ACRIN 6691

Monitoring and Predicting Breast Cancer Neoadjuvant Chemotherapy Response Using Diffuse Optical Spectroscopic Imaging (DOSI)

CRF Set

A0

ACRIN 6691

Monitoring and Predicting Breast Cancer Response Using DOSI

Registration/Eligibility Checklist

ACRIN Study 6691

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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

DEMOGRAPHICS

Instructions: The eligibility checklist (A0) must be used to determine and confirm study eligibility status. This information is submitted to ACRIN via the website: www.acrin.org. At the time of enrollment, the participant is to review, sign and date the consent.

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]

5. Participant's Initials *(last, first) (L, F)* _____ [5]

6. Verifying physician (Site PI) _____ [6]

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

11. Gender [11] O 1 Male O 2 Female

12. Participant's country of residence **(if other, complete Q12a)** [12]

O 1 United States
O 2 Canada
O 3 Other
O 9 Unknown

12a. Other country, specify (completed if Q12 is coded **"other"**) _____ [18]

13. Zip Code **(5 digit code, US residents)** _____ [13]

14. Participant's insurance status [14]

O 0 Other
O 1 Private Insurance
O 2 Medicare
O 3 Medicare and Private Insurance
O 4 Medicaid
O 5 Medicaid and Medicare
O 6 Military or Veteran's Administration
O 7 Self Pay
O 8 No means of payment
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)

18. ☐ American Indian or Alaskan Native [19]
19. ☐ Asian [20]
20. ☐ Black or African American [21]
21. ☐ Native Hawaiian or other Pacific Islander [22]
22. ☐ White [23]
23. ☐ Unknown [24]

A0

ACRIN 6691

Monitoring and Predicting Breast Cancer Response Using DOSI

Registration/Eligibility Checklist

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

ACRIN Study 6691

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

INCLUSION CRITERIA

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

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

ACRIN Study 6691

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

EXCLUSION CRITERIA

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 psychiatiatric 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

_____-_____-_____ [54]
Date Form Completed (mm-dd-yyyy)

A1

ACRIN 6691

Monitoring and Predicting Breast Cancer Response Using DOSI

Eligibility Status

ACRIN Study 6691

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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

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]

AE

ACRIN 6691

Monitoring and Predicting Breast Cancer Response Using DOSI

Adverse Event Form

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

ACRIN Study 6691

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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 _____ [1, 2]

AE Short Name (online look-up) _____ [3]

Grade [4]	**Attribution** [5]	**Expectedness** [6]	**Serious AE?** [42]	**Expedited Report Submitted** [7]	**Action Taken** (mark ☒ all that apply)	**Outcome** [9]	**Date of AE Onset and Resolution** (mm-dd-yyyy); mark ☒ the box "ongoing" if the AE is ongoing at the time of report
O Mild O Moderate O Severe O Life threatening or disabling O Fatal	O Unrelated O Unlikely O Possible O Probable O Definite	O Expected O Unexpected	O No O Yes	O No O Yes	☐ None [43] ☐ Medication therapy [44] ☐ Procedure [45] ☐ Hospitalization [46] ☐ Other [47]	O Recovered O Improved O Ongoing O Death O Unknown	Start date: ____ - ____ - ____ [10] Resolution date: ____ - ____ - ____ [11] ☐ Ongoing [12]

Comments: _____ [37], [38]

Additional AEs to report? [39]
- O No
- O Yes (Please complete an additional AE form)

Was the AE assessed, reviewed and signed by the investigator? [40]
- O No
- O Yes

____-____-____ [41]
Date form completed (mm-dd-yyyy)

_____ [50]
Investigator's initials

Investigator's signature _____ *(for external use only)*

CD

ACRIN 6691

Central Pathology Review Discrepancy Form

ACRIN Study 6691

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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.

Item # [1]	Form ID [2]	Breast [3]	Lesion # [4]	Bilateral lesion [5]	Question Description [6]	Issue [7, 8]	Notification of resolution requested [9]	Response corresponds to measured breast [10]
1	O IP O SP	O Left O Right	O 1 O 2 O 3	O No O Yes			O No O Yes	O No O Yes
2	O IP O SP	O Left O Right	O 1 O 2 O 3	O No O Yes			O No O Yes	O No O Yes
3	O IP O SP	O Left O Right	O 1 O 2 O 3	O No O Yes			O No O Yes	O No O Yes
4	O IP O SP	O Left O Right	O 1 O 2 O 3	O No O Yes			O No O Yes	O No O Yes
5	O IP O SP	O Left O Right	O 1 O 2 O 3	O No O Yes			O No O Yes	O No O Yes

CR

ACRIN 6691
Central Pathology Form

ACRIN Study 6691
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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

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]

_____ [16]
Initials of person(s) completing form

_____-_____-_____ [17]
Date form completed (mm-dd-yyyy)

DS

ACRIN 6691

Monitoring and Predicting Breast Cancer Response Using DOSI

End of Study Disposition

ACRIN Study 6691

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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

1. Provide reason for study disposition by selecting *one* of the following: [1]

- 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: _____[2]/_____[3]/_____[4] *(mm/dd/yyyy)*

  Cause of death [5]

  - O 1 Disease Progression
  - O 88 Other, specify _____[6]
- O 5 Adverse Event / Side Effects / Complications
- O 8 Study terminated by sponsor
- O 88 Other *(specify reason below)*

  Specify reason: _____[13]

2. Date of disposition: _____/_____/_____ *(mm/dd/yyyy)* [14]

3. Did the investigator review and sign off on the participant's disposition? [15]

- O 1 No
- O 2 Yes

Comments: _____[16]

_____[17]
Initials of person completing the form

_____/_____/_____[18]
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 _____

DV

ACRIN 6691

Monitoring and Predicting Breast Cancer Neoadjuvant Chemotherapy Response Using DOSI

DOSI Visit Form

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

ACRIN Study 6691

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Part I. Imaging Visit Details

1. Timepoint: [1]

- O Baseline DOSI (Visit 1)
- O Early Therapy DOSI (Visit 2)
- O Mid-therapy DOSI (Visit 3)
- O Post-therapy DOSI (Visit 4)
- O Repeat Baseline DOSI (Visit 1)
- O Repeat Early Therapy DOSI (Visit 2)
- O Repeat Mid-therapy DOSI (Visit 3)
- O Repeat Post-therapy DOSI (Visit 4)

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

3. Was imaging initiated? [3]

- O No, complete Q3a then skip to Q7
- O 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]
- ☐ Other, [9] specify: _____ [10]

4. Was imaging completed? [11]

- O No, complete Q4a
- O 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]

- O No
- O 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]

- O No
- O Yes
- O 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:

- ☐ Mammogram [20] # imaging visits: _____ [21]
- ☐ Ultrasound [22] # imaging visits: _____ [23]
- ☐ MRI [24] # imaging visits: _____ [25]
- ☐ Other imaging [26] # imaging visits: _____ [27]

  Specify type(s) of imaging:

  _____ [28]
- ☐ Unknown [29]

8. Any adverse event(s) to report? [32]

- O No
- O Yes (complete AE form)

_____ [30]

Initials of Person(s) Completing This Form

_____-_____-_____ *mm-dd-yyyy* [31]

Date Form Completed

I0

ACRIN 6691

Monitoring and Predicting Breast Cancer Using DOSI
Registration Visit
Study Procedures and Patient Information

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

ACRIN Study 6691

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Part I. Visit Details

1. Date of Visit: [1] _____ - _____ - _____ *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 particpants **Required for all female participants of childbearing potential**

☐ *Physical Exam [2]

☐ **Pregnancy Test [3], ***Date*****: _____ - _____ - _____ [4] *mm-dd-yyyy*

☐ *Medical History [5]

☐ *Clinical Test Results [6]

☐ *Pathology Report [7] *from initial biopsy*

☐ *Diagnostic Imaging reports [8]

☐ *Prognostic Imaging reports [9]

☐ *Medical Records [10]

