

## N083E FORMS PACKET

N083E, Phase II Safety Study of Docetaxel and Carboplatin in Combination with Trastuzumab and Lapatinib in Early Breast Cancer

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  - ✓
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✓ designates revised/new forms

\*Generic forms completion instructions are available on the NCCTG web site under “the CRA link in the Remote Registration and Data Entry section and are titled “Remote Data Entry Screen Instructions (Forms Completion)”

NORTH CENTRAL CANCER TREATMENT GROUP

Eligibility Checklist

009/25/2009

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N083E: Phase II Safety Study of Docetaxel and Carboplatin in Combination with Trastuzumab and Lapatinib in Early Breast Cancer

**Prior to discussing this protocol with a patient, call the NCCTG Registration Office (507/284-4130) to see if there is a place available for your patient.**

**To register a patient, call the NCCTG Registration Office at (507/284-4130) or fax (507/284-0885) a completed eligibility checklist to the NCCTG Registration Office between 8 a.m. and 4:30 p.m. central time Monday through Friday.**

Registration date (date on) (mm/dd/yyyy) \_\_\_/\_\_\_/\_\_\_\_\_

Patient study ID number (provided at time of Reg/Random) \_\_\_\_\_

NCCTG member (participant sponsor) \_\_\_\_\_

NCCTG treating location \_\_\_\_\_

NCCTG treating physician \_\_\_\_\_

Institution patient number (local subject number) \_\_\_\_\_

IRB approval date (mm/dd/yyyy) \_\_\_/\_\_\_/\_\_\_\_\_

Person Completing Form:

Last Name: **(print)** \_\_\_\_\_ First Name: **(print)** \_\_\_\_\_

Phone: \_\_\_\_\_ Fax: \_\_\_\_\_ Email: \_\_\_\_\_

Patient initials (last, first, middle) \_\_\_\_\_

Gender (check one) \_\_\_ Male \_\_\_ Female \_\_\_ Unknown

Date of birth (mm/dd/yyyy) \_\_\_/\_\_\_/\_\_\_\_\_

ZIP code \_\_\_\_\_

Country of Residence \_\_\_\_\_

Race (check all that apply)

- \_\_\_ White
- \_\_\_ Black or African American
- \_\_\_ Native Hawaiian or Other Pacific Islander
- \_\_\_ Asian
- \_\_\_ American Indian or Alaska Native
- \_\_\_ Not reported: Patient refused or not available
- \_\_\_ Unknown: Patient unsure

Method of payment (check one)

- \_\_\_ PI (Private Insurance)
- \_\_\_ MR (Medicare)
- \_\_\_ MRP (Medicare and Private Insurance)
- \_\_\_ MD (Medicaid)
- \_\_\_ MM (Medicaid and Medicare)
- \_\_\_ MVA (Military or Veterans Sponsored,  
Not Otherwise Specified ( NOS))
- \_\_\_ MS (Military Sponsored [including CHAMPUS & TRCARE])
- \_\_\_ MV (Veterans Sponsored)
- \_\_\_ SP (Self pay [no insurance])
- \_\_\_ NP (No means of payment [no insurance])
- \_\_\_ OTH (Other)
- \_\_\_ UNK (Unknown)

Ethnicity (check one)

- \_\_\_ Not Hispanic or Latino
- \_\_\_ Hispanic or Latino
- \_\_\_ Not reported: Refused or data not available
- \_\_\_ Unknown: Unsure of their ethnicity

Addendum 2 dated September 25, 2009 IRB approved?

\_\_\_ Yes. If Yes, Addendum 2 approval date (mm/dd/yyyy) \_\_\_/\_\_\_/\_\_\_\_\_

\_\_\_ No. If No, End form, Addendum 2 IRB approval required.

Patient study ID number \_\_\_\_\_

**Eligibility Check** - Answer questions below (yes/no). All requirements must be confirmed. All dates are to be *mm/dd/yyyy*.

**Inclusion Criteria**

Yes No NA

Women or men $\geq 18$ years of age. Age = _____.	_____	_____	_____
Eastern Cooperative Oncology Group (ECOG) performance status $\leq 1$ . ECOG performance status = _____.	_____	_____	_____
Non-metastatic operable primary invasive adenocarcinoma of the breast fulfilling the following:			
a. Histologically confirmed;			
b. Adequately excised. NOTE: Patients who have ‘non-resectable’ deep margin invasion are eligible provided they have had or will receive radiotherapy encompassing the region concerned. NOTE: Patients with histologically documented infiltration of the skin (pT4) are eligible provided they have undergone or will receive radiotherapy encompassing the tumor bed.			
c. Sentinel lymph node dissection (SLND) and/or auxiliary lymph node dissection (ALND)	_____	_____	_____
d. Node positive patient OR Node negative patient and determined by physician to be eligible to receive adjuvant trastuzumab. NOTE: Isolated tumor cells (ITC) are considered pN0 and micrometastases are considered pN1.			
Known hormone receptor status (ER/PgR or ER alone).	_____	_____	_____
Baseline LVEF $\geq 50\%$ measured by echocardiography or MUGA scan.	_____	_____	_____
Over expression and/or amplification of HER2 in the invasive component of the primary tumor, according to one of the following definitions [Wolff, 2007]: - 3+ over expression by IHC ( $>30\%$ of invasive tumor cells); - 2+ or 3+ (in 30% or less neoplastic cells) over expression by IHC AND <i>in situ</i> hybridization (FISH/CISH) test demonstrating HER2 gene amplification; - HER2 gene amplification by FISH/CISH ( $>6$ HER2 gene copies per nucleus, or a FISH ratio [HER2 gene copies to chromosome 17 signals] of $>2.2$ ). NOTE: Patients with a negative or equivocal overall result (FISH test ratio of $<2.2$ , $<6.0$ HER2 gene copies per nucleus) and staining scores of 0, 1+, 2+ or 3+ (in 30% or less neoplastic cells) by IHC are not eligible for participation in the trial.			
The following laboratory values must be obtained $\leq 14$ days prior to registration. Earliest laboratory test date ___/___/_____; latest laboratory test date ___/___/_____. NOTE: These dates pertain to the following labs only.			
• Hemoglobin $\geq 10.0$ g/dL. Hemoglobin = _____.	_____	_____	_____
• Absolute neutrophil count (ANC) $\geq 1500/\text{mm}^3$ . Absolute neutrophil count (ANC) = _____.	_____	_____	_____
• Platelets $\geq 100,000/\text{mm}^3$ . Platelets = _____.	_____	_____	_____
• Serum creatinine $\leq 2.0$ x institutional upper limit of normal (ULN) Serum creatinine = _____. ULN = _____.	_____	_____	_____
• AST (SGOT) $\leq 2.5$ x ULN. AST (SGOT) = _____. ULN = _____.	_____	_____	_____
• ALT (SGPT) $\leq 2.5$ x ULN. ALT (SGPT) = _____. ULN = _____.	_____	_____	_____
• Alkaline phosphatase $\leq 2.5$ x ULN. Alkaline phosphatase = _____. ULN = _____.	_____	_____	_____
• Bilirubin $\leq 1.5$ x ULN ( $\leq 2.0$ x ULN if known Gilbert’s Syndrome). Is there known Gilbert’s Syndrome? (This question may be answered yes or no). ____ Yes $\rightarrow$ Bilirubin ( $\leq 2.0$ x ULN) = _____. ULN = _____. ____ No $\rightarrow$ Bilirubin ( $\leq 1.5$ x ULN) = _____. ULN = _____.	_____	_____	_____
Negative pregnancy test done $\leq 7$ days prior to registration, for women of childbearing potential only. If not a woman of childbearing potential or male ( <i>check NA</i> ) If a woman of childbearing potential – Negative pregnancy test date ___/___/_____. _____	_____	_____	_____
Availability of diagnostic tissue and operative and pathology reports from breast cancer diagnosis (see Sections 6.0 and 17.0).	_____	_____	_____

All responses in above section must be “Yes” unless specified as “NA.”

