Breast Project Data Elements

DEMOGRAPHICS

Data Elements	Options
1. Provider	• First/Last
2. Date of initial Radiation/Oncology consult	• mm/dd/yyyy
3. Date of Birth	• mm/yyyy
4. Gender *(Select only one)*	• Male/Female
5. Race *(Select only one)*	• American Indian/Alaska Native • Asian • Native Hawaiian or Other Pacific Islander • Black or African American • White • Arab/Middle Eastern • Unknown or not reported • Other (free text)
6. Medical Insurance *(Check all that apply)*	• No insurance/self-pay • Medicare(all) • Medicare Advantage-BCN • Medicare Advantage- BCBSM • Medicaid-Straight • Medicaid -HMO • Other Payer (government) • Other Payer (Michigan and outstate) • BCBSM-Michigan • BCN- Michigan • Commercial-HMO

7. Current Marital Status *(Select only one)*	• Married/ Domestic Partner • Divorced • Never Married • Separated • Widowed • Living with someone • Single
8. Cancer Type *(Select only one)*	• Breast Cancer • Lung Cancer

B1: Patient: Pre-Treatment Breast Cancer Questionnaire

Time points: Pre RT Evaluation

Data Elements	Options
Please rate your breast pain	
Please rate your breast pain by circling the one number that best describes your breast pain **at its worst** in the last 24 hours.	0 (No pain) To 10 (Pain as bad as you can imagine)
Please rate your breast pain by circling the one number that best describes your breast pain **at its least** in the last 24 hours	
Please rate your breast pain by circling the one number that best describes your breast pain **on the average** in the last 24 hours	
Please rate your breast pain by circling the one number that tells how much breast pain you have **right now**	

Are you using any treatments or medications for the breast to be treated with radiation (lotions, creams, medicine etc.)? If Yes, what treatments are you using? (Check all that apply)	• YES/NO • Calendula • Aquaphor • Alra • Miaderm • Biafene • Silvadene • Aloe vera gel • Corn starch • Hydrogel • Domeboro solution • Eucerin • Cocoa butter • Corticosteroids used on the skin (such as cortisone cream) • Other (agents) treatments used on the skin(specify):_____ • Oral pain medication (specify):_____ • Oral antibiotic • Other oral agent (specify):_____
Please rate the following items on this four-point scale, according to your evaluation at this point in time:	a. Breast size b. Breast texture (hardening) c. Arm heaviness d. Nipple appearance e. Shoulder movement f. Arm movement g. Breast pain h. Ability to lift objects i. Fit of shirt sleeve j. Breast tenderness k. Shoulder stiffness l. Breast shape m. Breast elevation (how high the breast is) n. Scar tissue o. Shoulder pain p. Arm pain q. Arm swelling r. Breast swelling s. Arm stiffness t. Fit of bra u. Breast sensitivity v. Fit of clothing **None** **Slight** **Moderate** **Large**

Have you ever, even once, used Cannabis?	• Prefer not to answer • No – • Yes
Think specifically about the past 30 days up to and including today. What is your best estimate of the number of days you used Cannabis during the past 30 days?	• 0 days - Proceed to question 6 • 1 or 2 days • 3 to 5 days • 6 to 9 days • 10 to 19 days • 20 to 29 days • All 30 days
During the past 30 days, which one of the following ways did you use cannabis most often? Did you usually:	• Smoke it (for example, in a joint, bong, pipe, or blunt) • Eat it (for example, in brownies, cakes, cookies, or candy) • Drink it (for example, in tea, cola, or alcohol) • Vaporize it (for example, in an e-cigarette-like vaporizer or another vaporizing device) • Dab it (for example, using waxes or concentrates) • Apply to skin (for example, using lotions or oils) • Administer rectally (for example, using suppositories). • Use it some other way (please specify:
What is the major active ingredient in the cannabis product that you use the most? (This information can often be found on the package label.)	• THC –also called tetrahydrocannabinol • CBD –also called cannabidiol • Balanced levels of THC and CBD • I don't know • Other_____

What was your bra size before surgery (please answer both number and letter, i.e.36C)?	• 30 or smaller • 32 • 34 • 36 • 38 • 40 • 42 • 44 • 46 or larger • A • B • C • D • DD • Larger than DD
What is the highest level of education you have completed?	• Grade School or less • Some College or Technical School • Some High School • Associate's Degree • High School Graduate or G.E.D. • College Graduate (Bachelor's Degree) • Graduate Degree
Which of the following best describes your race?	• American Indian/Alaska Native • Asian • Native Hawaiian or other Pacific Islander • Black or African American • White • Arab/Middle Eastern • Other (please specify) _____
Are you of Hispanic/Latino origin?	• YES/NO
Which of the following are you currently taking/receiving?	• Tamoxifen • Any other hormonal/endocrine/anti-hormonal therapy • Chemotherapy • Herceptin/Trastuzumab • None/nothing

B2:Patient: Weekly Breast Cancer Treatment Questionnaire

Time points: Weekly On-Treatment Visits

Data Elements	Options
Please rate your breast pain	
Please rate your breast pain by circling the one number that best describes your breast pain **at its worst** in the last 24 hours.	0 (No pain) To 10 (Pain as bad as you can imagine)
Please rate your breast pain by circling the one number that best describes your breast pain **at its least** in the last 24 hours	
Please rate your breast pain by circling the one number that best describes your breast pain **on the average** in the last 24 hours	
Please rate your breast pain by circling the one number that tells how much breast pain you have **right now**	
Are you using any treatments or medications for the breast to be treated with radiation (lotions, creams, medicine etc.)? If Yes, what treatments are you using? (Check all that apply)	• YES/NO • Calendula • Aquaphor • Alra • Miaderm • Biafene • Silvadene • Aloe vera gel • Corn starch • Hydrogel • Domeboro solution • Eucerin • Cocoa butter • Corticosteroids used on the skin (such as cortisone cream) • Other (agents) treatments used on the skin(specify): _____ • Oral pain medication (specify):_____ • Oral antibiotic • Other oral agent (specify):_____
During the past week, how often have you been bothered by?	
Itching of the skin of your treated breast	

Burning or stinging of the skin of your treated breast Your treated breast hurting Swelling of your treated breast Your skin reaction to radiation making it hard to work or do what you enjoy	• Never • Rarely • Sometimes • Often • All the Time
In general, during the past four weeks, how often did you: Feel significant fatigue?	• Always • Most of the time • Sometimes • Rarely • Never

B3: Breast Cancer Treatment Questionnaire: End of Treatment

Time points: Last week of treatment

Data Elements	Options
Please rate your breast pain	
Please rate your breast pain by circling the one number that best describes your breast pain **at its worst** in the last 24 hours. Please rate your breast pain by circling the one number that best describes your breast pain **at its least** in the last 24 hours Please rate your breast pain by circling the one number that best describes your breast pain **on the average** in the last 24 hours Please rate your breast pain by circling the one number that tells how much breast pain you have **right now**	0 (No pain) To 10 (Pain as bad as you can imagine)
Are you using any treatments or medications for the breast to be treated with radiation (lotions, creams, medicine etc.)? If Yes, what treatments are you using? (Check all that apply)	• YES/NO • Calendula • Domeboro solution

