The following represents a SUMMARY OF ALL SURGERIES (as such this will require continuous updating).

I. General patient & protocol information

Patient ID
Patient ID (protocol ID + sequentially assigned number based on order of registration) ____________________

Patient Characteristics at Registration

Patient age at registration (in years) ________________
Note: Can be computed from Date of Birth and Date of Registration by local system.

Menopausal Status (check one)

☐ Pre (<6 mo since LMP AND no prior bilateral ovariectomy AND not on estrogen replacement)
☐ Post (prior bilateral ovariectomy OR >12 mo since LMP with no prior hysterectomy AND not currently receiving therapy with LH-RH analogs (e.g., Zoladex))
☐ Above categories not applicable AND Age < 50
☐ Above categories not applicable AND Age >= 50

Patient’s Vital Status  ☐ Alive  ☐ Dead

Primary Cause of Death (check one)

☐ Due to this disease  ☐ Due to other cause  ☐ Due to protocol treatment
☐ Accidental  ☐ Suicide  ☐ Other

Describe cause of death ________________________________________________________________

Patient Performance Status

ECOG Performance Status (check one)

☐ 0 = Fully active, able to carry on all pre-disease performance without restriction. (Karnofsky 90 - 100)
☐ 1 = 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). (K 70 - 80)
☐ 2 = Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours. (K 50 - 60)
☐ 3 = Capable of only limited self-care, confined to bed or chair more than 50% of waking hours. (K 30 - 40)
☐ 4 = Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair. (K 10 - 20)

Karnofsky Performance Status (check one)

☐ 100 = Normal, no complaints, no evidence of disease
☐ 90 = Able to carry on normal activity; minor signs or symptoms of disease
☐ 80 = Normal activity with effort; some signs or symptoms of disease
☐ 70 = Cares for self, unable to carry on normal activity or to do active work
☐ 60 = Requires occasional assistance, but is able to care for most of his/her needs
☐ 50 = Requires considerable assistance and frequent medical care
☐ 40 = Disabled, requires special care and assistance
☐ 30 = Severely disabled, hospitalization indicated. Death not imminent
□ 20 = Very sick, hospitalization indicated. Death not imminent
□ 10 = Moribund, fatal processes progressing rapidly
□ 0 = Dead

Protocol Design (To be adjusted per protocol specifics)

Assigned Treatment Arm

_____________________________________________________________________

Treatment Assignment Code Example (TAC) (protocol specific)

_____________________________________________________________________

TAC description (Note: The following fields can be prepopulated)

<table>
<thead>
<tr>
<th>Agent NSC Number*</th>
<th>Agent Name</th>
<th>Agent Dose</th>
<th>Unit**</th>
<th>Route***</th>
<th>Frequency****</th>
</tr>
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<tr>
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</tbody>
</table>

* Please check the CTEP Home Page for a list of agent NSC numbers.

** Unit = mg/m², mg/kg, mg

*** Route = IM, IV, NASAL, PO, Transdermal, TOP, or Vaginal

**** Frequency = bid (Twice a Day), tid (Three Times Daily), qid (Four Times Daily), qd (Daily), q2d (Every two days), q3d (Every three days), qd x 3 (Once a day for 3 days), qd x 4 (Once a day for 4 days), qd x 5 (Once a day for 5 days), qod (Every Other Day), qam (Every Morning), qhs (Every night), PRN (As Needed), qwk (Weekly), 2 times/week, 3 times/week, Tiw (Three Times a Week), Biw (Every two weeks), q2wk (Every two weeks), qmonth (Monthly), ac (Before meals), pc (After Meals), q1h (Every one hour), q2h (Every two hours), q3h (Every three hours), q4h (Every four hours), q6h (Every six hours), q8h (Every eight hours), q12h (Every twelve hours), x1 (One Time), x2 (Two Times), x3 (Three Times), x4 (Four Times)

II. Disease Description

Initial Diagnostic Specimen (BIOPLY)