Patient study ID number \_\_\_\_\_

**Exclusion Criteria**

Yes No NA

Any prior mediastinal irradiation except internal mammary node irradiation for the present breast cancer.	___	___	
Positive or suspicious internal mammary nodes identified by sentinel node technique which have not been irradiated or will not be irradiated, OR Supraclavicular lymph node involvement (confirmed by fine needle aspirate or biopsy).			
Prior use of anti-HER2 therapy for any reason or other prior biologic or immunotherapy for breast cancer.	___	___	
Concurrent anti-cancer treatment, except hormonal therapy or radiotherapy for the present breast cancer.	___	___	
Concurrent anti-cancer treatment in another investigational trial with hormone therapy or immunotherapy unless approved by the Study Chair.	___	___	
Serious cardiac illness or medical conditions including but not confined to: - History of documented congestive heart failure (CHF) (any NYHA class) or systolic dysfunction (LVEF <50%) - High-risk uncontrolled arrhythmias (ventricular tachycardia, high-grade AV-block (2 <sup>nd</sup> degree or higher), supraventricular arrhythmias which are not adequately rate-controlled) - Angina pectoris requiring antianginal medication - Clinically significant valvular heart disease - Evidence of transmural infarction on ECG - Poorly controlled hypertension ( any reading systolic >180 mm Hg or diastolic >100mm Hg)			
Other concurrent serious diseases that may interfere with planned treatment including severe pulmonary conditions/illness.	___	___	
Ulcerative colitis, malabsorption syndrome, any disease significantly affecting gastrointestinal function, or resection of the stomach or small bowel, or inability to swallow oral medication.			
Pregnant or lactating women.	___	___	
Women of childbearing potential and male participants with partners of childbearing potential, including women whose last menstrual period was <1 year ago (unless surgically sterile – hysterectomy and/or ovariectomy) who are unable or unwilling to use adequate contraceptive measures during study treatment.			
Concomitant use of CYP3A4 inhibitors or inducers. (See Appendix V for list of common inhibitors and inducers).	___	___	

**All responses in above section must be “No.”**

Registration Check - Answer questions below (yes/no). All requirements must be confirmed. All dates are to be mm/dd/yyyy.

Yes No NA

Consent form signed and dated. Date of consent ___/___/_____	___	___	
Authorization for use and disclosure of protected health information signed and dated. If not a USA institution ( <i>check NA</i> ); If a USA institution - Date of authorization ___/___/_____	___	___	___
This protocol has mandatory safety monitoring – sites enrolling first 10 patients must participate in twice monthly conference calls (see Section 16.73).			
Expedited reporting is required for the first 10 patients registered to the trial. In order to assess the adverse event profile of the first 10 patients in a timely manner, the expected CRFs for these patients must be entered <= 14 days after adverse event reporting for Cycle 1 (ie within 14 days of first day of Cycle 2). If site is not able to comply with this requirement, patient may not be registered as one of first 10 patients on trial.			
Treatment on this protocol must commence at the accruing membership under the supervision of an NCCTG member physician.			
Treatment cannot begin prior to registration and must begin ≤14 days after registration.	___	___	

Patient study ID number \_\_\_\_\_

Registration Check - continued

Yes No NA

Pretreatment tests/procedures must be completed ≤14 days prior to registration (see Section 4.0). Earliest pretreatment test date ___/___/____; latest pretreatment test date ___/___/____ NOTE: The earliest pretreatment test date must be less than or equal to the earliest laboratory test date <b>and</b> the latest pretreatment test date must be greater than or equal to the latest laboratory test date.	_____
<b>Exceptions to the above dates</b> (see Section 4.0): <ul style="list-style-type: none"> <li>Mammography or breast MRI may be completed ≤12 months (360 days) prior to registration Chest                      Earliest exception test date ___/___/____; latest exception test date ___/___/____.</li> </ul> <b>Note:</b> The earliest exception test date must be less than or equal to the latest exception test date.	_____
<ul style="list-style-type: none"> <li>Chest x-ray or chest CT or PET may be completed ≤2 months (60 days) prior to registration.                      Earliest exception test date ___/___/____; latest exception test date ___/___/____.</li> </ul> <b>Note:</b> The earliest exception test date must be less than or equal to the latest exception test date.	_____
All required baseline symptoms must be documented and graded (see Section 10.3).	_____
Study drug availability checked.	_____
Blood draw kit availability checked. (Kit must be available on site for this patient.)	_____

**All responses in above section must be “Yes” unless specified as “NA.”**

Registration Office will register patients separately to the optional translational research component of this study (see Section 14.0). The following will be recorded: <ul style="list-style-type: none"> <li>Patient has given permission to give blood sample(s) for research testing</li> </ul>	_____
<ul style="list-style-type: none"> <li>Patient has given permission to give tissue sample(s) for research testing</li> </ul>	_____
At the time of registration, the following will also be recorded: <ul style="list-style-type: none"> <li>Patient has given permission to keep sample(s) for use in future research to learn about, prevent, or treat cancer.</li> </ul>	_____
<ul style="list-style-type: none"> <li>Patient has given permission to keep sample(s) for use in future research to learn about, prevent, or treat other health problems (for example: diabetes, Alzheimer’s disease, or heart disease).</li> </ul>	_____
<ul style="list-style-type: none"> <li>Patient has given NCCTG permission to give my sample(s) to outside researchers.</li> </ul>	_____

**All responses in above section may be “Yes” or “No”.**

Assigned Treatment

\_\_\_ Arm A: TATER+CBDCA+HERCEP+TYKERB

Person registering Signature \_\_\_\_\_ Registration Office specialist initials \_\_\_\_\_

Physician Signature \_\_\_\_\_ Date (mm/dd/yyyy) \_\_\_/\_\_\_/\_\_\_\_

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP**

Protocol Number:     N083E    

**ON-STUDY FORM**

Patient ID Number: \_\_\_\_\_ Patient Initials: \_\_\_\_\_

L F M

Institution Number: \_\_\_\_\_

Institution: \_\_\_\_\_

**ALL ITEMS MUST BE COMPLETED** pg 1 of 2

**Are data amended? (check one)**  Yes  No  
*(if data are amended, please circle in red when using paper form)*

**Description of Primary Disease**

MedDRA disease code: 10006190 [*Invasive breast carcinoma*]

Primary Tumor Site: Breast

Cell Type: (check one)