	• Aquaphor • Alra • Miaderm • Biafene • Silvadene • Aloe vera gel • Corn starch • Hydrogel • Eucerin • Cocoa butter • Corticosteroids used on the skin (such as cortisone cream • Other (agents) treatments used on the skin(specify): _____ • Oral pain medication (specify): _____ • Oral antibiotic • Other oral agent (specify):_____
During the past week, how often have you been bothered by?	
Itching of the skin of your treated breast	• Never • Rarely • Sometimes • Often • All the Time
Burning or stinging of the skin of your treated breast	
Your treated breast hurting	
Swelling of your treated breast	
Your skin reaction to radiation making it hard to work or do what you enjoy	
In general, during the past four weeks, how often did you	
Feel that your radiation therapy limited your daily activities?	• Always • Most of the time • Sometimes • Rarely • Never
Feel bothered by the side effects of your radiation treatment?	
Feel upset about the side effects of your radiation therapy?	
Feel that your radiation therapy was worth doing even with the side effects?	
Think about stopping your radiation therapy?	
Feel significant fatigue?	

Please rate the following items on this four-point scale, according to your evaluation at this point in time:	a. Breast size b. Breast texture (hardening) c. Arm heaviness d. Nipple appearance e. Shoulder movement f. Arm movement g. Breast pain h. Ability to lift objects i. Fit of shirt sleeve j. Breast tenderness k. Shoulder stiffness l. Breast shape m. Breast elevation (how high the breast is) n. Scar tissue o. Shoulder pain p. Arm pain q. Arm swelling r. Breast swelling s. Arm stiffness t. Fit of bra u. Breast sensitivity v. Fit of clothing **None** **Slight** **Moderate** **Large**
Overall, my radiation therapy treatments have been	• Very inconvenient • Inconvenient • Neither convenient nor inconvenient • Convenient • Very convenient
Overall, how bothered have you been by the amount of time it took to have your radiation therapy treatments?	• Very bothered • Quite bothered • Moderately bothered • A little bothered • Not bothered at all
Overall, are the side effects of radiation therapy as you expected?	• Much better than I expected • Somewhat better than I expected • Exactly as I expected • Somewhat worse than I expected • Much worse than I expected
Overall, how satisfied are you with your radiation therapy treatment?	• Very satisfied • Satisfied • Neither satisfied nor dissatisfied • Dissatisfied

	• Very Dissatisfied
Have any of your radiation oncology providers ever asked if you use cannabis? If the only mention of cannabis that you recall is from a survey form, then the answer is "No".	• Yes/No
Have you been satisfied with your radiation oncology providers' ability to answer questions about cannabis?	• I have not asked any questions about cannabis • No • Yes
Have you used cannabis, even once, since the first treatment in your course of radiation?	• Prefer not to answer • No • Yes
If you use cannabis, please check ALL of the reason(s) that you have chosen to do so.	• For pain • For nausea • For anxiety • For depression • For poor appetite • For trouble sleeping • For the high (recreational) • To fight Cancer • Other: _____
Taking everything into consideration, if given the choice again, would you decide to have radiation therapy?	• Yes, definitely • Probably yes • I don't know • Probably not • Definitely not

B4: Patient: Breast Cancer Follow-Up Questionnaire

Time points: Follow-up visits 2 weeks-3 months

Data Elements	Options
Please rate your breast pain	
Please rate your breast pain by circling the one number that best describes your breast pain **at its worst** in the last 24 hours.	0 (No pain) To 10 (Pain as bad as you can imagine)
Please rate your breast pain by circling the one number that best describes your breast pain **at its least** in the last 24 hours	
Please rate your breast pain by circling the one number that best describes your breast pain **on the average** in the last 24 hours	

Please rate your breast pain by circling the one number that tells how much breast pain you have **right now**	
Are you using any treatments or medications for the breast to be treated with radiation (lotions, creams, medicine etc.)? If Yes, what treatments are you using? (Check all that apply)	• YES/NO • Calendula • Aquaphor • Alra • Miaderm • Biafene • Silvadene • Aloe vera gel • Corn starch • Hydrogel • Domeboro solution • Eucerin • Cocoa butter • Corticosteroids used on the skin (such as cortisone cream) • Other (agents) treatments used on the skin(specify): _____ • Oral pain medication (specify): _____ • Oral antibiotic • Other oral agent (specify): _____
During the past week, how often have you been bothered by?	
Itching of the skin of your treated breast	• Never • Rarely • Sometimes • Often • All the Time
Burning or stinging of the skin of your treated breast	
Your treated breast hurting	
Swelling of your treated breast	
Your skin reaction to radiation making it hard to work or do what you enjoy	
Differences between treated and untreated breast:	
Please rate the following items on this four-point scale, according to your evaluation at this point in time:	
Breast size	
Breast texture (hardening)	
Arm heaviness	
Nipple appearance	

Shoulder movement	• None • Slight • Moderate • Large
Arm movement	
Breast pain	
Ability to lift objects	
Fit of shirt sleeve	
Breast tenderness	
Shoulder stiffness	
Breast shape	
Breast elevation (how high the breast is)	
Scar tissue	
Shoulder pain	
Arm pain	
Arm swelling	
Breast swelling	
Arm stiffness	
Fit of bra	
Breast sensitivity	
Fit of clothing	
Overall, how satisfied are you with your radiation therapy treatment?	• Very satisfied • Satisfied • Neither satisfied nor dissatisfied • Dissatisfied • Very Dissatisfied
Taking everything into consideration, if given the choice again, would you decide to have radiation therapy?	• Yes, definitely • Probably yes • I don't know • Probably not • Definitely not
In general, during the past four weeks, how often did you feel significant fatigue?	• Always • Most of the time • Sometimes • Rarely • Never

Has hormonal/endocrine/anti-hormonal therapy been prescribed for you?	• Yes • No • I chose not to take hormonal/endocrine/anti-hormonal therapy
If Yes, what has been prescribed for you:	• Tamoxifen • Aromatase Inhibitors • Other, Specify: _____
If Yes, are you still taking the hormonal/endocrine/anti-hormonal therapy?	• Yes • No

B5: Breast Cancer Baseline Clinical Data

Time points: Last week of treatment & Follow-up visit 3 months

Data Elements	Options
Weight (specify lbs or kg):	_____
BMI OR Height (specify inches or cm): ***If you do not have access to the height and weight, please ask the patient**.	_____
Breast Cancer / Pre-treatment Characteristics	
Tumor Stage: a. Pathologic stage: A value for each (T-N-M) is required. If the physician has left N and M blank, **you must verify** with the physician if the answer is unknown(X) or negative (0).	• T _____ • N_____ • M _____