☐ Other imaging[11], specify: _____ [12]

☐ Other [13], specify: _____ [14]

2a. If any of the protocol required (*) visit procedures were not done provide reason: [15]

O Participant refusal
O Time constraints
O Not clinically indicated per treating physician
O Other, specify: _____ [16]

Part III. General Participant Information

3. Weight [17]: _____ . _____ O lbs [18]
O kg

4. Height [19]: _____ . _____ O in [20]
O cm

5. Bra cup size (if breasts are different sizes, check larger) [21]:

O A
O B
O C
O D
O DD
O E
O Other, specify: _____ [22]

6. Skin color [23]:

O Light
O Medium
O Dark

Part IV. Smoking Habits

7. Has participant ever smoked? [24] O No, continue to Q8
O Yes, complete 7a-7c

7a. Age when first started smoking: _____ [25]
☐ Unknown [26]

7b. Packs per day: _____ [27]
☐ Unknown [28]

7c. Does the participant currently smoke? [29] O No
O Yes

Part V. Family Cancer History

8. Is there a family history of breast cancer? [30] O No, continue to Q9
O Yes, complete 8a-8b

8a. Number of relatives: _____ [31]

8b. List 4 closest relatives: *use code table*

_____ [32] **Family member A, diagnosed at the age of:** _____ [33] **years** ☐ Unknown [34]

_____ [35] **Family member B, diagnosed at the age of:** _____ [36] **years** ☐ Unknown [37]

_____ [38] **Family member C, diagnosed at the age of:** _____ [39] **years** ☐ Unknown [40]

_____ [41] **Family member D, diagnosed at the age of:** _____ [42] **years** ☐ Unknown [43]

Code table for relatives
1= Mother
2= Sister
3= Daughter
4= Maternal grandmother
5= Paternal grandmother
6= Maternal aunt
7= Paternal aunt
8= Father
88= Other

9. Family history of ovarian cancer? [44] O No, continue to 10
O Yes, complete 9a-9b

9a. Number of relatives: _____ [45]

9b. List 4 closest relatives: *use code table*

_____ [46] **Family member A, diagnosed at the age of:** _____ [47] **years** ☐ Unknown [48]

_____ [49] **Family member B, diagnosed at the age of:** _____ [50] **years** ☐ Unknown [51]

_____ [52] **Family member C, diagnosed at the age of:** _____ [53] **years** ☐ Unknown [54]

_____ [55] **Family member D, diagnosed at the age of:** _____ [56] **years** ☐ Unknown [57]

Part VI. Pregnancy History

10. Number of pregnancies (including miscarriages): _____ [58] 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
such as estrogen, progesterone, HRT, androgens 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? [75] O No, continue to Q19
such as Tamoxifen, Raloxifene O Yes, complete 18a-18b

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

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

Part IX. Medical History

19. Has the participant ever had:	Never	Yes, *current*	Yes, *not currently*
19a. Heart Disease [78]	O	O	O
19b. Hypertension [79]	O	O	O
19c. Stroke [80]	O	O	O
19d. Diabetes (Type I or II) [81]	O	O	O
19e. Breast infection [82]	O	O	O
19f. High cholesterol [83]	O	O	O
19g. Anemia [84]	O	O	O
19h. Sickle cell [85]	O	O	O
19i. Hemophilia [86]	O	O	O
19j. Blood clots [87]	O	O	O
19k. Thyroid/ other metabolic [88]	O	O	O

Part X. Surgical History

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

20a. Type of implant: _____ [90]

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

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

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

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

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

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

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

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

24a. Type of surgery: _____ [99]

24b. Date of procedure: _____ - _____ - _____ [100] *mm-dd-yyyy*
☐ Unknown [101]

_____ [102]
Initials of Person(s) Completing This Form

_____ - _____ - _____ [103] *mm-dd-yyyy*
Date Form Completed

IP

ACRIN 6691

Monitoring and Predicting Breast Cancer Response using DOSI

Initial Pathology

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

ACRIN Study 6691

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Part I. General Information

1. Procedure: [1]
- O**FNA**
- O**Core Needle**
- O**Mammotome**
- O**Other, specify** _____ [2]

2. Institution performing procedure: [3] _____

3. Date of procedure: [4] _____ - _____ - _____ *mm-dd-yyyy*

4. Total number of lesions: [5]
- O **1, complete Q5, Q6, and part II (skip pt III and IV)**
- O **2, complete Q5, Q6, part II, and part III (skip part IV)**
- O **3, complete Q5, Q6, part II, III, and IV**
- O **> 3 complete Q5, Q6, part II, III, and IV**

5. Initials of Person(s) Completing This Form: [186] _____

6. Date Form Completed: [187] _____ - _____ - _____ *mm-dd-yyyy*

IP

ACRIN 6691

Monitoring and Predicting Breast Cancer Response using DOSI

Initial Pathology

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

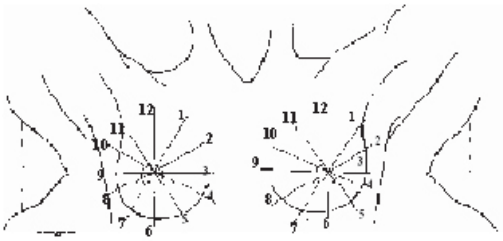
ACRIN Study 6691

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Part II. Lesion 1 Details

Description	Specimen Accession # [6]		_____
	Lesion # [7]		_____
	Breast [8]		O Right O Left
	Lesion Location [9]		 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 3-3:30 O 3:30-4 O 4-4:30 O 4:30-5 O 5-5:30 O 5:30-6 O 6-6:30 O 6:30-7 O 7-7:30 O 7:30-8 O 8-8:30 O 8:30-9 O 9-9:30 O 9:30-10 O 10-10:30 O 10:30-11 O 11-11:30 O 11:30-12 O sub-areolar nipple O axillary tail
	Distance From Nipple [10]		___ ___ ___ mm ☐ Unknown [11]
	Distance From Skin (depth) [12]		___ ___ ___ mm ☐ Unknown [13]
Pathological Diagnosis and Grade	Histological Diagnosis: DCIS [14]		O No O Yes, percentage: ___ ___ ___% [15] ☐ Unknown [16] O Unknown
	Histological Diagnosis: IDC [17]		O No O Yes, percentage: ___ ___ ___% [18] ☐ Unknown [19] O Unknown
	Histological Diagnosis: ILC [20]		O No O Yes, percentage: ___ ___ ___% [21] ☐ Unknown [22] O Unknown
	Histological Diagnosis: Inflammatory [23]		O No O Yes, percentage: ___ ___ ___% [24] ☐ Unknown [25] O Unknown
	Histological Diagnosis: Other [26]		O No O Yes, specify _____ [27] percentage: ___ ___ ___% [28] ☐ Unknown [29]
	Bloom Richardson Score [30]		O3 O4 O5 O6 O7 O8 O9 O Unknown
	Tubules [31]		O1 O2 O3 O Unknown
	Nuclear grade [32]		O1 O2 O3 O Unknown
	Mitosis [33]		O1 O2 O3 O Unknown
	Skin Involvement [34]		O No O Yes O Unknown
	Lymphatic Invasion [35]		O No O Yes O Unknown
	Vascular Invasion [36]		O No O Yes O Unknown
Biological Markers	Necrosis [37]		O No O Yes O Unknown
	Other Notes [38]		O No O Yes, specify _____ [39]
	ER Status [40]		O negative O positive, %= _____ [41] ☐ Unknown [42] O Unknown Threshold used to determine positivity: _____ [43] Allred Score (0-8): _____ [45] ☐ Unknown [46] ☐ Unknown [44]
	PR Status [47]		O negative O positive, %= _____ [48] ☐ Unknown [49] O Unknown Threshold used to determine positivity: _____ [50] Allred Score (0-8): _____ [52] ☐ Unknown [53] ☐ Unknown [51]
	P53 Status [54]		O negative O positive, %= _____ [55] ☐ Unknown [56] O Unknown Threshold used to determine positivity: _____ [57] ☐ Unknown [58]
	Ki-67 [59]		O negative O positive, %= _____ [60] ☐ Unknown [61] O Unknown Threshold used to determine positivity: _____ [62] ☐ Unknown [63]
	HER2/Neu Status (IHC) [64]		O0 O1 O2 O3 O Unknown
	FISH [65]		O Amplified O Not Amplified O Unknown