- |  |  |
|--|--|
| 1 <input type="checkbox"/> Infiltrating ductal                   | 6 <input type="checkbox"/> Mucinous (colloid)    |
| 2 <input type="checkbox"/> Infiltrating lobular                  | 7 <input type="checkbox"/> Papillary             |
| 3 <input type="checkbox"/> Comedo                                | 8 <input type="checkbox"/> Scirrhus              |
| 4 <input type="checkbox"/> Inflammatory                          | 9 <input type="checkbox"/> Tubular               |
| 5 <input type="checkbox"/> Medullary with lymphocytic infiltrate | 10 <input type="checkbox"/> Other, specify _____ |

Nottingham Grade: (check one)

- |                                     |                                    |
|-------------------------------------|------------------------------------|
| 1 <input type="checkbox"/> Well     | 3 <input type="checkbox"/> Poor    |
| 2 <input type="checkbox"/> Moderate | 9 <input type="checkbox"/> Unknown |

Tumor Laterality: (check one)

- |                                 |                                  |                                      |
|---------------------------------|----------------------------------|--------------------------------------|
| 1 <input type="checkbox"/> Left | 2 <input type="checkbox"/> Right | 3 <input type="checkbox"/> Bilateral |
|---------------------------------|----------------------------------|--------------------------------------|

**Chronology of Diagnoses**

Date (mm/dd/yyyy)

Method of Diagnosis\*

\_\_\_/\_\_\_/\_\_\_

Primary

\* ( 2=Yes, biopsy 3=Yes, cytology 4=Yes, clinical)

**Previous Breast Surgery Related to Tumors:** (check one) 1  Yes 2  No

Operative Procedure  
(check all that apply)

Date  
(mm/dd/yyyy)

Lumpectomy \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

Mastectomy \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

Sentinel node dissection \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

1  Positive 2  Negative

Axillary lymph node dissection (ALND) \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

Number of positive nodes (include both sentinel node biopsy and ALND results) \_\_\_\_\_

Number of nodes examined (include both sentinel node biopsy and ALND results) \_\_\_\_\_

Other, \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP**

Protocol Number:  N083E

**ON-STUDY FORM**

Patient ID Number: \_\_\_\_\_ Patient Initials: \_\_\_\_\_

L F M

Institution Number: \_\_\_\_\_

Institution: \_\_\_\_\_

**ALL ITEMS MUST BE COMPLETED** pg 2 of 2

**Are data amended? (check one)**  Yes  No  
*(if data are amended, please circle in red when using paper form)*

Any Previous Cancer: (check one) 2  No 1  Yes. If Yes, Site \_\_\_\_\_

Date of Diagnosis: (mm/dd/yyyy) \_\_/\_\_/\_\_\_\_

Treatment: \_\_\_\_\_

Other Current Diseases: (check one) 2  No 1  Yes. If Yes, specify \_\_\_\_\_

**Estrogen/Progesterone Data**

Most recent result prior to registration:

Estrogen (check one) Date: (mm/dd/yyyy) \_\_/\_\_/\_\_\_\_ Actual Score: \_\_ %  
1  Positive  
2  Negative  
3  Unknown

Progesterone (check one) Date: (mm/dd/yyyy) \_\_/\_\_/\_\_\_\_ Actual Score: \_\_ %  
1  Positive  
2  Negative  
3  Unknown

**Descriptive Factors**

Nodal Status: (check one) 1  Node Positive (axillary nodal dissection with 1-3+ nodes)  
2  Node Positive (axillary nodal dissection with 4-9+ nodes)  
3  Node Positive (axillary nodal dissection with 10+ nodes)  
4  Node Positive (positive sentinel node only without full axillary dissection)  
5  Node Negative (either by negative sentinel node or by axillary dissection)

Lapatinib starting dose level: (check one) 1  1000 mg/day 2  750 mg/day

Menopausal status: (check one) 1  Premenopausal (regular menstrual periods)  
2  Perimenopausal  
3  Postmenopausal (≥1 year since last menstrual period or history of bilateral oophorectomy)

Planned radiation therapy: (check one) 1  Yes 2  No

Planned hormonal therapy: (check one) 1  Tamoxifen  
2  Aromatase inhibitor  
3  None planned

Current use of hypertensive medications: (check one) 1  Yes 2  No

History of diabetes: (check one) 1  Yes 2  No

Smoking history: (check one) 1  Never smoked  
2  Current smoker  
If current smoker, current packs per day: \_\_\_\_\_  
How many years smoked: \_\_\_\_\_  
3  Former smoker (non-smoker for ≥6 months)  
If former smoker, record time since last smoked (in years): \_\_\_\_\_  
Number of packs per day when a smoker: \_\_\_\_\_  
How many years smoked: \_\_\_\_\_

Height: (cm) \_\_\_\_\_ .

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP  
PATHOLOGY REPORTING FORM  
BREAST CARCINOMA**

Protocol # N083E

Patient ID # \_\_\_\_\_ Initials: \_\_\_\_\_

L F M

Local ID # \_\_\_\_\_ Institution \_\_\_\_\_

Primary Pathologist: \_\_\_\_\_ No. of slides sent: \_\_\_\_\_

Clinic/Hospital: \_\_\_\_\_ Date sent: \_\_\_\_\_

Reviewer: \_\_\_\_\_ Slide No. \_\_\_\_\_ Sequence No. \_\_\_\_\_

I. Data Manager

1. DATE OF OPERATIVE PROCEDURE

/   /      
m m d d y y y y

\_\_\_\_\_ to \_\_\_\_\_  
\_\_\_\_\_ to \_\_\_\_\_

2. OPERATIVE PROCEDURE

- 1. Lumpectomy only
- 2. Mastectomy only
- 3. Lumpectomy and axillary dissection
- 4. Mastectomy and axillary dissection
- 5. Other (specify) \_\_\_\_\_

3. SIDE OF PRIMARY TUMOR (use one form for each side)

- 1. Right
- 2. Left

II. Information obtained from pathology report

4. SIZE OF PRIMARY NEOPLASM (Enter all 3 dimensions if possible OR the GREATEST dimension)

mm x    mm x    mm

5. HISTOLOGIC FEATURES OF PRIMARY NEOPLASM

A. HISTOLOGIC TYPE (Predominant)

- 1. Infiltrating ductal (scirrhous)
- 2. Medullary
- 3. Colloid (mucinous)
- 4. Tubular
- 5. Papillary
- 6. Infiltrating lobular
- 7. Intraductal, comedo
- 8. Intraductal, non-comedo
- 9. Other (specify): \_\_\_\_\_

B. HISTOLOGIC GRADE (Nottingham)

- 1. Well differentiated
- 2. Moderately differentiated
- 3. Poorly differentiated
- 9. Unknown

C. NUCLEAR GRADE

- 1. Grade 1
- 2. Grade 2
- 3. Grade 3

D. APPROXIMATE PERCENT OF INTRADUCTAL COMPONENT

- 1. 0-10%
- 2. 11-20%
- 3. 21-30%
- 4. >30%
- 9. Unknown

6. EXTENT OF LOCAL SPREAD

- 1. Confined to breast parenchyma
- 2. Involvement of breast parenchyma and skin (specify level of skin): \_\_\_\_\_
- 3. Involvement of breast parenchyma and fascia or muscle
- 4. Involvement of breast parenchyma, skin and muscle
- 5. Involvement of breast and chest wall (ribs and intercostal muscle)
- 6. Other (specify): \_\_\_\_\_

7. REGIONAL LYMPH NODE STATUS

- Number of nodes positive (specify location): \_\_\_\_\_
- Number of nodes examined
- Extracapsular spread 1. Yes 2. No
- Matted nodes 1. Yes 2. No

8. OTHER MICROSCOPIC FEATURES

- Pagets disease of nipple 1. Yes 2. No
- Infiltration of dermal lymphatics 1. Yes 2. No

9. TNM STAGING (for primary breast cancer)

- T (1,2,3,4)
- (a,b,c,d)
- N (0,1,2,3)

COMMENTS: \_\_\_\_\_

\_\_\_\_\_

NCCTG Study No.: N083E

Central Pathology ID Number: \_\_\_\_\_ Patient Initials: \_\_\_\_\_

L F M

Institution Number: \_\_\_\_\_

Institution: \_\_\_\_\_

**NORTH CENTRAL CANCER TREATMENT GROUP**

**PATHOLOGY SPECIMEN SUBMISSION FORM**

**INSTRUCTIONS:**

- Complete this form for eligibility determination and submit with the specimens.