Histology	• DCIS • Invasive ductal carcinoma (predominant) • Invasive lobular carcinoma (predominant) • Other (specify): _____
Tumor Grade	• Grade 1: well differentiated • Grade 2: moderately differentiated • Grade 3: poorly differentiated • Not Specified
ER Status	• Pos • Neg • Unknown
PR Status	• Pos • Neg • Unknown
Her2Neu	• Pos • Neg • Unknown
Method of determining Her2Neu	• FISH/DISH • IHC • Both • N/A • Unknown
Date of last lumpectomy or excisional biopsy	mm/dd/yyyy
Margin Status	• Pos

If close, how many mm from margin?	• Neg • Close
Axillary surgery (check all that apply)	• None • Axillary lymph node dissection • Sampling • Sentinel node bx • Other (Specify): _____
Number of total lymph nodes **taken**	_____
Number of total lymph nodes **positive**	_____
1. lymphovenous bypass: Procedure date_____(mm/dd/yyyy)	• Performed • Not Done
Current smoker?	• Yes • No • Unknown
Former smoker? (quit at least one month prior to diagnosis)	• Yes • No • Unknown
Was this patient counseled by a doctor or other healthcare worker about quitting cigarettes? (applies to current smokers only)	• Yes • No
Comorbidities: Does the patient have?	
Hypertension Diabetes mellitus Scleroderma Rheumatoid Arthritis Lupus Cerebrovascular disease Chronic pulmonary disease	• Yes • No

Congestive heart failure Connective tissue disease Confusion Hemiplegia Leukemia Malignant lymphoma Myocardial infarction Peripheral vascular disease Ulcer disease Liver disease Renal disease Malignant solid tumor (other than breast)	

B6: Breast Systemic Therapy Data

Time points: Last week of treatment & Follow-up visit 3 months

Data Elements	Options
Did the patient receive systemic therapy?	• Yes • No
If yes, how was systemic therapy administered (check all that apply)?	
Neo adjuvant therapy (prior to breast-conserving surgery (BCS)) Agents Administered (check all that apply):	• Adriamycin/Doxorubicin • Cyclophosphamide/Cytoxan • Paclitaxel/Taxol • Docetaxel/Taxotere • Methotrexate/Trexall • 5-fluorouracil/ 5-FU • Trastuzumab/Herceptin • Other (specify) _____
Concurrently with Radiation Therapy Agents Administered (check all that apply):	• Adriamycin/Doxorubicin • Cyclophosphamide/Cytoxan • Paclitaxel/Taxol • Docetaxel/Taxotere • Methotrexate/Trexall • 5-fluorouracil/5-FU • Trastuzumab/Herceptin • Other (specify) _____
Adjuvant therapy (after BCS) Agents Administered (check all that apply):	• Adriamycin/Doxorubicin • Cyclophosphamide/Cytoxan • Paclitaxel/Taxol • Docetaxel/Taxotere • Methotrexate/Trexall • 5-fluorouracil/5-FU • Trastuzumab/Herceptin

	• Other (specify) _____
Concurrently with Radiation Therapy Agents Administered (check all that apply):	• Adriamycin/Doxorubicin • Cyclophosphamide/Cytoxan • Paclitaxel/Taxol • Docetaxel/Taxotere • Methotrexate/Trexall • 5-fluorouracil/5-FU • Trastuzumab/Herceptin • Other (specify) _____
Has hormonal therapy been prescribed?	• Yes • No • Patient chose to opt out of hormonal therapy
If Yes, Agents Administered:	• Tamoxifen • Aromatase Inhibitors • Other, Specify: _____

B7: Physician: Toxicity Evaluation First Week of Treatment

Time points: Weekly On-Treatment Visits

Toxicity Scoring (CTCAE v 4.0)

		Grade				
Adverse Event	**0**	**1**	**2**	**3**	**4**	**5**
Breast						
Breast pain	none	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self-care ADL		
Lymphedema of breast	none	Trace thickening or faint discoloration	Marked discoloration; leathery skin texture; papillary formation; limiting instrumental ADL	Severe symptoms; limiting self-care ADL		
Skin Disorders						
Radiation dermatitis	none	Faint erythema or dry desquamation	Moderate to brisk erythema; patchy moist desquamation, mostly confined to skin folds and creases; moderate edema	Moist desquamation in areas other than skin folds and creases; bleeding induced by minor trauma or abrasion	Life-threatening consequences; skin necrosis or ulceration of full thickness dermis; spontaneous bleeding from involved site; skin graft indicated	Death
Pruritus	none	Mild or localized; topical intervention indicated	Intense or widespread; intermittent; skin changes from scratching (e.g., edema, population, excoriations, lichenification, oozing/crusts); oral intervention indicated; limiting instrumental ADL	Intense or widespread; constant; limiting self-care ADL or sleep; oral corticosteroid or immunosuppressive therapy indicated		
Skin induration	none	Mild induration, able to move skin parallel to plane (sliding) and perpendicular to skin (pinching up).	Moderate induration, able to slide skin, unable to pinch skin; limiting instrumental to ADL	Severe induration, unable to slide or pinch skin; limiting joint movement or orifice (e.g., mouth, anus); limiting self-care ADL	Generalized; associated with signs or symptoms or impaired breathing or feeding	Death

Musculoskeletal and connective tissue disorders						
Chest wall pain	none	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self-care ADL		
Cardiac disorders						
Pericarditis	none	Asymptomatic, ECG or physical findings (e.g., rub) consistent with pericarditis	Symptomatic pericarditis (e.g., chest pain)	Pericarditis with physiologic consequences (e.g., pericardial constriction)	Life-threatening consequences; urgent intervention indicated	Death
Pericardial effusion	none		Asymptomatic effusion size small to moderate	Effusion with physiologic consequences	Life-threatening consequences; urgent intervention indicated	Death
Respiratory, thoracic and mediastinal disorders						
Dyspnea	none	Shortness of breath with moderate exertion	Shortness of breath with minimal exertion; limiting instrumental ADL	Shortness of breath at rest; limiting self-care ADL	Life-threatening consequences; urgent intervention indicated	Death
Pleuritic pain	none	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self-careADL		
Pneumonitis	none	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; medical intervention indicated; limiting instrumental ADL	Severe symptoms; limiting self-care ADL; oxygen indicated	Life-threatening respiratory compromise; urgent intervention indicated (e.g., tracheotomy or intubation)	Death
General disorders						
Fatigue	none	Fatigue relieved by rest	Fatigue not relieved by rest; limiting instrumental ADL	Fatigue not relieved by rest, limiting self-care ADL		
ECOG Performance Status**						
*As published in Am. J. Clin. Oncol.: Oken, M.M., Creech, R.H., Tormey, D.C., Horton, J., Davis, T.E., McFadden, E.T., Carbone, P.P.: Toxicity And Response Criteria Of The Eastern Cooperative Oncology Group. Am J Clin Oncol 5:649-655, 1982.	Fully active	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature,e.g., light housework, office work	Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours	Capable of only limited self-care, confined to bed or chair more than 50% of waking hours	Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair	Dead