IP

ACRIN 6691

Monitoring and Predicting Breast Cancer Response using DOSI

Initial Pathology

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

ACRIN Study 6691

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Part III. Lesion 2 Details

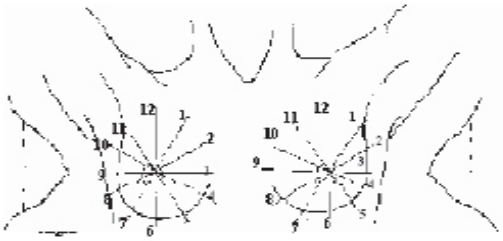
Description

Specimen Accession # [66] _____

Lesion # [67] _____

Breast [68] O**Right** O**Left**

Lesion Location [69]



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 **3-3:30** O **3:30-4** O **4-4:30** O **4:30-5**
O **5-5:30** O **5:30-6** O **6-6:30** O **6:30-7** O **7-7:30**
O **7:30-8** O **8-8:30** O **8:30-9** O **9-9:30** O **9:30-10**
O **10-10:30** O **10:30-11** O **11-11:30** O **11:30-12**
O **sub-areolar nipple** O **axillary tail**

Distance From Nipple [70] ___ ___ ___ **mm** ☐ Unknown [71]

Distance From Skin (depth) [72] ___ ___ ___ **mm** ☐ Unknown [73]

Pathological Diagnosis and Grade

Histological Diagnosis

DCIS [74] O **No** O **Yes, percentage:** ___ ___ ___**%** [75] ☐ Unknown [76] O **Unknown**

IDC [77] O **No** O **Yes, percentage:** ___ ___ ___**%** [78] ☐ Unknown [79] O **Unknown**

ILC [80] O **No** O **Yes, percentage:** ___ ___ ___**%** [81] ☐ Unknown [82] O **Unknown**

Inflammatory [83] O **No** O **Yes, percentage:** ___ ___ ___**%** [84] ☐ Unknown [85] O **Unknown**

Other [86] O **No** O **Yes, specify** _____ [87]
percentage: ___ ___ ___**%** [88] ☐ Unknown [89]

Bloom Richardson Score [90] O3 O4 O5 O6 O7 O8 O9 O Unknown

Tubules [91] O1 O2 O3 O Unknown

Nuclear grade [92] O1 O2 O3 O Unknown

Mitosis [93] O1 O2 O3 O Unknown

Skin Involvement [94] O **No** O **Yes** O Unknown

Lymphatic Invasion [95] O **No** O **Yes** O Unknown

Vascular Invasion [96] O **No** O **Yes** O Unknown

Biological Markers

Necrosis [97] O **No** O **Yes** O Unknown

Other Notes [98] O **No** O **Yes, specify** _____ [99]

ER Status [100] O **negative** O **positive, %=** _____ [101] ☐ Unknown [102] O Unknown
Threshold used to determine positivity: _____ [103]
Allred Score (0-8): _____ [105] ☐ Unknown [106] ☐ Unknown [104]

PR Status [107] O **negative** O **positive, %=** _____ [108] ☐ Unknown [109] O Unknown
Threshold used to determine positivity: _____ [110]
Allred Score (0-8): _____ [112] ☐ Unknown [113] ☐ Unknown [111]

P53 Status [114] O **negative** O **positive, %=** _____ [115] ☐ Unknown [116] O Unknown
Threshold used to determine positivity: _____ [117] ☐ Unknown [118]

Ki-67 [119] O **negative** O **positive, %=** _____ [120] ☐ Unknown [121] O Unknown
Threshold used to determine positivity: _____ [122] ☐ Unknown [123]

HER2/Neu Status (IHC) [124] O0 O1 O2 O3 O Unknown

FISH [125] O **Amplified** O **Not Amplified** O Unknown

IP

ACRIN 6691

Monitoring and Predicting Breast Cancer Response using DOSI

Initial Pathology

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

ACRIN Study 6691

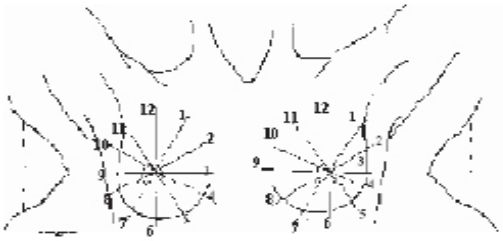
PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Part IV. Lesion 3 Details

Description

Specimen Accession # [126]	_____
Lesion # [127]	_____
Breast [128]	O**Right** O**Left**
Lesion Location [129]	 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 **3-3:30** O **3:30-4** O **4-4:30** O **4:30-5** O **5-5:30** O **5:30-6** O **6-6:30** O **6:30-7** O **7-7:30** O **7:30-8** O **8-8:30** O **8:30-9** O **9-9:30** O **9:30-10** O **10-10:30** O **10:30-11** O **11-11:30** O **11:30-12** O **sub-areolar nipple** O **axillary tail**
Distance From Nipple [130]	___ ___ ___ **mm** ☐ Unknown [131]
Distance From Skin (depth) [132]	___ ___ ___ **mm** ☐ Unknown [133]

Pathological Diagnosis and Grade

Histological Diagnosis — **DCIS** [134]	O **No** O **Yes, percentage:** ___ ___ ___**%** [135] ☐ Unknown [136] O **Unknown**
IDC [137]	O **No** O **Yes, percentage:** ___ ___ ___**%** [138] ☐ Unknown [139] O **Unknown**
ILC [140]	O **No** O **Yes, percentage:** ___ ___ ___**%** [141] ☐ Unknown [142] O **Unknown**
Inflammatory [143]	O **No** O **Yes, percentage:** ___ ___ ___**%** [144] ☐ Unknown [145] O **Unknown**
Other [146]	O **No** O **Yes, specify** _____ [147] **percentage:** ___ ___ ___**%** [148] ☐ Unknown [149]
Bloom Richardson Score [150]	O3 O4 O5 O6 O7 O8 O9 O Unknown
Tubules [151]	O1 O2 O3 O Unknown
Nuclear grade [152]	O1 O2 O3 O Unknown
Mitosis [153]	O1 O2 O3 O Unknown
Skin Involvement [154]	O **No** O **Yes** O Unknown
Lymphatic Invasion [155]	O **No** O **Yes** O Unknown
Vascular Invasion [156]	O **No** O **Yes** O Unknown

Biological Markers

Necrosis [157]	O **No** O **Yes** O Unknown
Other Notes [158]	O **No** O **Yes, specify** _____ [159]
ER Status [160]	O **negative** O **positive, %=** _____ [161] ☐ Unknown [162] O Unknown **Threshold used to determine positivity:** _____ [163] **Allred Score (0-8):** _____ [165] ☐ Unknown [166] ☐ Unknown [164]
PR Status [167]	O **negative** O **positive, %=** _____ [168] ☐ Unknown [169] O Unknown **Threshold used to determine positivity:** _____ [170] **Allred Score (0-8):** _____ [172] ☐ Unknown [173] ☐ Unknown [171]
P53 Status [174]	O **negative** O **positive, %=** _____ [175] ☐ Unknown [176] O Unknown **Threshold used to determine positivity:** _____ [177] ☐ Unknown [178]
Ki-67 [179]	O **negative** O **positive, %=** _____ [180] ☐ Unknown [181] O Unknown **Threshold used to determine positivity:** _____ [182] ☐ Unknown [183]
HER2/Neu Status (IHC) [184]	O0 O1 O2 O3 O Unknown
FISH [185]	O **Amplified** O **Not Amplified** O Unknown

MM

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. ☐

ACRIN Study **6691**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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)*