Date specimen shipped: (dd-mth-yyyy) \_\_\_\_-\_\_\_\_-\_\_\_\_

Number of blocks sent: \_\_\_\_

Local ER/PgR Result:

ER Status: (check one) 1  Positive 2  Negative

ER: % cells stained positive \_\_\_\_% or  Mark an 'X' if NA (Not available)

PgR Status: (check one) 1  Positive 2  Negative 3  Not done

PgR: % cells stained positive \_\_\_\_% or  Mark an 'X' if NA (Not available)

Is the accession number (including block number) of the block used to determine the ER/PgR result (reported above) available? (check one) 2  No

1  Yes. If Yes, Accession number (including block number): \_\_\_\_\_

Local HER2 Results:

IHC: 1. Result: (check one) 1  Positive (3+ with >30% invasive cells)  
2  Equivocal (2+ with >10% invasive cells; or 3+ with >10% ≤ 30% invasive cells)  
3  Negative (0 or 1+)  
4  Not done / Not available

2. % of invasive tumor cells with strong complete membrane staining: \_\_\_\_%  
or  Mark an 'X' if NA (Not done / Not available)

3. Staining Antibody: (check one) 1  DAKO Herceptest [TM]  
2  DAKO A0485  
3  CB-11/Ventana Kit  
4  TAB-250  
5  NCL-c-erbB2-316  
6  Other, specify \_\_\_\_\_  
7  IHC not done

4. Is the accession number (including block number) of the block used to determine the IHC HER2 result (reported above) available? (check one)

2  No

1  Yes. If Yes, Accession number (including block number): \_\_\_\_\_

FISH: 1. Result (check one) 1  Amplified (>2.2)  
2  Equivocal (≥1.8, ≤2.2)  
3  Not amplified (<1.8)  
4  Not done

2. FISH HER2/neu chromosome 17 ratio (RG ratio) \_\_\_\_ . \_\_\_\_

3. Chromosome 17 copy number: (check one) 1  Polysomy (3 or more signals in ≥ 30% cells)  
2  Monosomy (1 or no signals in ≥ 60% cells)  
3  Normal  
4  Not done / Not available

NCCTG Study No.: N083E

Central Pathology ID Number: \_\_\_\_\_ Patient Initials: \_\_\_\_\_

L F M

Institution Number: \_\_\_\_\_

Institution: \_\_\_\_\_

**NORTH CENTRAL CANCER TREATMENT GROUP**

**PATHOLOGY SPECIMEN SUBMISSION FORM**

FISH: *(continued)*

4. FISH Kit or Test Type: *(check one)*

1  Ventana/Oncor probe

2  Vysis Tricolor probe

3  Ventana INFORM

4  Other, specify \_\_\_\_\_

5  FISH not done

5. Is the accession number (including block number) of the block used to determine the FISH HER2 result (reported above) available? *(check one)*

2  No

1  Yes. If Yes, Accession number (including block number): \_\_\_\_\_

Accession number including a block number (on the blocks sent):

*(The protocol requests one normal block and one tumor block. Please identify.)*

\_\_\_\_\_ This block is the: *(check one)*    1  Normal block    2  Tumor block

Specimen Type: *(check one)*    1  Biopsy    2  Surgical

\_\_\_\_\_ This block is the: *(check one)*    1  Normal block    2  Tumor block

Specimen Type: *(check one)*    1  Biopsy    2  Surgical

\_\_\_\_\_ This block is the: *(check one)*    1  Normal block    2  Tumor block

Specimen Type: *(check one)*    1  Biopsy    2  Surgical

\_\_\_\_\_ This block is the: *(check one)*    1  Normal block    2  Tumor block

Specimen Type: *(check one)*    1  Biopsy    2  Surgical

Comments:

**Institution Contact information for pathology materials: (Please Print)**

CRA/Nurse Contact: \_\_\_\_\_

Institution Name: \_\_\_\_\_

Street Address: \_\_\_\_\_

City: \_\_\_\_\_

State: \_\_\_\_\_ Zip: \_\_\_\_\_

Phone Number: \_\_\_\_\_

Fax Number: \_\_\_\_\_

E-mail Address: \_\_\_\_\_

Additional e-mail address for questions about tissue specimen *(optional)*: \_\_\_\_\_

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP**

Protocol Number: N083E

Patient ID: \_\_\_\_\_ Patient Initials: \_\_\_\_\_

L F M

Institution Number: \_\_\_\_\_

Institution: \_\_\_\_\_

**BASELINE  
ADVERSE EVENTS FORM**

**ALL ITEMS MUST BE COMPLETED**

Are data amended? (*check one*)  Yes  No  
(if data are amended, please circle in red when using paper form)

**Required Baseline Adverse Events from Section 10.0 of Protocol**

CTC Adverse Event Term	MedDRA Code (v. 10.0)	CTC Adverse Event Grade
<b>Baseline number of stools per day:</b> _____		
Left ventricular diastolic dysfunction	10049694	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Left ventricular systolic dysfunction	10024119	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Fatigue (asthenia, lethargy, malaise)	10016256	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Alkaline phosphatase	10001675	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
ALT, SGPT (serum glutamic pyruvic transaminase)	10001551	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
ALT, SGOT (serum glutamic oxaloacetic transaminase)	10003481	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Bilirubin (hyperbilirubinemia)	10004690	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Pain - <i>Selects</i>		
- Bone	10006002	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
- Muscle	10028411	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Cough	10011224	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3
Dyspnea (shortness of breath)	10013963	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP**

**NADIR/ADVERSE EVENT FORM**

**ALL ITEMS MUST BE COMPLETED**

Pg. 1 of 4

**Are data amended? (check one)  Yes  No**

(if data are amended, please circle in red when using paper form)

Protocol Number: N083E

Patient ID: \_\_\_\_\_ Patient Initials: \_\_\_\_\_

L F M

Institution Number: \_\_\_\_\_

Institution: \_\_\_\_\_

Current Cycle Number (nadir/adverse events associated with this cycle): \_\_\_\_\_