Tumor Laterality (check one)  □ Left  □ Right  □ Bilateral

Method of Evaluation: □ Fine needle aspiration biopsy  □ Core biopsy  □ Incisional biopsy
□ Excisional biopsy or lumpectomy  □ Skin biopsy  □ Excisional biopsy with frozen section

Histologic Type  □ Invasive (infiltrating) ductal carcinoma
□ Invasive (infiltrating) lobular carcinoma
□ Invasive mixed ductal and lobular carcinoma
□ Invasive mammary carcinoma (not otherwise specified)
□ Other (please specify) __________________________
**Histologic Grade** (note, this is the summary of architectural, nuclear, and mitotic count itemized below)

- Low  
- Intermediate  
- High  
- Unknown

Architectural grade (tubule formation), if ductal carcinoma  
- 1  
- 2  
- 3

Nuclear grade  
- Low  
- Intermediate  
- High  
- Unknown/Not reported

Mitotic Count  
- 1  
- 2  
- 3  
- Unknown

Lymphovascular invasion  
- Yes  
- No  
- Equivocal  
- Unknown/Not reported

Tumor infiltrating lymphocytes:  
- None/minimal  
- Present  
- Extensive  
- Unknown/not reported

**IN SITU DISEASE in Biopsy**

**Assessment of Ductal Carcinoma In Situ (DCIS)**

Is DCIS present?  
- Yes  
- No  
- Unknown

Is DCIS present with invasive cancer?  
- Yes  
- No  
- Unknown

*If present with invasive disease, Is an extensive intraductal component (EIC) present?  
- Yes  
- No

Is cancerization of lobules present?  
- Yes  
- No

**DCIS Histologic Type** (check all that apply)

- Comedo  
- Solid  
- Cribriform  
- Micropapillary  
- Clinging  
- Apocrine  
- Intra-cystic (encysted papillary)  
- Papillary  
- Other, specify ____________________________

Is Paget’s disease of the nipple present?  
- Yes  
- No  
- Unknown

Is microinvasive cancer present?  
- Yes  
- No  
- Unknown

**Assessment of Lobular Carcinoma In Situ (LCIS)**

Is LCIS present?  
- Yes  
- No

Is LCIS present with invasive cancer?  
- Yes  
- No

**Extent of LCIS**  
- Focal  
- Extensive  
- Not specified

**Marker Status**

**Estrogen Receptor (ER) Status**

- Negative  
- Positive  
- Low Positive  
- 1+  
- 2+  
- 3+  
- Unknown/Not reported

If reported, % cells (+) ______ %

- Attempted, but technically inadequate
Staining Antibody

Antigen Retrieval  □ Unknown  □ No  □ Yes, specify __________________________

**Progesterone Receptor (PgR) Status**

□ Negative  □ Positive  □ Low Positive
□ 1+ □ 2+ □ 3+ □ Unknown/Not reported
PgR % cells stained positive ______ %
□ Attempted, but technically inadequate

Staining Antibody

Antigen Retrieval  □ Unknown  □ No  □ Yes, specify __________________________

**Her2/neu expression by immunohistochemistry**

□ Negative  □ 1+  □ 2+  □ 3+  □ Unknown/Not reported
□ Positive  □ Low Positive
□ Attempted, but technically inadequate
If reported, % cells (+) ______ %

Staining Antibody

Antigen Retrieval  □ Unknown  □ No  □ Yes, specify __________________________

**HER2 status by FISH**

FISH HER2/neu chromosome 17 (HER2:cep17) Ratio ______ : _______
□ Amplified (HER2:cep17 ratio >2.2) □ Amplified (HER2 copy number >6)
□ Not amplified (HER2:cep17 ratio <1.8) □ Not amplified (HER2 copy number <4)
□ Equivocal (HER2:cep17 ratio 1.8-2.2) □ Equivocal (HER2 copy number 4-6)
□ Not done/Not reported
□ Attempted, but technically inadequate