What was the date of the first fraction?	_____
Please rate the patient's current breast pain on a scale of 0-10	_____
Please characterize the extent of any breast erythema at present	• None • Mild • Moderate • Severe

Characterize the severity of any breast hyperpigmentation at present	• None • Mild • Moderate • Severe
Characterize the severity of any breast hypopigmentation at present	• None • Mild • Moderate • Severe
Is this patient enrolled on any breast cancer clinical trial, study, or protocol (do not include MROQC)? a. Does this study (these studies) influence your radiation dose/treatment plan, or expected toxicity for this patient?	• Yes • No • Yes • No
For patients meeting the 2018 ASTRO AWBI guidelines who are NOT receiving AWBI, please record the reason (Please check all that apply)	• N/A-patient does not meet the guideline • Patient age < 40 • Patient enrolled in a clinical trial that specifies no use of hypo fractionation • Patient preference/choice • Patient received or receiving chemotherapy • Physician preference/choice • Triple negative disease (TNBC) • Other, please specify: _____ • N/A-patient received AWBI
Is the patient receiving regional nodal irradiation? a. If **YES,** please complete the edema measurements and toxicity scoring**.**	• Yes No **Arm circumference LEFT arm, 10 cm ABOVE olecranon: _____** **Arm circumference LEFT arm, 10 cm BELOW olecranon: _____**

	Arm circumference RIGHT arm, 10 cm ABOVE olecranon: _____
	Arm circumference RIGHT arm, 10 cm BELOW olecranon: _____

		Grade				
Adverse Event	**0**	**1**	**2**	**3**	**4**	**5**
Breast						
Edema limbs	none	5 - 10% inter-limb discrepancy in volume or circumference at point of greatest visible difference; swelling or obscuration of anatomic architecture on close inspection	>10 - 30% inter-limb discrepancy in volume or circumference at point of greatest visible difference; readily apparent obscuration of anatomic architecture; obliteration of skin folds; readily apparent deviation from normal anatomic contour; limiting instrumental ADL	>30% inter-limb discrepancy in volume; gross deviation from normal anatomic contour; limiting self care ADL		
Musculoskeletal and connective tissue disorders						
Joint range of motion decreased	none	<=25% loss of ROM (range of motion); decreased ROM limiting athletic activity	>25 - 50% decrease in ROM; limiting instrumental ADL	>50% decrease in ROM; limiting self care ADL; disabling		
Fibrosis deep connective tissue/ Superficial soft tissue fibrosis	none	Mild induration, able to move skin parallel to plane (sliding) and perpendicular to skin (pinching up)	Moderate induration, able to slide skin, unable to pinch skin; limiting instrumental ADL	Severe induration; unable to slide or pinch skin; limiting joint or orifice movement (e.g. mouth, anus); limiting self care ADL	Generalized; associated with signs or symptoms of impaired breathing or feeding	Death
Nervous system disorders						
Brachial plexopathy	none	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Moderate symptoms; limiting instrumental ADL	Severe symptoms; limiting self care ADL		

B8: Physician: Toxicity Evaluation First Week of Treatment

Time points: Weekly On-Treatment Visits

Complete each week during treatment (Excluding first and last week)

Toxicity Scoring (CTCAE 4.0)

MROQC Breast Data Elements Guide

	Grade					
Adverse Event	0	1	2	3	4	5
Breast						
Breast pain	None	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self-care ADL		
Lymphedema of breast	None	Trace thickening or faint discoloration	Marked discoloration; leathery skin texture; papillary formation; limiting instrumental ADL	Severe symptoms; limiting self-care ADL		
Skin Disorders						
Radiation dermatitis	None	Faint erythema or dry desquamation	Moderate to brisk erythema; patchy moist desquamation, mostly confined to skin folds and creases; moderate edema	Moist desquamation in areas other than skin folds and creases; bleeding induced by minor trauma or abrasion	Life-threatening consequences; skin necrosis or ulceration of full thickness dermis; spontaneous bleeding from involved site; skin graft indicated	Death
Pruritus	None	Mild or localized; topical intervention indicated	Intense or widespread; intermittent; skin changes from scratching (e.g., edema, population, excoriations, lichenification, oozing/crusts); oral intervention indicated; limiting instrumental ADL	Intense or widespread; constant; limiting self-care ADL or sleep; oral corticosteroid or immunosuppressive therapy indicated		
Musculoskeletal and connective tissue disorders						
Chest wall pain	None	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self-care ADL		
General Disorders						
Fatigue	None	Fatigue relieved by rest	Fatigue not relieved by rest; limiting instrumental ADL	Fatigue not relieved by rest; limiting self-care ADL		
ECOG Performance Status*						
*As published in Am. J. Clin. Oncol.: Oken, M.M., Creech, R.H., Tormey, D.C., Horton, J., Davis, T.E., McFadden, E.T., Carbone, P.P.: Toxicity And Response Criteria Of The Eastern Cooperative Oncology Group. Am J Clin Oncol 5:649-655, 1982.	Fully active	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature,e.g., light housework, office work	Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours	Capable of only limited self-care, confined to bed or chair more than 50% of waking hours	Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair	Dead

Does the patient have MOIST desquamation?	• Yes • No
Does the patient have DRY desquamation?	• Yes • No

Characterize the severity of any breast **hyper**pigmentation at present	• None • Mild • Moderate • Severe
Characterize the severity of any breast **hypo**pigmentation at present	• None • Mild • Moderate • Severe

B9: Breast Cancer Outcomes: Last Week of Treatment

Time points: Last week of treatment

Data Elements	**Options**
Patient's Status:	
Rate patient's current breast pain on a scale of 0-1	_____
Does the patient have **MOIST** desquamation?	• Yes • No
Does the patient have **DRY** desquamation?	• Yes • No
Characterize extent of breast **erythema** at present	• None • Mild • Moderate • Severe
Characterize the severity of any breast **hyper**pigmentation at present	• None • Mild • Moderate • Severe
Characterize the severity of any breast **hypo**pigmentation at present	• None • Mild • Moderate • Severe
Please select all treatments recommended for management of acute reaction to RT within the past month:	• None • Calendula • Aquaphor • Alra • Miaderm • Biafene • Silvadene • Corn starch • Hydrogel

	• Domeboro solution • Eucerin • Cocoa butter • Topical corticosteroids • Other topical agent (specify): _____ • Oral anti-inflammatory or analgesic medication (specify): _____ • Oral antibiotic • Other oral agent (specify): _____ • Other intervention (specify): _____
How was the boost volume defined?	• No boost given • Volume defined by Ultrasound • Volume defined clinically on set • Volume defined on CT • Other, please specify: _____
If CT was used to define boost volume, the tumor bed was contoured based on: (check all that apply)	• N/A • Surgical clips • Surgical changes • Surgical clips and surgical changes • Scar • Other please specify ____
What was the date of the last fraction	_____
Did any break in treatment occur? If Yes, was it due to toxicity? Was the toxicity-related treatment break >5 days?	• Yes • No • Yes • No • Yes • No