Date of evaluation: (mm/dd/yyyy) \_\_\_/\_\_\_/\_\_\_\_\_

Test	Nadir/Worst Date (Date of lab test) (mm/dd/yyyy)	Nadir/Worst Value (The nadir is the lowest value of counts occurring between two treatments. If the only count available is taken the day of retreatment, use that value as the nadir.)	Is nadir below LLN?  (check one)	CTC AE Attribution Code (If Grade >0)  1 = Unrelated 2 = Unlikely 3 = Possible 4 = Probable 5 = Definite	Has an adverse event expedited report been submitted?*(Enter 1 for Yes or 2 for No)
Platelets (PLT) K/uL or 10 <sup>9</sup> /L	___/___/_____	_____.	1 <input type="checkbox"/> Yes → 2 <input type="checkbox"/> No (Go to Hgb)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	_____
Hemoglobin (Hgb) g/dL	___/___/_____	_____.	1 <input type="checkbox"/> Yes → 2 <input type="checkbox"/> No → (Go to ANC)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	_____
Absolute Neutrophil Count (ANC) K/uL or 10 <sup>9</sup> /L	___/___/_____	_____.	1 <input type="checkbox"/> Yes → 2 <input type="checkbox"/> No → (Go to Adverse Event)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	_____

CTC Adverse Event Term	MedDRA Code (v. 10.0) (must be completed)	CTC Adverse Event Grade (highest grade this cycle)  <b>INCLUDE GRADE 0's</b>	CTC AE Attribution Code (If Grade > 0)  1 = Unrelated 2 = Unlikely 3 = Possible 4 = Probable 5 = Definite	Has an adverse event expedited report been submitted?*(Enter 1 for Yes or 2 for No)
------------------------	--	---	--	---

**Required Adverse Events from Section 10.0 of Protocol**

Allergic reaction/hypersensitivity (including drug fever)	10020751	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	_____
Left ventricular diastolic dysfunction	10049694	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	_____
Left ventricular systolic dysfunction	10024119	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	_____
Fatigue (asthenia, lethargy, malaise)	10016256	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	_____

\* See Section 10.0 of the protocol.

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP**

**NADIR/ADVERSE EVENT FORM**

**ALL ITEMS MUST BE COMPLETED**

Pg. 2 of 4

**Are data amended? (check one)  Yes  No**

(if data are amended, please circle in red when using paper form)

Protocol Number: N083E

Patient ID: \_\_\_\_\_ Patient Initials: \_\_\_\_\_

L F M

Institution Number: \_\_\_\_\_

Institution: \_\_\_\_\_

Current Cycle Number (nadir/adverse events associated with this cycle): \_\_\_\_\_

CTC Adverse Event Term	MedDRA Code (v. 10.0) (must be completed)	CTC Adverse Event Grade (highest grade this cycle)  <b>INCLUDE GRADE 0's</b>	CTC AE Attribution Code (If Grade > 0)  1 = Unrelated 2 = Unlikely 3 = Possible 4 = Probable 5 = Definite	Has an adverse event expedited report been submitted?*(Enter 1 for Yes or 2 for No)
------------------------	---	--	---	---

**Required Adverse Events from Section 10.0 of Protocol**

Rash/desquamation	10037853	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	___
Diarrhea	10012727	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	___
Mucositis/stomatitis (clinical exam) - <i>Selects</i>				
- Oral Cavity	10056848	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	___
- Pharynx	10065717	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	___
Mucositis/stomatitis (functional/symptomatic) - <i>Selects</i>				
- Oral Cavity	10028130	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	___
- Pharynx	10065881	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	___
Nausea	10028813	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	___
Vomiting	10047700	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	___
Alkaline phosphatase	10001675	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	___
ALT, SGPT (serum glutamic pyruvic transaminase)	10001551	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	___
AST, SGOT (serum glutamic oxaloacetic transaminase)	10003481	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	___
Bilirubin (hyperbilirubinemia)	10004690	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	___
Neuropathy: motor	10034580	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	___
Neuropathy: sensory	10034620	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	___

\* See Section 10.0 of the protocol.

PLACE LABEL HERE

Protocol Number: N083E

Patient ID: \_\_\_\_\_ Patient Initials: \_\_\_\_\_

L F M

Institution Number: \_\_\_\_\_

Institution: \_\_\_\_\_

**NORTH CENTRAL CANCER TREATMENT GROUP**

**ADVERSE EVENT FORM**

**ALL ITEMS MUST BE COMPLETED**

Pg. 3 of 4

**Are data amended? (check one)**  Yes  No  
*(if data are amended, please circle in red when using paper form)*

Current Cycle Number (*adverse events associated with this cycle*): \_\_\_\_\_

CTC Adverse Event Term	<b>MedDRA Code (v. 10.0)</b> <i>(must be completed)</i>	CTC Adverse Event Grade <i>(highest grade this cycle)</i>  <b>INCLUDE GRADE 0's</b>	CTC AE Attribution Code <b>(If Grade &gt; 0)</b>  1 = Unrelated 2 = Unlikely 3 = Possible 4 = Probable 5 = Definite	Has an adverse event expedited report been submitted?* <i>(Enter 1 for Yes or 2 for No)</i>
------------------------	--	--	--	--

**Required Adverse Events from Section 10.0 of Protocol**

*Pain - Selects*

- Bone	10006002	0 1 2 3 4	1 2 3 4 5	_____
- Muscle	10028411	0 1 2 3 4	1 2 3 4 5	_____
Cough	10011224	0 1 2 3	1 2 3 4 5	_____
Dyspnea (shortness of breath)	10013963	0 1 2 3 4 5 (death)	1 2 3 4 5	_____

\* See Section 10.0 of the protocol.

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP**

Protocol Number: N083E

Patient ID: \_\_\_\_\_ Patient Initials: \_\_\_\_\_

L F M

Institution Number: \_\_\_\_\_

Institution: \_\_\_\_\_

**NADIR/ADVERSE EVENT FORM**

**ALL ITEMS MUST BE COMPLETED**

Pg. 4 of 4

Are data amended? (*check one*)  Yes  No  
 (if data are amended, please circle in red when using paper form)

Current Cycle Number (*adverse events associated with this cycle*): \_\_\_\_\_

Were (*other*) adverse events assessed during this report period?

1  Yes, and reportable adverse events occurred

3  Yes, but no reportable adverse events occurred (*Stop here*)

2  No (*Stop here*)



**Adverse Events\*\* beyond those required in Section 10.0 of the protocol. Record grade 2 with attribution of possible, probable or definite and all grade 3, 4 and 5 regardless of attribution.**

Other CTC Adverse Event Term not listed	MedDRA Code (v. 10.0) ( <i>must be completed</i> )	CTC Adverse Event Grade ( <i>highest grade this cycle</i> )	CTC AE Attribution Code ( <i>If Grade &gt; 0</i> ) 1 = Unrelated 2 = Unlikely 3 = Possible 4 = Probable 5 = Definite	Has an adverse event expedited report been submitted?*( <i>Enter 1 for Yes or 2 for No</i> )
	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	—
	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	—
	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	—
	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	—
	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	—
	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	—
	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	—
	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	—
	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	—
	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	—
	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	—

\* See Section 10.0 of the protocol.

\*\* Both hematologic (*except for the nadirs listed on page 1*) and nonhematologic Adverse Events must be graded on this form as applicable.