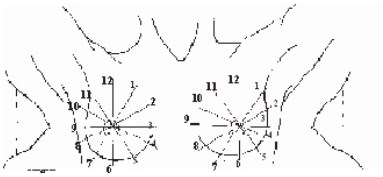
4. **Reader ID:** [4] _____

5. **Clinically relevant 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

Study Breast [9]	O Right O Left
Size of the Lesion	**x =** _____ **mm** medial-lateral [12] **y =** _____ **mm** superior-inferior [13] **z =** _____ **mm** anterior-posterior [14]
Lesion Max Dimension [15]	_____ **m m**
Distance from nipple [16]	_____ **m m** ☐ Unknown [43]
Distance from skin [17]	_____ **m m** ☐ Unknown [44]
 **Location** [18]	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 3-3:30 O 3:30-4 O 4-4:30 O 4:30-5 O 5-5:30 O 5:30-6 O 6-6:30 O 6:30-7 O 7-7:30 O 7:30-8 O 8-8:30 O 8:30-9 O 9-9:30 O 9:30-10 O 10-10:30 O 10:30-11 O 11-11:30 O 11:30-12 O Sub-areolar nipple O Axillary tail

MM

ACRIN 6691
Monitoring and Predicting Breast Cancer Response Using Using DOSI
SOC Mammogram Local Interpretation

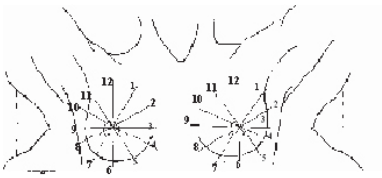
If this is a revised or corrected form, please √box. ☐

ACRIN Study **6691**
PLACE LABEL HERE

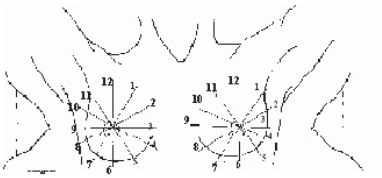
Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Part III. Lesion 2 Description

Study Breast [19]	O Right O Left
Size of the Lesion	**x =** _____ **mm** medial-lateral [22] **y =** _____ **mm** superior-inferior [23] **z =** _____ **mm** anterior-posterior [24]
Lesion Max Dimension [25]	_____ **m m**
Distance from nipple [26]	_____ **m m** ☐ Unknown [45]
Distance from skin [27]	_____ **m m** ☐ Unknown [46]
 **Location** [28]	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 3-3:30 O 3:30-4 O 4-4:30 O 4:30-5 O 5-5:30 O 5:30-6 O 6-6:30 O 6:30-7 O 7-7:30 O 7:30-8 O 8-8:30 O 8:30-9 O 9-9:30 O 9:30-10 O 10-10:30 O 10:30-11 O 11-11:30 O 11:30-12 O Sub-areolar nipple O Axillary tail

Part IV. Lesion 3 Description

Study Breast [29]	O Right O Left
Size of the Lesion	**x =** _____ **mm** medial-lateral [32] **y =** _____ **mm** superior-inferior [33] **z =** _____ **mm** anterior-posterior [34]
Lesion Max Dimension [35]	_____ **m m**
Distance from nipple [36]	_____ **m m** ☐ Unknown [47]
Distance from skin [37]	_____ **m m** ☐ Unknown [48]
 **Location** [38]	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 3-3:30 O 3:30-4 O 4-4:30 O 4:30-5 O 5-5:30 O 5:30-6 O 6-6:30 O 6:30-7 O 7-7:30 O 7:30-8 O 8-8:30 O 8:30-9 O 9-9:30 O 9:30-10 O 10-10:30 O 10:30-11 O 11-11:30 O 11:30-12 O Sub-areolar nipple O Axillary tail

_____ [39]
Initials of Person (s) Completing This Form

_____ - _____ - _____ *(mm-dd-yyyy)* [40]
Date form completed

MR

ACRIN 6691
Monitoring and Predicting Breast Cancer Response Using Using DOSI

SOC MRI Local Interpretation

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

ACRIN Study 6691
PLACE LABEL HERE

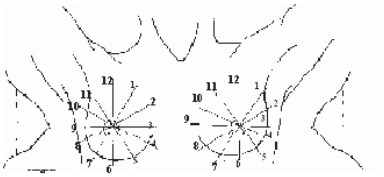
Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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. **Weight:** [5] ___ ___ ___ . ___ O lbs [6] O kg
6. **Total amount of gadolinium injected:** [8] _____ O cc [9] O other, _____ [10]
7. **Clinically Relevant Enhancing Lesion(s) Identified?** [11] O No, initial and date form O Yes, continue to Q8
8. **Total Number of Clinically Relevant Lesions:** [12] 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 [13]	O Right O Left
Size of the Lesion	**x =** _____ **mm** medial-lateral [16] **z =** _____ **mm** anterior-posterior [18] **y =** _____ **mm** superior-inferior [17]
Lesion Max Dimension [19]	_____ **mm**
Distance from nipple [20]	_____ **mm** ☐ Unknown [77]
Distance from skin [21]	_____ **mm** ☐ Unknown [78]
 **Location** [22]	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 3-3:30 O 3:30-4 O 4-4:30 O 4:30-5 O 5-5:30 O 5:30-6 O 6-6:30 O 6:30-7 O 7-7:30 O 7:30-8 O 8-8:30 O 8:30-9 O 9-9:30 O 9:30-10 O 10-10:30 O 10:30-11 O 11-11:30 O 11:30-12 O Sub-areolar nipple O Axillary tail
T2 appearance [23] ***to surrounding tissue***	O Hyperintense O Isointense O Hypointense O Unable to evaluate
Degree of Enhancement [24]	O Minimal O Moderate O Marked
Enhancement Pattern [25]	O Gradual O Sustained O Washout
Series and Image Number of Representative Slices *list up to 3*	**Series:** _____ [26] **Image #** _____ [27] **Series:** _____ [28] **Image #** _____ [29] **Series:** _____ [30] **Image #** _____ [31]
Has this been independently biopsied? [32]	O No O Yes O Unknown

MR

ACRIN 6691
Monitoring and Predicting Breast Cancer Response Using Using DOSI

SOC MRI Local Interpretation

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

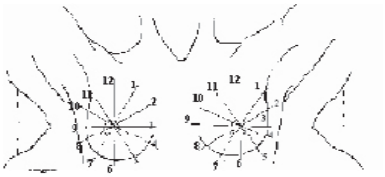
ACRIN Study **6691**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Part III. Lesion 2 Description

Study Breast [33]	O Right O Left
Size of the Lesion	**x =** _____ **mm** medial-lateral [36] **z =** _____ **mm** anterior-posterior [38] **y =** _____ **mm** superior-inferior [37]
Lesion Max Dimension [39]	_____ **mm**
Distance from nipple [40]	_____ **mm** ☐ Unknown [79]
Distance from skin [41]	_____ **mm** ☐ Unknown [80]
 **Location** [42]	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 3-3:30 O 3:30-4 O 4-4:30 O 4:30-5 O 5-5:30 O 5:30-6 O 6-6:30 O 6:30-7 O 7-7:30 O 7:30-8 O 8-8:30 O 8:30-9 O 9-9:30 O 9:30-10 O 10-10:30 O 10:30-11 O 11-11:30 O 11:30-12 O Sub-areolar nipple O Axillary tail
T2 appearance [43] ***to surrounding tissue***	O Hyperintense O Isointense O Hypointense O Unable to evaluate
Degree of Enhancement [44]	O Minimal O Moderate O Marked
Enhancement Pattern [45]	O Gradual O Sustained O Washout
Series and Image Number of Representative Slices *list up to 3*	**Series:** _____ [46] **Image #** _____ [47] **Series:** _____ [48] **Image #** _____ [49] **Series:** _____ [50] **Image #** _____ [51]
Has this been independently biopsied? [52]	O No O Yes O Unknown