Method/Kit Used:

Final HER2 status
□ Negative  □ Positive  □ Equivocal  □ Not done/Not reported

**Lymph Nodes**

Did the patient undergo lymph node sampling prior to definitive surgery (at diagnosis)?  □ No  □ Yes
If yes, was there histologic or cytologic evidence of lymph node involvement?
□ N/A  □ No  □ Yes  □ Equivocal

Date of lymph node sampling  __ __ / __ __ / __ __ __ __

Method of Evaluation: □ Fine needle aspiration biopsy □ Core biopsy □ Incisional biopsy □ Excisional biopsy or lumpectomy □ Sentinel node biopsy
Surgical Procedures

See Surgical CDE

Pathologic Disease Classification After Definitive Surgery  *Indicate highest stage*

Largest diameter of residual invasive cancer (for T Stage)  ____ mm

**Histologic Type**  
☐ Invasive (infiltrating) ductal carcinoma  
☐ Invasive (infiltrating) lobular carcinoma  
☐ Invasive mixed ductal and lobular carcinoma  
☐ Invasive mammary carcinoma (not otherwise specified)  
☐ Other (please specify) __________________________

Lymphovascular invasion  
☐ Yes  ☐ No  ☐ Equivocal  ☐ Unknown/Not reported

Tumor infiltrating lymphocytes:  
☐ None/minimal  ☐ Present  ☐ Extensive  ☐ Unknown/Not reported

Pathologic status of surgical margins (see Surgical CDE)

Histologic Grade  
☐ Grade I (Low)  ☐ Grade II (Intermediate)  ☐ Grade III (High)  ☐ Not reported

Nuclear grade  
☐ Low  ☐ Intermediate  ☐ High  ☐ Unknown

**Mitotic Count**

☐ 1 (less than 10 mitoses per 10 high HPF (25X objective) or 0 to 5 mitoses per 10 HPF (40X objective)

☐ 2 (10-20 mitoses per 10 high power fields (25X objective) or 6 to 10 mitoses per 10 high power fields (40X objective)

☐ 3 (Greater than 20 mitoses per 10 HPF (25X objective) or greater than 10 mitoses per 10 HPF (40X objective)

☐ U (Unknown)

Percentage of tumor cells that are mitotic:  __________%

If evaluated, Architectural grade, Tubule formation  
☐ 1 (>75%)  ☐ 2 (10-75%)  ☐ 3 (<10%)  
☐ Unknown/Not reported

**Pathologic Stage**

AJCC classification version:  
☐ 1st  ☐ 2nd  ☐ 3rd  ☐ 4th  ☐ 5th  ☐ 6th  ☐ 7th

T Stage, Pathologic  
☐ T0  ☐ T1  ☐ T1a  ☐ T1b  ☐ T1c  ☐ T1mi  ☐ T2  ☐ T3  ☐ T4  ☐ T4a  
☐ T4b  ☐ T4c  ☐ T4d  ☐ Tis(DCIS)  ☐ Tis (LCIS)  ☐ Tis(Paget’s)  ☐ TX
Pathology: Assessment of Lymph Nodes (After Definitive Surgery)

Was sentinel node sampling performed?  □ Yes  □ No

If yes, Sentinel Node Site  □ Axillary  □ Internal Mammary  □ Supraclavicular  □ Unknown

If yes, Number of Sentinel Nodes Examined ______  Total No. of Other Involved Sentinel Nodes ______

Total Number of Positive Sentinel Nodes ______
Number of Positive Sentinel Nodes by H&E ______
Number of Positive Sentinel Nodes by Immunohistochemistry (IHC) only ______
Measurement of Largest Metastasis  □ > or = 2 mm  □ 0.2 - 2 mm  □ <0.2mm

Was axillary dissection performed?  □ Yes  □ No  □ Unknown

If yes, Number of Lymph Nodes Examined _____  Number of Positive Lymph Nodes _____
Number of Lymph Nodes with Macrometastases ______
Number of Lymph Nodes with Micrometastases ______