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N083E

Patient ID: \_\_\_\_\_ Patient Initials: \_\_\_\_\_  
L F M

Institution Number: \_\_\_\_\_

Institution: \_\_\_\_\_

**BLOOD SPECIMEN SUBMISSION FORM  
ALL ITEMS MUST BE COMPLETED**

**Are data amended? (check one)**  Yes  No  
*(if data are amended, please circle in red when using paper form)*

**INSTRUCTIONS:**

*Complete this form for all patients and enter into the remote data entry system within 7 days of specimen collection. See Section 14 of the protocol for specimen requirements and shipment. Submit one form per each time point.*

Time point: *(check one)*

- 1  Prior to Cycle 1 treatment (*baseline*)
- 2  Prior to treatment on Cycle 7, Day 1 (*Week 19-20*)
- 3  At the end of all study treatment (*Week 52, including those who stop prior to Week 52*)
- 4  At recurrence

Was a research blood specimen collected? *(check one)*

- 1  Yes. If Yes: Date of collection: (*mm/dd/yyyy*)   /  /   \_\_\_\_\_  
Date sent: (*mm/dd/yyyy*)   /  /   \_\_\_\_\_

- 2  No. If No, reason: \_\_\_\_\_

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP**

**BASELINE  
TISSUE SPECIMEN SUBMISSION FORM**

**ALL ITEMS MUST BE COMPLETED**

**Are data amended? (check one)**  Yes  No  
*(if data are amended, please circle in red when using paper form)*

Protocol Number: N083E  
Patient ID: \_\_\_\_\_ Patient Initials: \_\_\_\_\_  
L F M  
Institution Number: \_\_\_\_\_  
Institution: \_\_\_\_\_

**INSTRUCTIONS:**

- Complete this form **for all patients** and enter into the remote data entry system within 30 days of study entry.
- See Section 17 of the protocol for specimen requirements and shipment.
- Include a copy of this form with tissue submission (see Section 17).

Was a research tissue specimen collected? (check one)

- 1  Yes. If Yes: Date of collection: (mm/dd/yyyy) \_\_\_/\_\_\_/\_\_\_\_\_  
Date Specimen Shipped: (mm/dd/yyyy) \_\_\_/\_\_\_/\_\_\_\_\_  
2  No. If No, reason: \_\_\_\_\_

**Institution Contact Information: (Please Print)**

Contact Person at Institution (CRA/Nurse):

\_\_\_\_\_

Institution Name: \_\_\_\_\_

Street Address: \_\_\_\_\_

\_\_\_\_\_

City: \_\_\_\_\_

State: \_\_\_\_\_

Zip Code: \_\_\_\_\_

Phone Number: \_\_\_\_\_

Fax Number: \_\_\_\_\_

E-mail Address: \_\_\_\_\_

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP**

**BASELINE  
CONCURRENT TREATMENT FORM**

**ALL ITEMS MUST BE COMPLETED**

**Are data amended? (check one)**  Yes  No  
*(if data are amended, please circle in red when using paper form)*

Protocol Number: N083E

Patient ID: \_\_\_\_\_ Patient Initials: \_\_\_\_\_

L F M

Institution Number: \_\_\_\_\_

Institution: \_\_\_\_\_

Date of evaluation: (mm/dd/yyyy) \_\_\_/\_\_\_/\_\_\_\_\_

Is the patient taking any concomitant medications? (check one)

1  Yes      2  No (Stop here)

If Yes, enter all medications (including prescription, over-the-counter, and alternative medications)

Concomitant Medication

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP**

**ACTIVE MONITORING  
CONCURRENT TREATMENT FORM**

**ALL ITEMS MUST BE COMPLETED**

**Are data amended? (check one)**  Yes  No  
*(if data are amended, please circle in red when using paper form)*

Protocol Number: N083E

Patient ID: \_\_\_\_\_ Patient Initials: \_\_\_\_\_  
L F M

Institution Number: \_\_\_\_\_

Institution: \_\_\_\_\_

Current Cycle Number: \_\_\_\_\_

Date of evaluation: (mm/dd/yyyy) \_\_\_/\_\_\_/\_\_\_\_

Has there been any change in medications since the previous visit? (check one)

1  Yes      2  No (Stop here)

If Yes, enter medications (including prescription, over-the-counter, and alternative medications) that have not been previously reported, no longer being taken or have a dose and/or schedule change.

Concomitant Medication	Concomitant Medication Reason: 1= New medication 2= Medication no longer being taken 3= Dose and/or schedule change
	_____
	_____
	_____
	_____
	_____
	_____
	_____
	_____
	_____
	_____

PLACE LABEL HERE

Protocol Number: N083E

Patient ID: \_\_\_\_\_ Patient Initials: \_\_\_\_\_

L F M

Institution Number: \_\_\_\_\_

Institution: \_\_\_\_\_

**NORTH CENTRAL CANCER TREATMENT GROUP  
CYCLES 1-6**

**EVALUATION/TREATMENT FORM**

pg 1 of 4

**ALL ITEMS MUST BE COMPLETED**

**Are data amended? (check one)**  Yes  No  
*(if data are amended, please circle in red when using paper form)*

**Use one form per cycle, one column per agent.**

Current Cycle Number: \_\_\_\_\_

Weight (kg): \_\_\_\_\_ . \_\_\_\_\_

*(used for this cycle, round to the nearest tenth)*

ECOG Performance Status: *(check one)*  0  1  2  3  4

*(used for this cycle)*

BSA (m<sup>2</sup>): *(used for this cycle)* \_\_\_\_\_ . \_\_\_\_\_

Was this cycle of treatment held (Day 1)? *(check one)* 1  Yes, planned 2  No 3  Yes, unplanned

*(If Yes, planned or unplanned) Primary reason treatment held: (check one)*

186  Blood/Bone Marrow

154  Metabolic/Laboratory

60  Gastrointestinal

70  Neurology

79  Cardiac General

97  Infection

45  Dermatology/Rash/Skin

38  Other non-hematologic adverse events

99  Other (not per protocol), specify \_\_\_\_\_

Agent	Docetaxel (TATER)
Agent Start Date <i>(this cycle) (mm/dd/yyyy)</i>	____/____/____
Initial Dose <i>(dose level day one this cycle)</i> <i>(If agent was not given this cycle, enter the dose level received on last day of treatment.)</i>	_____ mg/m <sup>2</sup>
Total Dose of Agents/Drugs for this cycle <i>(If agent was not given this cycle, enter 0 for total dose.)</i>	_____ mg
Dose (Level) modification <i>(Day 1)</i>	1 <input type="checkbox"/> Yes, planned 3 <input type="checkbox"/> Yes, unplanned 2 <input type="checkbox"/> No
Reason Modified <i>(If Yes, planned or unplanned, Primary Reason for Dose (Level) modification per Section 8.0). Not BSA changes.</i>  <i>(Check one)</i>	126 <input type="checkbox"/> Constitutional Symptoms (fatigue) 45 <input type="checkbox"/> Dermatology/rash/skin 60 <input type="checkbox"/> Gastrointestinal 70 <input type="checkbox"/> Neurology 97 <input type="checkbox"/> Infection 154 <input type="checkbox"/> Metabolic/Laboratory 49 <input type="checkbox"/> Allergy/Immunology 38 <input type="checkbox"/> Other non-hematologic adverse events 99 <input type="checkbox"/> Other (not per protocol), specify _____
Was (agent) omitted this cycle?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No