Toxicity Scoring (CTCAE v 4.0)

		Grade				
Adverse Event	**0**	**1**	**2**	**3**	**4**	**5**
Breast						
Breast pain	none	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self-care ADL		
Lymphedema of breast	none	Trace thickening or faint discoloration	Marked discoloration; leathery skin texture; papillary formation; limiting instrumental ADL	Severe symptoms; limiting self-care ADL		
Skin Disorders						

Radiation dermatitis	none	Faint erythema or dry desquamation	Moderate to brisk erythema; patchy moist desquamation, mostly confined to skin folds and creases; moderate edema	Moist desquamation in areas other than skin folds and creases; bleeding induced by minor trauma or abrasion	Life-threatening consequences; skin necrosis or ulceration of full thickness dermis; spontaneous bleeding from involved site; skin graft indicated	Death
Pruritus	none	Mild or localized; topical intervention indicated	Intense or widespread; intermittent; skin changes from scratching (e.g., edema, population, excoriations, lichenification, oozing/crusts); oral intervention indicated; limiting instrumental ADL	Intense or widespread; constant; limiting self-care ADL or sleep; oral corticosteroid or immunosuppressive therapy indicated		
Skin induration	none	Mild induration, able to move skin parallel to plane (sliding) and perpendicular to skin (pinching up).	Moderate induration, able to slide skin, unable to pinch skin; limiting instrumental to ADL	Severe induration, unable to slide or pinch skin; limiting joint movement or orifice (e.g., mouth, anus); limiting self-care ADL	Generalized; associated with signs or symptoms or impaired breathing or feeding	Death
Musculoskeletal and connective tissue disorders						
Chest wall pain	none	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self-care ADL		
Cardiac disorders						
Pericarditis	none	Asymptomatic, ECG or physical findings (e.g., rub) consistent with pericarditis	Symptomatic pericarditis (e.g., chest pain)	Pericarditis with physiologic consequences (e.g., pericardial constriction)	Life-threatening consequences; urgent intervention indicated	Death
Pericardial effusion	none		Asymptomatic effusion size small to moderate	Effusion with physiologic consequences	Life-threatening consequences; urgent intervention indicated	Death
Respiratory, thoracic and mediastinal disorders						
Dyspnea	none	Shortness of breath with moderate exertion	Shortness of breath with minimal exertion; limiting instrumental ADL	Shortness of breath at rest; limiting self-care ADL	Life-threatening consequences; urgent intervention indicated	Death
Pleuritic pain	none		Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL		
Pneumonitis	none	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; medical intervention indicated; limiting instrumental ADL	Severe symptoms; limiting self-care ADL; oxygen indicated	Life-threatening respiratory compromise; urgent intervention indicated (e.g., tracheotomy or intubation)	Death
General disorders						
Fatigue	none	Fatigue relieved by rest	Fatigue not relieved by rest; limiting instrumental ADL	Fatigue not relieved by rest, limiting self-care ADL		
ECOG Performance Status*						
*As published in Am. J. Clin. Oncol.: Oken, M.M., Creech, R.H., Tormey, D.C., Horton, J., Davis, T.E., McFadden, E.T., Carbone, P.P.: Toxicity And Response Criteria Of The Eastern Cooperative Oncology Group. Am J Clin Oncol 5:649-655, 1982.	Fully active	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature,e.g., light housework, office work	Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours	Capable of only limited self-care, confined to bed or chair more than 50% of waking hours	Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair	Dead

Is the patient receiving regional nodal irradiation? b. If **YES,** please complete the edema measurements and toxicity scoring**.**	• Yes No **Arm circumference LEFT arm, 10 cm ABOVE olecranon: _____** **Arm circumference LEFT arm, 10 cm BELOW olecranon: _____** **Arm circumference RIGHT arm, 10 cm ABOVE olecranon: _____** **Arm circumference RIGHT arm, 10 cm BELOW olecranon: _____**

		Grade				
Adverse Event	**0**	**1**	**2**	**3**	**4**	**5**
Breast						
Edema limbs	none	5 - 10% inter-limb discrepancy in volume or circumference at point of greatest visible difference; swelling or obscuration of anatomic architecture on close inspection	>10 - 30% inter-limb discrepancy in volume or circumference at point of greatest visible difference; readily apparent obscuration of anatomic architecture; obliteration of skin folds; readily apparent deviation from normal anatomic contour; limiting instrumental ADL	>30% inter-limb discrepancy in volume; gross deviation from normal anatomic contour; limiting self care ADL		
Musculoskeletal and connective tissue disorders						
Joint range of motion decreased	none	<=25% loss of ROM (range of motion); decreased ROM limiting athletic activity	>25 - 50% decrease in ROM; limiting instrumental ADL	>50% decrease in ROM; limiting self care ADL; disabling		
Fibrosis deep connective tissue/ Superficial soft tissue fibrosis	none	Mild induration, able to move skin parallel to plane (sliding) and perpendicular to skin (pinching up)	Moderate induration, able to slide skin, unable to pinch skin; limiting instrumental ADL	Severe induration; unable to slide or pinch skin; limiting joint or orifice movement (e.g. mouth, anus); limiting self care ADL	Generalized; associated with signs or symptoms of impaired breathing or feeding	Death
Nervous system disorders						
Brachial plexopathy	none	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Moderate symptoms; limiting instrumental ADL	Severe symptoms; limiting self care ADL		

B10: Physician: Breast Cancer Clinical Outcomes Follow-up

Time points: Follow-up visit 2 weeks - 3 months

Data Elements	Options
Patient's Status:	
Rate patient's current breast pain on a scale of 0-1	_____
Does the patient have MOIST desquamation	• Yes • No
Does the patient have DRY desquamation	• Yes • No
Characterize extent of breast erythema at present	• None • Mild • Moderate • Severe
Characterize the severity of any breast hyperpigmentation at present	• None • Mild • Moderate • Severe
Characterize the severity of any breast hypopigmentation at present	• None • Mild • Moderate • Severe
Please select all treatments recommended for management of acute reaction to RT within the past month:	• None • Calendula • Aquaphor • Alra • Miaderm • Biafene • Silvadene • Corn starch • Hydrogel • Domeboro solution • Eucerin • Cocoa butter • Topical corticosteroids • Other topical agent (specify): _____ • Oral anti-inflammatory or analgesic medication (specify): _____ • Oral antibiotic • Other oral agent (specify): _____ • Other intervention (specify): _____
Toxicity Scoring (CTCAE v 4.0)	

