
<th>Dose</th>
<th>Regimen</th>
<th>Indicate the cycle(s) this chemotherapy was given</th>
<th>Start Date</th>
<th>End Date</th>
<th>Any interruptions?</th>
<th>Additional Treatment Rows to Record?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1= Docetaxel</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>O No</td>
<td>O Yes provide details on T1 form</td>
</tr>
<tr>
<td></td>
<td>2= Doxorubicin</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>O Yes continue to next row</td>
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</tr>
<tr>
<td></td>
<td>3= Cyclophosphamide</td>
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<td></td>
<td></td>
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<td>4= Paclitaxel</td>
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<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>5= Fluorouracil</td>
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<td></td>
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<td></td>
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<td></td>
</tr>
<tr>
<td></td>
<td>6= Epirubicin</td>
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<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td></td>
<td>7= Methotrexate</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>8= Trastuzumab</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>9= Carboplatin</td>
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<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>88= Other</td>
<td></td>
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<td></td>
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<td></td>
</tr>
</tbody>
</table>

**Initials of Person (s) Completing This Form**

Date form completed.
ACRIN 6691
Monitoring and Predicting Breast Cancer Response Using Using DOSI
SOC Ultrasound Local Interpretation

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

Part I. Imaging Visit Details

1. Institution where imaging occurred: [1]

2. Date of Imaging: [2] ___________ (mm-dd-yyyy)

3. Date of Interpretation: [3] ___________ (mm-dd-yyyy)

4. Reader ID: [4]

5. Clinically Relevant Lesion(s) Identified? [5]
   - O No, initial and date form
   - O Yes, continue to Q6

6. Total Number of Clinically Relevant Lesions: [6]
   - O 1, complete Part II then initial and date form
   - O 2, complete Parts II and III, then initial and date form
   - O 3, complete Parts II-IV, then initial and date form
   - O >3, complete Parts II-IV, then initial and date form

Part II. Lesion 1 Description

Study Breast [7]
- O Right
- O Left

Doppler Characteristics [8]
- O Not applicable
- O Hypervascular
- O Hypovascular

Characterize the Lesion [9]
- O Cystic
- O Solid
- O Other, ___________ [10]
- O Unknown

Size of the Lesion
- x = _______ mm medial-lateral [11]
- y = _______ mm superior-inferior [12]
- z = _______ mm anterior-posterior [13]

Lesion Max Dimension [14]
- _______ mm

Distance from nipple [15]
- _______ mm
- O Unknown [44]

Distance from skin [16]
- _______ mm
- O Unknown [45]

Lesion Location [17]
- O 12:00-12:30
- O 12:30-1
- O 1:00-1:30
- O 1:30-2
- O 2:00-2:30
- O 2:30-3
- O 3:00-3:30
- O 3:30-4
- O 4:00-4:30
- O 4:30-5
- O 5:00-5:30
- O 5:30-6
- O 6:00-6:30
- O 6:30-7
- O 7:00-7:30
- O 7:30-8
- O 8:00-8:30
- O 8:30-9
- O 9:00-9:30
- O 9:30-10
- O 10:00-10:30
- O 10:30-11
- O 11:00-11:30
- O 11:30-12
- O Sub-areolar nipple
- O Axillary tail

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### Part III. Lesion 2 Description

<table>
<thead>
<tr>
<th>Study Breast</th>
<th>O Right</th>
<th>O Left</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doppler Characteristics</td>
<td>O Not applicable</td>
<td>O Hypervascular</td>
</tr>
<tr>
<td>Characterize the Lesion</td>
<td>O Cystic</td>
<td>O Solid</td>
</tr>
<tr>
<td>Size of the Lesion</td>
<td>x = ______ mm medial-lateral</td>
<td>y = ______ mm superior-inferior</td>
</tr>
<tr>
<td>Lesion Max Dimension</td>
<td>______ m m</td>
<td></td>
</tr>
<tr>
<td>Distance from nipple</td>
<td>______ m m</td>
<td>Unknown</td>
</tr>
<tr>
<td>Distance from skin</td>
<td>______ m m</td>
<td>Unknown</td>
</tr>
<tr>
<td>Lesion Location</td>
<td>O 12-12:30</td>
<td>O 12:30-1</td>
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<tr>
<td></td>
<td>O 2:30-3</td>
<td>O 3-3:30</td>
</tr>
<tr>
<td></td>
<td>O 5-5:30</td>
<td>O 5:30-6</td>
</tr>
<tr>
<td></td>
<td>O 7:30-8</td>
<td>O 8-8:30</td>
</tr>
<tr>
<td></td>
<td>O 10-10:30</td>
<td>O 10:30-11</td>
</tr>
<tr>
<td></td>
<td>O Sub-areolar nipple</td>
<td>O Axillary tail</td>
</tr>
</tbody>
</table>

### Part IV. Lesion 3 Description

<table>
<thead>
<tr>
<th>Study Breast</th>
<th>O Right</th>
<th>O Left</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doppler Characteristics</td>
<td>O Not applicable</td>
<td>O Hypervascular</td>
</tr>
<tr>
<td>Characterize the Lesion</td>
<td>O Cystic</td>
<td>O Solid</td>
</tr>
<tr>
<td>Size of the Lesion</td>
<td>x = ______ mm medial-lateral</td>
<td>y = ______ mm superior-inferior</td>
</tr>
<tr>
<td>Lesion Max Dimension</td>
<td>______ m m</td>
<td></td>
</tr>
<tr>
<td>Distance from nipple</td>
<td>______ m m</td>
<td>Unknown</td>
</tr>
<tr>
<td>Distance from skin</td>
<td>______ m m</td>
<td>Unknown</td>
</tr>
<tr>
<td>Lesion Location</td>
<td>O 12-12:30</td>
<td>O 12:30-1</td>
</tr>
<tr>
<td></td>
<td>O 2:30-3</td>
<td>O 3-3:30</td>
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<tr>
<td></td>
<td>O 5-5:30</td>
<td>O 5:30-6</td>
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<tr>
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<td>O 7:30-8</td>
<td>O 8-8:30</td>
</tr>
<tr>
<td></td>
<td>O 10-10:30</td>
<td>O 10:30-11</td>
</tr>
<tr>
<td></td>
<td>O Sub-areolar nipple</td>
<td>O Axillary tail</td>
</tr>
</tbody>
</table>

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Initials of Person(s) Completing This Form

Date form completed

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