PLACE LABEL HERE

Protocol Number: N083E

Patient ID: \_\_\_\_\_ Patient Initials: \_\_\_\_\_  
L F M

Institution Number: \_\_\_\_\_

Institution: \_\_\_\_\_

**NORTH CENTRAL CANCER TREATMENT GROUP  
CYCLES 1-6**

**EVALUATION/TREATMENT FORM**

pg 2 of 4

**ALL ITEMS MUST BE COMPLETED**

**Are data amended? (check one)**  Yes  No  
(if data are amended, please circle in red when using paper form)

**Use one form per cycle, one column per agent.**

Agent	Carboplatin (CBDCA)
Agent Start Date (this cycle) (mm/dd/yyyy)	___/___/___
Initial Dose (dose level day one this cycle) (If agent was not given this cycle, enter the dose level received on last day of treatment.)	6 <input type="checkbox"/> AUC 6 5 <input type="checkbox"/> AUC 5 4 <input type="checkbox"/> AUC 4
Total Dose of Agents/Drugs for this cycle (If agent was not given this cycle, enter 0 for total dose.)	_____ mg
Dose (Level) modification (Day 1)	1 <input type="checkbox"/> Yes, planned 3 <input type="checkbox"/> Yes, unplanned 2 <input type="checkbox"/> No
Reason Modified (If Yes, planned or unplanned, <b>Primary Reason</b> for Dose (Level) modification per Section 8.0). Not BSA changes.  (Check one)	126 <input type="checkbox"/> Constitutional Symptoms (fatigue) 60 <input type="checkbox"/> Gastrointestinal (diarrhea) 70 <input type="checkbox"/> Neurology 97 <input type="checkbox"/> Infection 49 <input type="checkbox"/> Allergy/Immunology 38 <input type="checkbox"/> Other non-hematologic adverse events 99 <input type="checkbox"/> Other (not per protocol), specify _____
Was (agent) omitted this cycle?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No

PLACE LABEL HERE

Protocol Number: N083E

Patient ID: \_\_\_\_\_ Patient Initials: \_\_\_\_\_  
L F M

Institution Number: \_\_\_\_\_

Institution: \_\_\_\_\_

**NORTH CENTRAL CANCER TREATMENT GROUP  
CYCLES 1-6**

**EVALUATION/TREATMENT FORM**

pg 3 of 4

**ALL ITEMS MUST BE COMPLETED**

**Are data amended? (check one)**  Yes  No  
*(if data are amended, please circle in red when using paper form)*

**Use one form per cycle, one column per agent.**

Agent	Trastuzumab (HERCEP)
Agent Start Date ( <i>this cycle</i> ) (mm/dd/yyyy)	___/___/_____
Initial Dose ( <i>dose level day one this cycle</i> ) ( <i>If agent was not given this cycle, enter the dose level received on last day of treatment.</i> )	mg/kg
Total Dose of Agents/Drugs for this cycle ( <i>If agent was not given this cycle, enter 0 for total dose.</i> )	mg
Dose (Level) modification ( <i>Days 1, 8, 15</i> )	1 <input type="checkbox"/> Yes, planned 3 <input type="checkbox"/> Yes, unplanned 2 <input type="checkbox"/> No
Reason Modified ( <i>If Yes, planned or unplanned, <b>Primary Reason</b> for Dose (Level) modification per Section 8.0). Not BSA changes. (Check one)</i> )	79 <input type="checkbox"/> Cardiac General 140 <input type="checkbox"/> Pulmonary 38 <input type="checkbox"/> Other non-hematologic adverse events 99 <input type="checkbox"/> Other (not per protocol), specify _____
Was (agent) omitted this cycle?	1 <input type="checkbox"/> Yes    2 <input type="checkbox"/> No
If Yes, which days were omitted? ( <i>check all that apply</i> )	<input type="checkbox"/> 1 <input type="checkbox"/> 8 <input type="checkbox"/> 15

PLACE LABEL HERE

Protocol Number: N083E

Patient ID: \_\_\_\_\_ Patient Initials: \_\_\_\_\_  
L F M

Institution Number: \_\_\_\_\_

Institution: \_\_\_\_\_

**NORTH CENTRAL CANCER TREATMENT GROUP  
CYCLES 1-6**

**EVALUATION/TREATMENT FORM**

pg 4 of 4

**ALL ITEMS MUST BE COMPLETED**

**Are data amended? (check one)**  Yes  No  
*(if data are amended, please circle in red when using paper form)*

**Use one form per cycle, one column per agent.**

Agent	Lapatinib (TYKERB)
Agent Start Date ( <i>this cycle</i> ) (mm/dd/yyyy)	___/___/_____
Initial Dose ( <i>dose level day one this cycle</i> ) ( <i>If agent was not given this cycle, enter the dose level received on last day of treatment.</i> )	_____ mg
Total Dose of Agents/Drugs for this cycle ( <i>If agent was not given this cycle, enter 0 for total dose.</i> )	_____ mg
Dose (Level) modification	1 <input type="checkbox"/> Yes, planned 3 <input type="checkbox"/> Yes, unplanned 2 <input type="checkbox"/> No
Reason Modified ( <i>If Yes, planned or unplanned, <b>Primary Reason</b> for Dose (Level) modification per Section 8.0). Not BSA changes.</i> )  ( <i>Check one</i> )	45 <input type="checkbox"/> Dermatology/rash/skin 79 <input type="checkbox"/> Cardiac General 60 <input type="checkbox"/> Gastrointestinal 154 <input type="checkbox"/> Metabolic/laboratory 140 <input type="checkbox"/> Pulmonary 38 <input type="checkbox"/> Other non-hematologic adverse events 99 <input type="checkbox"/> Other (not per protocol), specify _____
Was (agent) omitted this cycle?	1 <input type="checkbox"/> Yes    2 <input type="checkbox"/> No

PLACE LABEL HERE

Protocol Number: N083E

Patient ID: \_\_\_\_\_ Patient Initials: \_\_\_\_\_  
L F M

Institution Number: \_\_\_\_\_

Institution: \_\_\_\_\_

**NORTH CENTRAL CANCER TREATMENT GROUP  
CYCLES 7-18**

**EVALUATION/TREATMENT FORM**

pg 1 of 2

**ALL ITEMS MUST BE COMPLETED**

**Are data amended? (check one)**  Yes  No  
*(if data are amended, please circle in red when using paper form)*

**Use one form per cycle, one column per agent.**

Agent	Trastuzumab (HERCEP)
Agent Start Date ( <i>this cycle</i> ) (mm/dd/yyyy)	___/___/____
Initial Dose ( <i>dose level day one this cycle</i> ) ( <i>If agent was not given this cycle, enter the dose level received on last day of treatment.</i> )	mg/kg
Total Dose of Agents/Drugs for this cycle ( <i>If agent was not given this cycle, enter 0 for total dose.</i> )	mg
Dose (Level) modification	1 <input type="checkbox"/> Yes, planned 3 <input type="checkbox"/> Yes, unplanned 2 <input type="checkbox"/> No
Reason Modified ( <i>If Yes, planned or unplanned, <b>Primary Reason</b> for Dose (Level) modification per Section 8.0). Not BSA changes. (Check one)</i> )	79 <input type="checkbox"/> Cardiac General 140 <input type="checkbox"/> Pulmonary 38 <input type="checkbox"/> Other non-hematologic adverse events 99 <input type="checkbox"/> Other (not per protocol), specify _____
Was (agent) omitted this cycle?	1 <input type="checkbox"/> Yes    2 <input type="checkbox"/> No