		Grade				
Adverse Event	**0**	**1**	**2**	**3**	**4**	**5**
Breast						

Breast pain	none	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL		
Lymphedema of breast	none	Trace thickening or faint discoloration	Marked discoloration; leathery skin texture; papillary formation; limiting instrumental ADL	Severe symptoms; limiting self-care ADL		
Skin Disorders						
Radiation dermatitis	none	Faint erythema or dry desquamation	Moderate to brisk erythema; patchy moist desquamation, mostly confined to skin folds and creases; moderate edema	Moist desquamation in areas other than skin folds and creases; bleeding induced by minor trauma or abrasion	Life-threatening consequences; skin necrosis or ulceration of full thickness dermis; spontaneous bleeding from involved site; skin graft indicated	Death
Pruritus	none	Mild or localized; topical intervention indicated	Intense or widespread; intermittent; skin changes from scratching (e.g., edema, population, excoriations, lichenification, oozing/crusts); oral intervention indicated; limiting instrumental ADL	Intense or widespread; constant; limiting self care ADL or sleep; oral corticosteroid or immunosuppressive therapy indicated		
Skin induration	none	Mild induration, able to move skin parallel to plane (sliding) and perpendicular to skin (pinching up).	Moderate induration, able to slide skin, unable to pinch skin; limiting instrumental to ADL	Severe induration, unable to slide or pinch skin; limiting joint movement or orifice (e.g., mouth, anus); limiting self-care ADL	Generalized; associated with signs or symptoms or impaired breathing or feeding	Death
Musculoskeletal and connective tissue disorders						
Chest wall pain	none	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL		
Cardiac disorders						
Pericarditis	none	Asymptomatic, ECG or physical findings (e.g., rub) consistent with pericarditis	Symptomatic pericarditis (e.g., chest pain)	Pericarditis with physiologic consequences (e.g., pericardial constriction)	Life-threatening consequences; urgent intervention indicated	Death
Pericardia effusion	none		Asymptomatic effusion size small to moderate	Effusion with physiologic consequences	Life-threatening consequences; urgent intervention indicated	Death
Respiratory, thoracic and mediastinal disorders						
Dyspnea	none	Shortness of breath with moderate exertion	Shortness of breath with minimal exertion; limiting instrumental ADL	Shortness of breath at rest; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death
Pleuritic pain	none	Mild pain	Moderate pain; limiting instrumental AD	Severe pain; limiting self care ADL		
Pneumonitis	none	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; medical intervention indicated; limiting instrumental ADL	Severe symptoms; limiting self care ADL; oxygen indicated	Life-threatening respiratory compromise; urgent intervention indicated (e.g., tracheotomy or intubation)	Death
General disorders						
Fatigue	none	Fatigue relieved by rest	Fatigue not relieved by rest; limiting instrumental ADL	Fatigue not relieved by rest, limiting self care ADL		
ECOG Performance Status*						

*As published in Am. J. Clin. Oncol.: Oken, M.M., Creech, R.H., Tormey, D.C., Horton, J., Davis, T.E., McFadden, E.T., Carbone, P.P.: Toxicity And Response Criteria Of The Eastern Cooperative Oncology Group. Am J Clin Oncol 5:649-655, 1982.	Fully active	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature,e.g., light housework, office work	Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours	Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours	Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair	Dead

Is the patient receiving regional nodal irradiation?	• Yes No
c. If **YES,** please complete the edema measurements and toxicity scoring**.**	**Arm circumference LEFT arm, 10 cm ABOVE olecranon: _____**
	Arm circumference LEFT arm, 10 cm BELOW olecranon: _____
	Arm circumference RIGHT arm, 10 cm ABOVE olecranon: _____
	Arm circumference RIGHT arm, 10 cm BELOW olecranon: _____

		Grade				
Adverse Event	**0**	**1**	**2**	**3**	**4**	**5**
Breast						
Edema limbs	none	5 - 10% inter-limb discrepancy in volume or circumference at point of greatest visible difference; swelling or obscuration of anatomic architecture on close inspection	>10 - 30% inter-limb discrepancy in volume or circumference at point of greatest visible difference; readily apparent obscuration of anatomic architecture; obliteration of skin folds; readily apparent deviation from normal anatomic contour; limiting instrumental ADL	>30% inter-limb discrepancy in volume; gross deviation from normal anatomic contour; limiting self care ADL		
Musculoskeletal and connective tissue disorders						
Joint range of motion decreased	none	<=25% loss of ROM (range of motion); decreased ROM limiting athletic activity	>25 - 50% decrease in ROM; limiting instrumental ADL	>50% decrease in ROM; limiting self care ADL; disabling		
Fibrosis deep connective tissue/ Superficial soft tissue fibrosis	none	Mild induration, able to move skin parallel to plane (sliding) and perpendicular to skin (pinching up)	Moderate induration, able to slide skin, unable to pinch skin; limiting instrumental ADL	Severe induration; unable to slide or pinch skin; limiting joint or orifice movement (e.g. mouth, anus); limiting self care ADL	Generalized; associated with signs or symptoms of impaired breathing or feeding	Death
Nervous system disorders						
Brachial plexopathy	none	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Moderate symptoms; limiting instrumental ADL	Severe symptoms; limiting self care ADL		

B13: Patient: Breast Cancer Long-Term Follow-Up Questionnaire

Time points: Annually

Data Elements	**Options**
Please rate your breast pain:	
Please rate your breast pain by circling the one number that best describes your breast pain at its **worst** in the last 24 hours	0 (No pain) To 10 (Pain as bad as you can imagine)
Please rate your breast pain by circling the one number that best describes your breast pain at its **least** in the last 24 hours	
Please rate your breast pain by circling the one number that best describes your breast pain **on the average** in the last 24 hour	
Please rate your breast pain by circling the one number that tells how much breast pain you have **right now**	
Please rate the following items on this four-point scale, according to your evaluation at this point in time	**Difference between treated and untreated breast and breast area**
Breast size	
Breast texture (hardening)	
Arm heaviness	
Nipple appearance	

Shoulder movement	• None • Slight • Moderate • Large
Arm movement	
Breast pain	
Ability to lift objects	
Fit of shirt sleeve	
Breast tenderness	
Shoulder stiffness	
Breast shape	
Breast elevation (how high the breast is)	
Scar tissue	
Shoulder pain	• None • Slight • Moderate • Large
Arm pain	
Arm swelling	
Breast swelling	
Arm stiffness	
Fit of bra	
Breast sensitivity	
Fit of clothing	
Please check the box next to the description that best describes how your treated breast looks and feels now	**EXCELLENT:** when compared to the untreated breast or the original appearance of the breast, there is minimal or no difference in the size or shape of the treated breast. The way the breast feels (its texture) is the same or slightly different. There may be thickening, scar tissue or fluid accumulation within the breast, but not enough to change the appearance **GOOD**: there is a slight difference in the size or shape of the treated breast as compared to the opposite breast or the original appearance of the treated breast. There may be some mild reddening or darkening of the breast. The thickening or scar tissue within the breast causes only a mild change in the shape or size **FAIR:** obvious differences in the size and shape of the treated breast. This change involves a quarter or less of the breast. There can be moderate thickening or scar tissue of the skin and the breast, and there may be obvious color changes