Continue to next page for part IV and to initial / date

MR

ACRIN 6691
Monitoring and Predicting Breast Cancer Response Using Using DOSI

SOC MRI Local Interpretation

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

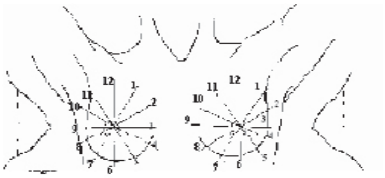
ACRIN Study **6691**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Part IV. Lesion 3 Description

Study Breast [53]	O Right O Left
Size of the Lesion	**x =** _____ **mm** medial-lateral [56] **z =** _____ **mm** anterior-posterior [58] **y =** _____ **mm** superior-inferior [57]
Lesion Max Dimension [59]	_____ **mm**
Distance from nipple [60]	_____ **mm** ☐ Unknown [81]
Distance from skin [61]	_____ **mm** ☐ Unknown [82]
 **Location** [62]	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 3-3:30 O 3:30-4 O 4-4:30 O 4:30-5 O 5-5:30 O 5:30-6 O 6-6:30 O 6:30-7 O 7-7:30 O 7:30-8 O 8-8:30 O 8:30-9 O 9-9:30 O 9:30-10 O 10-10:30 O 10:30-11 O 11-11:30 O 11:30-12 O Sub-areolar nipple O Axillary tail
T2 appearance [63] ***to surrounding tissue***	O Hyperintense O Isointense O Hypointense O Unable to evaluate
Degree of Enhancement [64]	O Minimal O Moderate O Marked
Enhancement Pattern [65]	O Gradual O Sustained O Washout
Series and Image Number of Representative Slices *list up to 3*	**Series:** _____ [66] **Image #** _____ [67] **Series:** _____ [68] **Image #** _____ [69] **Series:** _____ [70] **Image #** _____ [71]
Has this been independently biopsied? [72]	O No O Yes O Unknown

_____ [73]
Initials of Person (s) Completing This Form

_____ - _____ - _____ *(mm-dd-yyyy)* [74]
Date form completed

PR

ACRIN 6691
Monitoring and Predicting Breast Cancer Response Using Using DOSI

Protocol Variation Form

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

ACRIN Study 6691
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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.

1. Check the Protocol Deviation Being Reported: (check only one) [1]

- O Inclusion/exclusion criteria not met at time of registration
- O Imaging related deviation (complete 1a or 1b)
- O Study activity performed prior to participant signing study consent form
- O Visit procedures not performed per protocol
- O Case enrolled under expired IRB approval / FWA
- O Visit outside of time frame specified in protocol
- O Other, specify: _____ [2]

1a. DOSI Image Deviation: [3]

- O Scan not performed according to protocol specific guidelines
- O Images lost
- O Imaging not performed
- O Other, specify _____ [4]

1b. SOC Image Deviation: [5]

- O Images not submitted
- O Images lost
- O Interpretation not performed
- O Other, specify _____ [6]

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

2a. Timepoint: [8]

- O Registration visit
- O Baseline DOSI Visit (Visit 1)
- O Early therapy DOSI Visit (Visit 2)
- O Mid therapy DOSI Visit (Visit 3)
- O Post therapy DOSI Visit (Visit 4)
- O Post surgery

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

4. Describe the protocol deviation:

_____ [10]

_____ [11]

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

_____ [12]

_____ [13]

_____ [14]
Initials of person responsible for data (RA, study staff)

_____-_____-**20**_____ [15]
Date Form Completed (mm-dd-yyyy)

_____
Investigator Signature

SP

ACRIN 6691

Monitoring and Predicting Breast Cancer Response using DOSI

Surgical Pathology Form

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

ACRIN Study 6691

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Part I. Post-Chemotherapy Surgery

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

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

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

3a. If no indicate principal reason: [4]
O Multicentric disease
O Inflammatory disease
O Institutional norm
O Other, specify _____ [5]
O Patient choice / family history
O Diffuse microcalcifications
O Specific anatomy of primary

Part II. Pathology: Assessment of Lymph Nodes

4. Was sentinel node sampling performed? [6] O No O Yes (*complete A-C*) O 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] O No O Yes (*complete A-C*) O 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]
O T0 O Tis O T1mic O T1a O T1b O T1c O T2 O T3 O T4 O T4a chest wall O T4b skin O T4c chest wall and skin O T4d inflammatory O TX

7. N stage, pathologic [15]
O N0 O N1 O N1a O N1b O N1bi O N1bii O N1biii O N1biv O N2 O N3 O NX

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

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

Part IV. Pathology: Assessment of Invasive Tumor

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

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

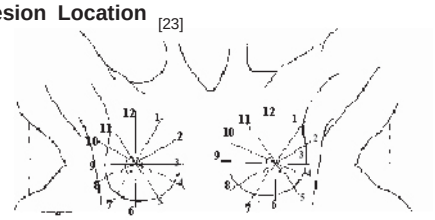
SP

ACRIN 6691
Monitoring and Predicting Breast Cancer Response using DOSI
Surgical Pathology Form

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

ACRIN Study 6691
PLACE LABEL HERE
Institution _____ **Institution No.** _____
Participant Initials _____ **Case No.** _____

Part V. Lesion 1 Details

Description	**Specimen Accession #** [20]	_____
	Lesion # [21]	_____
	Breast [22]	O Right O Left
	Lesion Location [23] 	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 3-3:30 O 3:30-4 O 4-4:30 O 4:30-5 O 5-5:30 O 5:30-6 O 6-6:30 O 6:30-7 O 7-7:30 O 7:30-8 O 8-8:30 O 8:30-9 O 9-9:30 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 [24]	___ ___ ___ mm
	Distance from skin [25]	___ ___ ___ mm
Assessment of DCIS	**DCIS present** [26]	O No, skip to assessment of invasive tumor O Yes O Unknown
	DCIS present with invasive cancer [27]	O No O Yes O Unknown
	Pathologic primary tumor size, *if pure DCIS* [28]	___ ___ ___ mm ☐ Unknown [29]
	Histologic Type *Check all that apply*	☐ Comedo [30] ☐ Clinging [37] ☐ Solid [31] ☐ Apocrine [38] ☐ Cribriform [32] ☐ Intra-cystic (encysted papillary) [39] ☐ Micropapillary [33] ☐ Papillary carcinoma in situ (papillary) [40] ☐ Other, [34] specify _____ [35] ☐ Unknown [36]
Assessment of Invasive Tumor	**Residual invasive carcinoma?** [41]	O No, skip to biologic markers O Yes O Unknown
	Max Invasive Tumor Dimension [42]	___ ___ ___ mm ☐ Unknown [43]
	Max Invasive Tumor Dimension, Microscopic [44]	___ ___ ___ mm ☐ Unknown [45]
	Histologic type [46]	O Ductal carcinoma O Mixed ductal / lobular carcinoma O Lobular carcinoma O Other, specify _____ [47] O Unknown
	Nuclear grade (mark highest grade) [48]	O Grade I (low) O Grade III (high) O Grade II (intermediate) O Unknown
	Mitotic count [49]	O 1 O 2 O 3 O Indeterminate O Unknown
	Architecture (tubule formation) [50]	O 1 O 2 O 3 O Indeterminate O Unknown
	Combined histologic grade-according to SBR / Elston classification [51]	O Grade I (low) O Grade III (high) O Grade II (intermediate) O Unknown
Biological Markers	**ER Status** [52]	O Negative O Positive, % = _____ [53] ☐ Unknown [54] O Unknown Threshold used to determine positivity: _____ [55] ☐ Unknown [56] Allred Score (0-8): _____ [57] ☐ Unknown [58]
	PR Status [59]	O Negative O Positive, % = _____ [60] ☐ Unknown [61] O Unknown Threshold used to determine positivity: _____ [62] ☐ Unknown [63] Allred Score (0-8): _____ [64] ☐ Unknown [65]
	P53 Status [66]	O Negative O Positive, % = _____ [67] ☐ Unknown [68] O Unknown Threshold used to determine positivity: _____ [69] ☐ Unknown [70]
	Ki-67 [71]	O Negative O Positive, % = _____ [72] ☐ Unknown [73] O Unknown Threshold used to determine positivity: _____ [74] ☐ Unknown [75]
	HER2/Neu Status (IHC) [76]	O 0 O 1 O 2 O 3 O Unknown
	FISH [77]	O Amplified O Not Amplified O Unknown