Lymph Node Assessment

<table>
<thead>
<tr>
<th>Lymph Node Type</th>
<th>Lymph Node Involvement</th>
<th>Size of Largest Nodal Met</th>
<th>No. of Positive Lymph Nodes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Axillary</td>
<td>□</td>
<td>□ &lt; 0.2 mm by IHC only</td>
<td>□ 2 mm to 2 cm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>□ 0.2 to 2 mm by H&amp;E</td>
<td>□ &gt; 2 cm</td>
</tr>
<tr>
<td>Internal mammary</td>
<td>□</td>
<td>□ &lt; 0.2 mm by IHC only</td>
<td>□ 2 mm to 2 cm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>□ 0.2 to 2 mm by H&amp;E</td>
<td>□ &gt; 2 cm</td>
</tr>
<tr>
<td>Supraclavicular</td>
<td>□</td>
<td>□ &lt; 0.2 mm by IHC only</td>
<td>□ 2 mm to 2 cm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>□ 0.2 to 2 mm by H&amp;E</td>
<td>□ &gt; 2 cm</td>
</tr>
<tr>
<td>Infraclavicular</td>
<td>□</td>
<td>□ &lt; 0.2 mm by IHC only</td>
<td>□ 2 mm to 2 cm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>□ 0.2 to 2 mm by H&amp;E</td>
<td>□ &gt; 2 cm</td>
</tr>
</tbody>
</table>

* Indicate Node Involvement:  0= Not evaluated/tested;  1= Positive Finding;  2= Negative Finding;  3= Equivocal;  4= Unknown

Marker Status (Definitive Surgery Specimen)

Estrogen Receptor (ER) Status
□ Negative  □ Positive  □ Low Positive  □ 1+ □ 2+ □ 3+ □ Unknown/Not reported
□ Attempted, but technically inadequate
If reported, % cells (+) ______ %
Staining Antibody ________________________________________________________________
Antigen Retrieval □ Unknown □ No □ Yes, specify______________________________

Progesterone Receptor (PgR) Status
□ Negative □ Positive □ Low Positive □ 1+ □ 2+ □ 3+ □ Unknown/Not reported
□ Attempted, but technically inadequate
PgR % cells stained positive ______ %
Staining Antibody ________________________________________________________________
Antigen Retrieval □ Unknown □ No □ Yes, specify______________________________

Her2/neu expression by immunohistochemistry
□ Negative □ Positive □ Low Positive □ 1+ □ 2+ □ 3+ □ Unknown/Not reported
□ Attempted, but technically inadequate
If reported, % cells (+) ______ %
Staining Antibody ________________________________________________________________
Antigen Retrieval □ Unknown □ No □ Yes, specify______________________________

Her2 status by FISH
FISH HER2/neu:chromosome 17 (HER2:cep17) Ratio ________ : __________
□ Amplified (HER2:cep17 ratio >2.2) □ Amplified (HER2 copy number >6)
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□ Equivocal (HER2:cep17 ratio 1.8-2.2) □ Equivocal (HER2 copy number 4-6)
□ Not done/Not reported
□ Attempted, but technically inadequate
Method/Kit Used: ________________________________

Final HER2 status
□ Negative □ Positive □ Equivocal □ Not done/Not reported

Assessment of Ductal Carcinoma In Situ (DCIS)
Is DCIS present? □ Yes □ No □ Unknown
   Is DCIS present with invasive cancer? □ Yes □ No □ Unknown
      If present with invasive disease, Is an extensive intraductal component (EIC) present? □ Yes □ No
Is cancerization of lobules present? □ Yes □ No
Histologic Type □ Comedo □ Apocrine □ Intra-cystic (encysted papillary)
   (check all that apply) □ Cribriform □ Papillary □ Micropapillary
      □ Clinging □ Other, specify ________________________________________________
Does the DCIS involve the surgical margin(s)? □ Yes □ No □ Unknown

If YES, describe the extent of margin involvement
□ Single margin, focal □ Single margin, extensive □ Multiple margins

If the DCIS does not involve the margins, is it < 2 mm from margin(s)? □ Yes □ No

If yes, describe the extent of DCIS close to the margin
□ Single margin, focal □ Single margin, extensive □ Multiple margins

If the DCIS is 2mm or further from the margin, how close is the nearest margin? ______ mm.