	POOR: marked change in the appearance of the treated breast involving more than a quarter of the breast tissue. The skin changes may be obvious and detract from the appearance of the breast. Severe scarring and thickening of the breast, which clearly alters the appearance of the breast, may be found
Overall, how satisfied are you with your radiation therapy treatment	• Very satisfied • Satisfied • Neither satisfied nor dissatisfied • Dissatisfied • Very dissatisfied
Taking everything into consideration, if given the choice again, would you decide to have radiation therapy	• Yes, definitely • Probably yes • I don't know • Probably not • Definitely not

B14: Physician: 1-year/Annual Follow-up Clinical Assessment

Time points: Annually

Data Elements	**Options**
Patient's Status:	
Rate patient's current breast pain on a scale of 0-10	_____
Please characterize the severity of any breast **edema** at present	• None • Mild • Moderate • Severe
Please characterize the severity of any breast **erythema** at present	• None • Mild • Moderate • Severe
Please characterize the severity of any breast **hyper**pigmentation at present	• None • Mild • Moderate • Severe
Please characterize the severity of any **hypo**pigmentation in the treated field at present	• None • Mild • Moderate • Severe
Since completing radiation treatment, has the patient had additional surgery on their treated breast? If yes, please specify (check all that apply):	• Yes • No • Biopsy • Mastectomy • Reconstructive surgery

	• Scar revision • Lipofilling • Other-specify _____
Toxicity Scoring	
Please assess the patient's overall breast cosmesis at this time **Circle the number (1 – 4)** next to the word and description that best fits today's cosmetic results.	**1. EXCELLENT:** when compared to the untreated breast or the original appearance of the breast, there is minimal or no difference in the size or shape of the treated breast. The way the breast feels (texture) is the same or slightly different. There may be thickening, scar tissue, or fluid accumulation within the breast, but not enough to change the appearance. **2. GOOD:** there is a slight difference in the size or shape of the treated breast as compared to the opposite breast or the original appearance of the treated breast. There may be some mild reddening or darkening of the breast. The thickening or scar tissue within the breast causes only a mild change in the shape or size. **3. FAIR:** there is an obvious difference in the size and shape of the treated breast. This change occupies a quarter or less of the breast. There can be moderate thickening or scar tissue of the skin and the breast, and there may be obvious color changes. **4. POOR:** there is a marked change in the appearance of the treated breast involving more than a quarter of the breast tissue. The skin changes may be obvious and detract from the appearance of the breast. Severe scarring and thickening of the breast, which clearly alters the appearance of the breast may be found.
Please circle the number which most closely describes the following possible outcomes • Skin telangiectasia • Skin atrophy • Scarring • Pigment change • Erythema • Fat necrosis • Fibrosis • Retraction or contour defect • Volume loss • Other significant treatment effects (Please specify)	• None - 0 • Present but doesn't affect cosmesis - 1 • Present and affects cosmesis - 2
Toxicity Scoring (CTCAE v 4.0)	

Adverse Event	0	1	2	3	4	5
Breast						
Breast pain	none	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self-care ADL		
Lymphedema of breast	none	Trace thickening or faint discoloration	Marked discoloration; leathery skin texture; papillary formation; limiting instrumental ADL	Severe symptoms; limiting self-care ADL		
Breast nipple/areolar deformity	none	Asymptomatic ; asymmetry with slight retraction and/or thickening of the nipple areolar complex	Symptomatic; asymmetry of nipple areolar complex with moderate retraction and/or thickening of the nipple areolar complex			
Breast volume/ hypoplasia REMARK: Breast volume is referenced with both arms straight overhead	none	Minimal asymmetry; minimal atrophy	Moderate asymmetry; moderate atrophy	Asymmetry >1/3 of breast volume; severe atrophy		
Skin Disorders						
Radiation dermatitis	none	Faint erythema or dry desquamation	Moderate to brisk erythema; patchy moist desquamation, mostly confined to skin folds and creases; moderate edema	Moist desquamation in areas other than skin folds and creases; bleeding induced by minor trauma or abrasion	Life-threatening consequences; skin necrosis or ulceration of full thickness dermis; spontaneous bleeding from involved site; skin graft indicated	Death
Pruritus	none	Mild or localized; topical intervention indicated	Intense or widespread; intermittent; skin changes from scratching (e.g., edema, population, excoriations, lichenification, oozing/crusts); oral intervention indicated; limiting instrumental ADL	Intense or widespread; constant; limiting self-care ADL or sleep; oral corticosteroid or immunosuppressive therapy indicated		
Skin induration	none	Mild induration, able to move skin parallel to plane (sliding) and perpendicular to skin (pinching up).	Moderate induration, able to slide skin, unable to pinch skin; limiting instrumental to ADL	Severe induration, unable to slide or pinch skin; limiting joint movement or orifice (e.g., mouth, anus); limiting self-care ADL	Generalized; associated with signs or symptoms or impaired breathing or feeding	Death
Musculoskeletal and connective tissue disorders						
Chest wall pain	none	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self-care ADL		
Fibrosis – deep connective tissue	none	Mild induration, able to move skin parallel to plane (sliding) and perpendicular to skin (pinching up)	Moderate induration, able to slide skin, unable to pinch skin; limiting instrumental to ADL	Severe induration, unable to slide or pinch skin; limiting joint movement or orifice (e.g., mouth, anus); limiting self-care ADL	Generalized; associated with signs or symptoms or impaired breathing or feeding	Death
Cardiac disorders						

Pericarditis	none	Asymptomatic, ECG or physical findings (e.g., rub) consistent with pericarditis	Symptomatic pericarditis (e.g., chest pain)	Pericarditis with physiologic consequences (e.g., pericardial constriction)	Life-threatening consequences; urgent intervention indicated	Death
Pericardial effusion	none		Asymptomatic effusion size small to moderate	Effusion with physiologic consequences	Life-threatening consequences; urgent intervention indicated	Death
Respiratory, thoracic and mediastinal disorders						
Dyspnea	none	Shortness of breath with moderate exertion	Shortness of breath with minimal exertion; limiting instrumental ADL	Shortness of breath at rest; limiting self-care ADL	Life-threatening consequences; urgent intervention indicated	Death
Pleuritic pain	none	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL		
Pneumonitis	none	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; medical intervention indicated; limiting instrumental ADL	Severe symptoms; limiting self-care ADL; oxygen indicated	Life-threatening respiratory compromise; urgent intervention indicated (e.g., tracheotomy or intubation)	Death
General disorders						
Fatigue	none	Fatigue relieved by rest	Fatigue not relieved by rest; limiting instrumental ADL	Fatigue not relieved by rest, limiting self-care ADL		
ECOG Performance Status*						
*As published in Am. J. Clin. Oncol.: Oken, M.M., Creech, R.H., Tormey, D.C., Horton, J., Davis, T.E., McFadden, E.T., Carbone, P.P.: Toxicity And Response Criteria Of The Eastern Cooperative Oncology Group. Am J Clin Oncol 5:649-655, 1982.	Fully active	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature,e.g., light housework, office work	Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours	Capable of only limited self-care, confined to bed or chair more than 50% of waking hours	Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair	Dead