SP

ACRIN 6691
Monitoring and Predicting Breast Cancer Response using DOSI
Surgical Pathology Form

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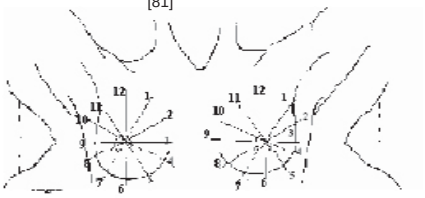
ACRIN Study 6691
PLACE LABEL HERE
Institution _____ **Institution No.** _____
Participant Initials _____ **Case No.** _____

Part VI. Lesion 2 Details

Description	**Specimen Accession #** [78]	_____
	Lesion # [79]	_____
	Breast [80]	O Right O Left
	Lesion Location [81] 	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 3-3:30 O 3:30-4 O 4-4:30 O 4:30-5 O 5-5:30 O 5:30-6 O 6-6:30 O 6:30-7 O 7-7:30 O 7:30-8 O 8-8:30 O 8:30-9 O 9-9:30 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 [82]	___ ___ ___ mm
	Distance from skin [83]	___ ___ ___ mm
Assessment of DCIS	**DCIS present** [84]	O No, skip to assessment of invasive tumor O Yes O Unknown
	DCIS present with invasive cancer [85]	O No O Yes O Unknown
	Pathologic primary tumor size, *if pure DCIS* [86]	___ ___ ___ mm ☐ Unknown [87]
	Histologic Type *Check all that apply*	☐ Comedo [88] ☐ Clinging [95] ☐ Solid [89] ☐ Apocrine [96] ☐ Cribriform [90] ☐ Intra-cystic (encysted papillary) [97] ☐ Micropapillary [91] ☐ Papillary carcinoma in situ (papillary) [98] ☐ Other, [92] specify _____ [93] ☐ Unknown [94]
Assessment of Invasive Tumor	**Residual invasive carcinoma?** [99]	O No, skip to biologic markers O Yes O Unknown
	Max Invasive Tumor Dimension [100]	___ ___ ___ mm ☐ Unknown [101]
	Max Invasive Tumor Dimension, Microscopic [102]	___ ___ ___ mm ☐ Unknown [103]
	Histologic type [104]	O Ductal carcinoma O Mixed ductal / lobular carcinoma O Lobular carcinoma O Other, specify _____ [105] O Unknown
	Nuclear grade (mark highest grade) [106]	O Grade I (low) O Grade III (high) O Grade II (intermediate) O Unknown
	Mitotic count [107]	O 1 O 2 O 3 O Indeterminate O Unknown
	Architecture (tubule formation) [108]	O 1 O 2 O 3 O Indeterminate O Unknown
	Combined histologic grade-according to SBR / Elston classification [109]	O Grade I (low) O Grade III (high) O Grade II (intermediate) O Unknown
Biological Markers	**ER Status** [110]	O Negative O Positive, % = _____ [111] ☐ Unknown [112] O Unknown Threshold used to determine positivity: _____ [113] ☐ Unknown [114] Allred Score (0-8): _____ [115] ☐ Unknown [116]
	PR Status [117]	O Negative O Positive, % = _____ [118] ☐ Unknown [119] O Unknown Threshold used to determine positivity: _____ [120] ☐ Unknown [121] Allred Score (0-8): _____ [122] ☐ Unknown [123]
	P53 Status [124]	O Negative O Positive, % = _____ [125] ☐ Unknown [126] O Unknown Threshold used to determine positivity: _____ [127] ☐ Unknown [128]
	Ki-67 [129]	O Negative O Positive, % = _____ [130] ☐ Unknown [131] O Unknown Threshold used to determine positivity: _____ [132] ☐ Unknown [133]
	HER2/Neu Status (IHC) [134]	O 0 O 1 O 2 O 3 O Unknown
	FISH [135]	O Amplified O Not Amplified O Unknown

SP

ACRIN 6691
Monitoring and Predicting Breast Cancer Response using DOSI
Surgical Pathology Form

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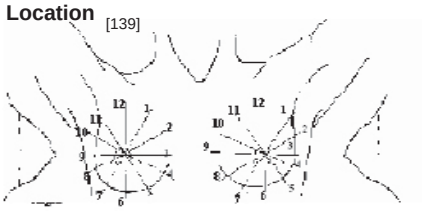
ACRIN Study 6691
PLACE LABEL HERE
Institution _____ **Institution No.** _____
Participant Initials _____ **Case No.** _____

Part VII. Lesion 3 Details

Description	**Specimen Accession #** [136]	_____
	Lesion # [137]	_____
	Breast [138]	O Right O Left
	Lesion Location [139] 	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 3-3:30 O 3:30-4 O 4-4:30 O 4:30-5 O 5-5:30 O 5:30-6 O 6-6:30 O 6:30-7 O 7-7:30 O 7:30-8 O 8-8:30 O 8:30-9 O 9-9:30 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]	___ ___ ___ mm
	Distance from skin [141]	___ ___ ___ mm
Assessment of DCIS	**DCIS present** [142]	O No, skip to assessment of invasive tumor O Yes O Unknown
	DCIS present with invasive cancer [143]	O No O Yes O Unknown
	Pathologic primary tumor size, *if pure DCIS* [144]	___ ___ ___ mm ☐ Unknown [145]
	Histologic Type *Check all that apply*	☐ Comedo [146] ☐ Clinging [153] ☐ Solid [147] ☐ Apocrine [154] ☐ Cribriform [148] ☐ Intra-cystic (encysted papillary) [155] ☐ Micropapillary [149] ☐ Papillary carcinoma in situ (papillary) [156] ☐ Other, [150] specify _____ [151] ☐ Unknown [152]
Assessment of Invasive Tumor	**Residual invasive carcinoma?** [157]	O No, skip to biologic markers O Yes O Unknown
	Max Invasive Tumor Dimension [158]	___ ___ ___ mm ☐ Unknown [159]
	Max Invasive Tumor Dimension, Microscopic [160]	___ ___ ___ mm ☐ Unknown [161]
	Histologic type [162]	O Ductal carcinoma O Mixed ductal / lobular carcinoma O Lobular carcinoma O Other, specify _____ [163] O Unknown
	Nuclear grade (mark highest grade) [164]	O Grade I (low) O Grade III (high) O Grade II (intermediate) O Unknown
	Mitotic count [165]	O 1 O 2 O 3 O Indeterminate O Unknown
	Architecture (tubule formation) [166]	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
Biological Markers	**ER Status** [168]	O Negative O Positive, % = _____ [169] ☐ Unknown [170] O Unknown Threshold used to determine positivity: _____ [171] ☐ Unknown [172] Allred Score (0-8): _____ [173] ☐ Unknown [174]
	PR Status [175]	O Negative O Positive, % = _____ [176] ☐ Unknown [177] O Unknown Threshold used to determine positivity: _____ [178] ☐ Unknown [179] Allred Score (0-8): _____ [180] ☐ Unknown [181]
	P53 Status [182]	O Negative O Positive, % = _____ [183] ☐ Unknown [184] O Unknown Threshold used to determine positivity: _____ [185] ☐ Unknown [186]
	Ki-67 [187]	O Negative O Positive, % = _____ [188] ☐ Unknown [189] O Unknown Threshold used to determine positivity: _____ [190] ☐ Unknown [191]
	HER2/Neu Status (IHC) [192]	O 0 O 1 O 2 O 3 O Unknown
	FISH [193]	O Amplified O Not Amplified O Unknown