Is Paget's disease of the nipple present? □ Yes □ No □ Unknown
Is microinvasive cancer present? □ Yes □ No □ Unknown

Assessment of Lobular Carcinoma In Situ (LCIS)

Is LCIS present? □ Yes □ No
Is LCIS present with invasive cancer? □ Yes □ No

Extent of LCIS □ Focal □ Extensive □ Not specified

Is LCIS at margin? □ Transected □ Greater than 10 mm □ Unknown
□ Less than 1 mm □ Involved, NOS
□ > or = 1 mm to 10 mm □ Not involved, NOS

CONTINUED ON NEXT PAGE
### III. Endpoints

#### Timepoints

<table>
<thead>
<tr>
<th>Time from registration to:</th>
<th>Event</th>
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<tbody>
<tr>
<td></td>
<td>First randomization</td>
</tr>
<tr>
<td></td>
<td>Biologic therapy start</td>
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<tr>
<td></td>
<td>Hormonal therapy stop</td>
</tr>
<tr>
<td></td>
<td>Radiation therapy start</td>
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<tr>
<td></td>
<td>Most extensive primary surgery</td>
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<tr>
<td></td>
<td>Local/regional invasive recurrence</td>
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<td>Distant invasive recurrence</td>
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<tr>
<td></td>
<td>Ipsilateral DCIS</td>
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<tr>
<td></td>
<td>Last assessment</td>
</tr>
</tbody>
</table>

Duration (in days/months rounded to tenths) 

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#### Time from most extensive surgery to:

<table>
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<tr>
<th>Event</th>
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<tr>
<td>First randomization</td>
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Duration (in days/months rounded to tenths) 

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#### Time from randomization to:

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Duration (in days/months rounded to tenths) 

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**CONTINUED ON NEXT PAGE**
Site(s) of Progression

First recurrence/progression  □ Local  □ Regional  □ Distant

Site of First Local-Regional Progression  □ Ipsilateral breast  □ Axillary nodes  □ Supraclavicular nodes
(check all that apply)  □ Chest wall  □ Internal mammary nodes  □ Infraclavicular nodes
  □ Axilla  □ Other

If sites other than specified, Indicate Name ________________________________

Site of Distant Progression  □ Brain  □ Skin  □ Bone
  □ Other, generalized NOS, carcinomatosis: ________________________________
  □ Central nervous system  □ Other CNS: ________________________________
  □ Distant nodes  □ Liver  □ Other Visceral: ________________________________
  □ Lung  □ Other NOS: ________________________________
  □ Peritoneum  □ Pleura  □ Other: ________________________________ □ None or none known

Progressive Disease  □ Target Lesions (At least a 20% increase in the Sum of Longest Diameters of Documentation Target Lesions, taking as reference the smallest sum recorded since the treatment started)
  □ Nontarget Lesions (Unequivocal progression of existing nontarget lesions)
  □ Appearance of one or more new lesions
  □ Other: ________________________________

(Note: Record all anatomic sites of progression on the Follow-Up form for the specific disease being treated.)

Methods of Evaluation: □ Clinical examination  □ CT Scan  □ MRI (NMR)  □ Bone Scan  □ Other
  □ Chest X-ray  □ Spiral CT Scan  □ Ultrasound  □ Cytology  □ Not evaluated

Notice of New Primary (Including second primary of the contralateral breast)

Has a new primary cancer or myelodysplastic syndrome (MDS) been diagnosed?  □ Yes  □ No

ICD-10 Code ________________________________