Is the patient receiving regional nodal irradiation?	• Yes No
d. If **YES,** please complete the edema measurements and toxicity scoring**.**	

	Arm circumference LEFT arm, 10 cm ABOVE olecranon: _____
	Arm circumference LEFT arm, 10 cm BELOW olecranon: _____
	Arm circumference RIGHT arm, 10 cm ABOVE olecranon: _____
	Arm circumference RIGHT arm, 10 cm BELOW olecranon: _____

		Grade				
Adverse Event	**0**	**1**	**2**	**3**	**4**	**5**
Breast						
Edema limbs	none	5 - 10% inter-limb discrepancy in volume or circumference at point of greatest visible difference; swelling or obscuration of anatomic architecture on close inspection	>10 - 30% inter-limb discrepancy in volume or circumference at point of greatest visible difference; readily apparent obscuration of anatomic architecture; obliteration of skin folds; readily apparent deviation from normal anatomic contour; limiting instrumental ADL	>30% inter-limb discrepancy in volume; gross deviation from normal anatomic contour; limiting self care ADL		
Musculoskeletal and connective tissue disorders						
Joint range of motion decreased	none	<=25% loss of ROM (range of motion); decreased ROM limiting athletic activity	>25 - 50% decrease in ROM; limiting instrumental ADL	>50% decrease in ROM; limiting self care ADL; disabling		
Fibrosis deep connective tissue/ Superficial soft tissue fibrosis	none	Mild induration, able to move skin parallel to plane (sliding) and perpendicular to skin (pinching up)	Moderate induration, able to slide skin, unable to pinch skin; limiting instrumental ADL	Severe induration; unable to slide or pinch skin; limiting joint or orifice movement (e.g. mouth, anus); limiting self care ADL	Generalized; associated with signs or symptoms of impaired breathing or feeding	Death
Nervous system disorders						
Brachial plexopathy	none	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Moderate symptoms; limiting instrumental ADL	Severe symptoms; limiting self care ADL		

Breast Radiotherapy Technical Details Form

Data Elements	**Options**
Simulation	
Which breast was treated?	• Right • Left
In what position was the patient simulated?	• Supine • Decubitus

	• Prone • Other. Please specify: _____
What positioning system was the patient immobilized with? Check all that apply.	• Breast board • No immobilization • Custom cradle • Evacuated bean bag • Other. Please Specify: _____
How was the breast immobilized? Check all that apply	• No special immobilization • Patient's bra (__cm) • Thermoplastic material (__cm) • Custom bra (__cm) • Breast cup (__cm) • Other. Please Specify: _____
Select the primary method used to assess the motion of the breast and organs-at-risk during simulation.	• 4DCT • Fluoroscopy • Slow CT • Not determined. Flash to ensure coverage • Scans at multiple breath hold states • Other. Please Specify: _____
Select the primary device or technique used to minimize or account for the impact of respiration on the patient's simulation	• No special instruction • Gating of radiotherapy (RPM, AlignRT, etc.) • Voluntary breath hold without device • Abdominal compression • Breath hold with device (ABC, SDX, etc.) • Other. Please Specify: _____
Was patient re-simulated for boost (new imaging and treatment plan)?	• Yes • No • Patient did not receive a boost

If yes, in what position was the patient's boost simulated? [if Q7 = Yes]	• Supine • Decubitus • Prone
Targets	
What is the patient's mid-breast separation?	_____cm [between 10 and 50]
[Q10] Were any of the following nodal regions intentionally treated? Check all that apply.	• Supraclavicular • Axillary (level I & II) • Infraclavicular (level III axillary) • Other. Please specify:____ • Internal Mammary • None
[Q11] Were contours for the lumpectomy cavity drawn for treatment planning?	• Yes • No
If the lumpectomy cavity is contoured, is a planning target volume (PTV) margin added for treatment planning?	[if Q11 = Yes] • Expansion added to cavity. Please specify: _____cm • Included in auto-shaping margin for planning (such as for electron cutouts) • Not explicitly considered
Treatment Planning	
[Q13] Select the number of plans treated	_____ [drop-down menu: 1-10]
For each plan, specify: a. Planning Type b. Dose delivered with this plan (Gy)	[The user should be able to complete this process for as many plans as were indicated in Q13] • Forward Planning • Inverse Planning _____ [between 1 and 70]

c. Number of fractions delivered with this plan	_____ [between 1 and 40]
d. Treatment region	• Breast • Lumpectomy bed • Breast & nodes • Nodes
e. Reason for plan	• Initial • Planned boost • Planned adaptation • Unplanned modification
f. If not initial, what was the reason?	[if Q14e=Planned adaptation or Unplanned modification] • Minimize dose to critical structures • Patient anatomy change • Change in motion management strategy • Other. Please specify:_____
g. Did this plan include a concomitant boost?	[if Q14e=Initial] • Yes • No
Prescription	
How is the dose to the breast prescribed?	• Midplane depth • ____ Gy to a reference point [between 20 and 70] • ____ Gy [between 20 and 70] to ___% Isodose Line [between 70 and 110] • ____ Gy [between 20 and 70] to ___% Volume [between 70 and 100]
How is the dose to the regional nodes prescribed?	[If Q10 ≠ None] • Depth • ____ Gy to a reference point [between 20 and 70] • ____ Gy [between 20 and 70] to ___% Isodose Line [between 70 and 110]

	• ____ Gy [between 20 and 70] to ___% Volume [between 70 and 100]
How is the dose to the lumpectomy bed prescribed? Note: If no boost was given, please enter 0 Gy for the second option.	• Midplane depth • ____ Gy to a reference point [between 0 and 30] • ____ Gy [between 5 and 30] to ___% Isodose Line [between 70 and 110] • ____ Gy [between 5 and 30] to ___% Volume [between 70 and 100]
Treatment Delivery and Image Guidance	
Select the primary motion management technique used for this patient for treatment delivery	• ITV to account for motion, free breathing • Abdominal compression • Voluntary breath hold without device • No special instruction • Breath hold with device (ABC, SDX, etc.) • Other. Please specify: _____ • Gating of radiotherapy (RPM, AlignRT, etc.)
What type of imaging was used to verify this patient's setup?	• kV/MV portal • CT (CBCT or TomoTherapy CT) • Films • Video-based system • Other. Please specify: _____
For each imaging type, specify how often the patient was imaged during treatment.	• Daily • Less than daily but more than weekly • Weekly • Other. Please specify: _____