_____ [194]
Initials of person completing form

_____-_____-_____ [195]
Date Form Completed *(mm-dd-yyyy)*

TI

ACRIN 6691

Monitoring and Predicting Breast Cancer Response Using DOSI

Treatment Interruptions

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

ACRIN Study 6691

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Row #	Chemotherapy Agent Codes 1= Docetaxel, 2= Doxorubicin, 3= Cyclophosphamide, 4= Paclitaxel, 5= Fluorouracil, 6= Epirubicin, 7= Methotrexate, 8= Trastuzumab, 9= Carboplatin, 88= Other	Start Date of Interruption *mm-dd-yyyy*	Stop Date of Interruption *mm-dd-yyyy*	Indicate the cycle this chemotherapy/dose was interrupted *Check only one*	Primary Reason for Modification 1= Toxicity, 2= Disease progression, 3= Scheduling problems, 4= Participant decision, 5= PCP decision, 6= Other complicating disease, 7= Alternative therapy, 99= Unknown	Type of Modification 1= Dose held, 2= Dose missed	Additional interruptions? *If yes, provide in next row*
[1] **1**	Code: _____ [2] *If other, specify* _____ [3]	[4] ____-____-____	[5] ____-____-____ ☐Ongoing [6]	[7] O 1 O 2 O 3 O 4 O 5 O 6 O 7 O 8	Code: _____ [8]	Code: _____ [9]	[10] O No O Yes
[11] **2**	Code: _____ [12] *If other, specify* _____ [13]	[14] ____-____-____	[15] ____-____-____ ☐Ongoing [16]	[17] O 1 O 2 O 3 O 4 O 5 O 6 O 7 O 8	Code: _____ [18]	Code: _____ [19]	[20] O No O Yes
[21] **3**	Code: _____ [22] *If other, specify* _____ [23]	[24] ____-____-____	[25] ____-____-____ ☐Ongoing [26]	[27] O 1 O 2 O 3 O 4 O 5 O 6 O 7 O 8	Code: _____ [28]	Code: _____ [29]	[30] O No O Yes
[31] **4**	Code: _____ [32] *If other, specify* _____ [33]	[34] ____-____-____	[35] ____-____-____ ☐Ongoing [36]	[37] O 1 O 2 O 3 O 4 O 5 O 6 O 7 O 8	Code: _____ [38]	Code: _____ [39]	[40] O No O Yes
[41] **5**	Code: _____ [42] *If other, specify* _____ [43]	[44] ____-____-____	[45] ____-____-____ ☐Ongoing [46]	[47] O 1 O 2 O 3 O 4 O 5 O 6 O 7 O 8	Code: _____ [48]	Code: _____ [49]	[50] O No O Yes
[51] **6**	Code: _____ [52] *If other, specify* _____ [53]	[54] ____-____-____	[55] ____-____-____ ☐Ongoing [56]	[57] O 1 O 2 O 3 O 4 O 5 O 6 O 7 O 8	Code: _____ [58]	Code: _____ [59]	[60] O No O Yes
[61] **7**	Code: _____ [62] *If other, specify* _____ [63]	[64] ____-____-____	[65] ____-____-____ ☐Ongoing [66]	[67] O 1 O 2 O 3 O 4 O 5 O 6 O 7 O 8	Code: _____ [68]	Code: _____ [69]	[70] O No O Yes
[71] **8**	Code: _____ [72] *If other, specify* _____ [73]	[74] ____-____-____	[75] ____-____-____ ☐Ongoing [76]	[77] O 1 O 2 O 3 O 4 O 5 O 6 O 7 O 8	Code: _____ [78]	Code: _____ [79]	[80] O No O Yes
[81] **9**	Code: _____ [82] *If other, specify* _____ [83]	[84] ____-____-____	[85] ____-____-____ ☐Ongoing [86]	[87] O 1 O 2 O 3 O 4 O 5 O 6 O 7 O 8	Code: _____ [88]	Code: _____ [89]	[90] O No O Yes
[91] **10**	Code: _____ [92] *If other, specify* _____ [93]	[94] ____-____-____	[95] ____-____-____ ☐Ongoing [96]	[97] O 1 O 2 O 3 O 4 O 5 O 6 O 7 O 8	Code: _____ [98]	Code: _____ [99]	[100] O No O Yes*

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]

TP

ACRIN 6691

Monitoring and Predicting Breast Cancer Response Using DOSI

Chemotherapy Treatment Plan

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

ACRIN Study 6691

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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)

Drug Number	Chemotherapy Agent Codes 1= Docetaxel 2= Doxorubicin 3= Cyclophosphamide 4= Paclitaxel 5= Fluorouracil 6= Epirubicin 7= Methotrexate 8= Trastuzumab 9= Carboplatin 88= Other	Planned Dose	Regimen	Indicate the cycle(s) this chemotherapy will be given *Check all that apply*	Planned Start Date	Planned End Date	Additional Treatment Rows to Record?
[5] **1**	Code: _____ [6] *If other, specify* _____ [7]	_____ Dose [8] O mg/kg [9] O mg O Other _____ [10]	O weekly [11] O Bi-weekly O Other, specify _____ [12]	☐ 1 [13] ☐ 4 [16] ☐ 7 [19] ☐ 2 [14] ☐ 5 [17] ☐ 8 [20] ☐ 3 [15] ☐ 6 [18]	____-____-____ (mm-dd-yyyy) [21]	____-____-____ (mm-dd-yyyy) [22]	O No [23] O Yes *go on to next row*
[24] **2**	Code: _____ [25] *If other, specify* _____ [26]	_____ Dose [27] O mg/kg [28] O mg O Other _____ [29]	O weekly [30] O Bi-weekly O Other, specify _____ [31]	☐ 1 [32] ☐ 4 [35] ☐ 7 [38] ☐ 2 [33] ☐ 5 [36] ☐ 8 [39] ☐ 3 [34] ☐ 6 [37]	____-____-____ (mm-dd-yyyy) [40]	____-____-____ (mm-dd-yyyy) [41]	O No [42] O Yes *go on to next row*
[43] **3**	Code: _____ [44] *If other, specify* _____ [45]	_____ Dose [46] O mg/kg [47] O mg O Other _____ [48]	O weekly [49] O Bi-weekly O Other, specify _____ [50]	☐ 1 [51] ☐ 4 [54] ☐ 7 [57] ☐ 2 [52] ☐ 5 [55] ☐ 8 [58] ☐ 3 [53] ☐ 6 [56]	____-____-____ (mm-dd-yyyy) [59]	____-____-____ (mm-dd-yyyy) [60]	O No [61] O Yes *go on to next row*
[62] **4**	Code: _____ [63] *If other, specify* _____ [64]	_____ Dose [65] O mg/kg [66] O mg O Other _____ [67]	O weekly [68] O Bi-weekly O Other, specify _____ [69]	☐ 1 [70] ☐ 4 [73] ☐ 7 [76] ☐ 2 [71] ☐ 5 [74] ☐ 8 [77] ☐ 3 [72] ☐ 6 [75]	____-____-____ (mm-dd-yyyy) [78]	____-____-____ (mm-dd-yyyy) [79]	O No [80] O Yes *go on to next row*
[81] **5**	Code: _____ [82] *If other, specify* _____ [83]	_____ Dose [84] O mg/kg [85] O mg O Other _____ [86]	O weekly [87] O Bi-weekly O Other, specify _____ [88]	☐ 1 [89] ☐ 4 [92] ☐ 7 [95] ☐ 2 [90] ☐ 5 [93] ☐ 8 [96] ☐ 3 [91] ☐ 6 [94]	____-____-____ (mm-dd-yyyy) [97]	____-____-____ (mm-dd-yyyy) [98]	O No [99] O Yes *complete supplemental TP form*

_____ [100]
Initials of Person (s) Completing This Form

_____ - _____ - _____ *(mm-dd-yyyy)* [101]
Date form completed

TX

ACRIN 6691

Monitoring and Predicting Breast Cancer Response Using DOSI Chemotherapy Treatment

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

ACRIN Study 6691

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

1. **Actual early therapy range:** _____-_____-_____ [1] **to** _____-_____-_____ [2]
   (mm-dd-yyyy) *(mm-dd-yyyy)*

2. **Actual 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 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).

Drug Number	Chemotherapy Agent Codes 1= Docetaxel 2= Doxorubicin 3= Cyclophosphamide 4= Paclitaxel 5= Fluorouracil 6= Epirubicin 7= Methotrexate 8= Trastuzumab 9= Carboplatin 88= Other	Dose	Regimen	Indicate the cycle(s) this chemotherapy was given *Check all that apply*	Start Date	End Date	Any interruptions?	Additional Treatment Rows to Record?
[5] **1**	Code: _____ [6] *If other, specify* _____ [7]	_____ Dose [8] O mg/kg [9] O mg O Other _____ [10]	O weekly [11] O Bi-weekly O Other, specify _____ [12]	☐ 1 [13] ☐ 4 [16] ☐ 7 [19] ☐ 2 [14] ☐ 5 [17] ☐ 8 [20] ☐ 3 [15] ☐ 6 [18]	____-____-____ *(mm-dd-yyyy)* [21]	____-____-____ *(mm-dd-yyyy)* [22]	O No [23] O Yes *provide details on T1 form*	O No [24] O Yes *continue to next row*
[25] **2**	Code: _____ [26] *If other, specify* _____ [27]	_____ Dose [28] O mg/kg [29] O mg O Other _____ [30]	O weekly [31] O Bi-weekly O Other, specify _____ [32]	☐ 1 [33] ☐ 4 [36] ☐ 7 [39] ☐ 2 [34] ☐ 5 [37] ☐ 8 [40] ☐ 3 [35] ☐ 6 [38]	____-____-____ *(mm-dd-yyyy)* [41]	____-____-____ *(mm-dd-yyyy)* [42]	O No [43] O Yes *provide details on T1 form*	O No [44] O Yes *continue to next row*
[45] **3**	Code: _____ [46] *If other, specify* _____ [47]	_____ Dose [48] O mg/kg [49] O mg O Other _____ [50]	O weekly [51] O Bi-weekly O Other, specify _____ [52]	☐ 1 [53] ☐ 4 [56] ☐ 7 [59] ☐ 2 [54] ☐ 5 [57] ☐ 8 [60] ☐ 3 [55] ☐ 6 [58]	____-____-____ *(mm-dd-yyyy)* [61]	____-____-____ *(mm-dd-yyyy)* [62]	O No [63] O Yes *provide details on T1 form*	O No [64] O Yes *continue to next row*
[65] **4**	Code: _____ [66] *If other, specify* _____ [67]	_____ Dose [68] O mg/kg [69] O mg O Other _____ [70]	O weekly [71] O Bi-weekly O Other, specify _____ [72]	☐ 1 [73] ☐ 4 [76] ☐ 7 [79] ☐ 2 [74] ☐ 5 [77] ☐ 8 [80] ☐ 3 [75] ☐ 6 [78]	____-____-____ *(mm-dd-yyyy)* [81]	____-____-____ *(mm-dd-yyyy)* [82]	O No [83] O Yes *provide details on T1 form*	O No [84] O Yes *continue to next row*
[85] **5**	Code: _____ [86] *If other, specify* _____ [87]	_____ Dose [88] O mg/kg [89] O mg O Other _____ [90]	O weekly [91] O Bi-weekly O Other, specify _____ [92]	☐ 1 [93] ☐ 4 [96] ☐ 7 [99] ☐ 2 [94] ☐ 5 [97] ☐ 8 [100] ☐ 3 [95] ☐ 6 [98]	____-____-____ *(mm-dd-yyyy)* [101]	____-____-____ *(mm-dd-yyyy)* [102]	O No [103] O Yes *provide details on T1 form*	O No [104] O Yes *complete supplemental TX form*

_____ [105]
Initials of Person (s) Completing This Form

_____ - _____ - _____ *(mm-dd-yyyy)* [106]
Date form completed

US

ACRIN 6691
Monitoring and Predicting Breast Cancer Response Using Using DOSI

SOC Ultrasound Local Interpretation

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

ACRIN Study **6691**

PLACE LABEL HERE

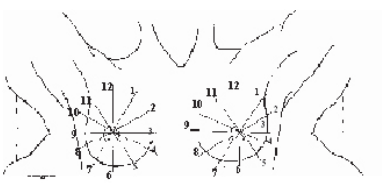
Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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]	_____ **m m**
Distance from nipple [15]	_____ **m m** ☐ Unknown [44]
Distance from skin [16]	_____ **m m** ☐ Unknown [45]
Lesion Location [17] 	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 3-3:30 O 3:30-4 O 4-4:30 O 4:30-5 O 5-5:30 O 5:30-6 O 6-6:30 O 6:30-7 O 7-7:30 O 7:30-8 O 8-8:30 O 8:30-9 O 9-9:30 O 9:30-10 O 10-10:30 O 10:30-11 O 11-11:30 O 11:30-12 O Sub-areolar nipple O Axillary tail

US

ACRIN 6691
Monitoring and Predicting Breast Cancer Response Using Using DOSI

SOC Ultrasound Local Interpretation

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

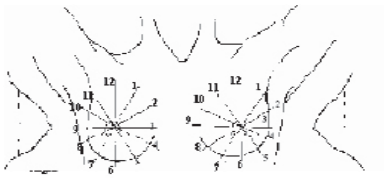
ACRIN Study **6691**

PLACE LABEL HERE

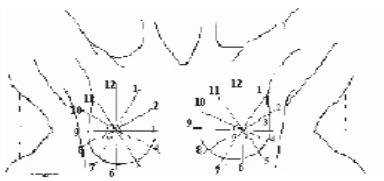
Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Part III. Lesion 2 Description

Study Breast [18]	O Right O Left
Doppler Characteristics [19]	O Not applicable O Hypervascular O Hypovascular
Characterize the Lesion [20]	O Cystic O Solid O Other, _____ [21] O Unknown
Size of the Lesion	**x =** _____ **mm** medial-lateral [22] **y =** _____ **mm** superior-inferior [23] **z =** _____ **mm** anterior-posterior [24]
Lesion Max Dimension [25]	_____ **m m**
Distance from nipple [26]	_____ **m m** ☐ Unknown [46]
Distance from skin [27]	_____ **m m** ☐ Unknown [47]
Lesion Location [28] 	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 3-3:30 O 3:30-4 O 4-4:30 O 4:30-5 O 5-5:30 O 5:30-6 O 6-6:30 O 6:30-7 O 7-7:30 O 7:30-8 O 8-8:30 O 8:30-9 O 9-9:30 O 9:30-10 O 10-10:30 O 10:30-11 O 11-11:30 O 11:30-12 O Sub-areolar nipple O Axillary tail

Part IV. Lesion 3 Description

Study Breast [29]	O Right O Left
Doppler Characteristics [30]	O Not applicable O Hypervascular O Hypovascular
Characterize the Lesion [31]	O Cystic O Solid O Other, _____ [32] O Unknown
Size of the Lesion	**x =** _____ **mm** medial-lateral [33] **y =** _____ **mm** superior-inferior [34] **z =** _____ **mm** anterior-posterior [35]
Lesion Max Dimension [36]	_____ **m m**
Distance from nipple [37]	_____ **m m** ☐ Unknown [48]
Distance from skin [38]	_____ **m m** ☐ Unknown [49]
Lesion Location [39] 	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 3-3:30 O 3:30-4 O 4-4:30 O 4:30-5 O 5-5:30 O 5:30-6 O 6-6:30 O 6:30-7 O 7-7:30 O 7:30-8 O 8-8:30 O 8:30-9 O 9-9:30 O 9:30-10 O 10-10:30 O 10:30-11 O 11-11:30 O 11:30-12 O Sub-areolar nipple O Axillary tail

_____ [40]
Initials of Person (s) Completing This Form

_____ - _____ - _____ *mm-dd-yyyy* [41]
Date form completed