PLACE LABEL HERE

Protocol Number: N083E

Patient ID: \_\_\_\_\_ Patient Initials: \_\_\_\_\_  
L F M

Institution Number: \_\_\_\_\_

Institution: \_\_\_\_\_

**NORTH CENTRAL CANCER TREATMENT GROUP  
CYCLES 7-18**

**EVALUATION/TREATMENT FORM**

pg 2 of 2

**ALL ITEMS MUST BE COMPLETED**

**Are data amended? (check one)**  Yes  No  
(if data are amended, please circle in red when using paper form)

**Use one form per cycle, one column per agent.**

Agent	Lapatinib (TYKERB)
Agent Start Date ( <i>this cycle</i> ) (mm/dd/yyyy)	___/___/_____
Initial Dose ( <i>dose level day one this cycle</i> ) ( <i>If agent was not given this cycle, enter the dose level received on last day of treatment.</i> )	_____ mg
Total Dose of Agents/Drugs for this cycle ( <i>If agent was not given this cycle, enter 0 for total dose.</i> )	_____ mg
Dose (Level) modification	1 <input type="checkbox"/> Yes, planned 3 <input type="checkbox"/> Yes, unplanned 2 <input type="checkbox"/> No
Reason Modified ( <i>If Yes, planned or unplanned, <b>Primary Reason</b> for Dose (Level) modification per Section 8.0). Not BSA changes.</i> )  ( <i>Check one</i> )	45 <input type="checkbox"/> Dermatology/rash/skin 79 <input type="checkbox"/> Cardiac General 60 <input type="checkbox"/> Gastrointestinal 154 <input type="checkbox"/> Metabolic/laboratory 140 <input type="checkbox"/> Pulmonary 38 <input type="checkbox"/> Other non-hematologic adverse events 99 <input type="checkbox"/> Other (not per protocol), specify _____
Was (agent) omitted this cycle?	1 <input type="checkbox"/> Yes    2 <input type="checkbox"/> No

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP**

**MUGA/ECHO REPORTING FORM**

**ALL ITEMS MUST BE COMPLETED**

**Are data amended? (check one)**  Yes  No  
*(if data are amended, please circle in red when using paper form)*

Protocol Number: N083E

Patient ID: \_\_\_\_\_ Patient Initials: \_\_\_\_\_

L F M

Institution Number: \_\_\_\_\_

Institution: \_\_\_\_\_

Time Point of Current MUGA/echocardiogram: *(check one)*

- 1  Baseline
- 2  Cycle 6 Day  $\geq 15$
- 3  Cycle 12
- 4  Cycle 18
- 5  18 months post-randomization
- 6  2 years post-randomization
- 7  3 years post-randomization
- 8  4 years post-randomization
- 9  5 years post-randomization

Date of Current MUGA/echocardiogram: *(mm/dd/yyyy)* \_\_\_/\_\_\_/\_\_\_\_\_

Was this a: *(check one)*

- 1  Resting MUGA
- 2  Echocardiogram
- 3  Stress MUGA

Current MUGA/echocardiogram LVEF \_\_\_ . \_\_\_ %

Is patient symptomatic?

1  Yes. If Yes, symptoms patient has experienced: *(check all that apply)*

- Shortness of breath on exertion
- Neck vein distension
- Peripheral edema
- Other (specify) \_\_\_\_\_

2  No. If No, Is patient receiving medications for acute treatment or for ongoing management of CHF?

1  Yes. If Yes, medications for CHF *(check all that apply)*

- ACE Inhibitor
- Beta-blocker
- Diuretic
- Other (specify): \_\_\_\_\_
- Digoxin

2  No

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP**

**CARDIAC DEATH REPORT FORM**

**ALL ITEMS MUST BE COMPLETED**

**Are data amended? (check one)**  Yes  No  
*(if data are amended, please circle in red when using paper form)*

Protocol Number: N083E

Patient ID: \_\_\_\_\_ Patient Initials: \_\_\_\_\_  
L F M

Institution Number: \_\_\_\_\_

Institution: \_\_\_\_\_

Date of cardiac death: (mm/dd/yyyy) \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_

Nature of cardiac death: (check one)

- 1  CHF
- 2  Myocardial infarction
- 3  Arrhythmia

Narrative description of cardiac death: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

*Fax this form with all pertinent documentation to the **NCCTG QCS (507/538-0269)**. Pertinent documentation that must be faxed along with this form includes, but is not limited to, the following information: related MUGA scan or echocardiogram reports, cardiology consult note, medical oncologist's note, and CT scan report and chest x-ray report if applicable.*

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP**

**CONGESTIVE HEART FAILURE REPORT FORM**

**ALL ITEMS MUST BE COMPLETED**

**Are data amended? (check one)**  Yes  No  
*(if data are amended, please circle in red when using paper form)*

Protocol Number: N083E

Patient ID: \_\_\_\_\_ Patient Initials: \_\_\_\_\_

L F M

Institution Number: \_\_\_\_\_

Institution: \_\_\_\_\_

Date of onset of symptoms: (mm/dd/yyyy) \_\_ \_\_/\_\_ \_\_/\_\_\_\_

Diagnosis: (check one)

1  Congestive heart failure confirmed

2  Other diagnosis (specify): \_\_\_\_\_

Symptoms patient has experienced: (check all that apply)

Shortness of breath on exertion

Neck vein distension

Peripheral edema

Other (specify): \_\_\_\_\_

Date of MUGA/echocardiogram related to diagnosis: (mm/dd/yyyy) \_\_ \_\_/\_\_ \_\_/\_\_\_\_

Was this a: (check one)

1  MUGA

2  Echocardiogram

LVEF from MUGA/echocardiogram: \_\_ \_\_ . \_\_ %

*Fax this form with all pertinent documentation to the **NCCTG QCS (507/538-0269)**. Pertinent documentation that must be faxed along with this form includes, but is not limited to, the following information: related MUGA scan or echocardiogram reports, cardiology consult note, medical oncologist's progress note, discharge summary, symptoms of congestive heart failure, CT scan report and chest x-ray report, cardiac enzymes and troponin test results, medications given for acute treatment and maintenance of congestive heart failure event (e.g. ACE inhibitors, beta-blockers, diuretics), history and physical, and amounts of AC, Taxol and Herceptin given to the patient.*

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP**

**ADJUVANT BREAST CANCER RADIOTHERAPY  
REPORT FORM**

**ALL ITEMS MUST BE COMPLETED**

pg 1 of 2

**Are data amended? (check one) Yes  No**

*(if data are amended, please circle in red when using paper form)*

Protocol Number: N083E

Patient ID: \_\_\_\_\_ Patient Initials: \_\_\_\_\_

L F M

Institution Number: \_\_\_\_\_

Institution: \_\_\_\_\_

Has this patient received radiotherapy (prior to treatment failure or second primary cancer)? (check one)

1  Yes

2  No. If No, reason patient did not receive radiotherapy: \_\_\_\_\_

**If the patient received radiotherapy, complete the remainder of this form.**

Date Radiotherapy began: (mm/dd/yyyy) \_\_\_/\_\_\_/\_\_\_

Date of last Radiotherapy: (mm/dd/yyyy) \_\_\_/\_\_\_/\_\_\_

Nature of Radiotherapy:

- 1  Whole-Breast Radiotherapy following Breast-Conserving Surgery
- 2  Whole-Breast and Regional Lymphatic Radiotherapy following Breast-Conserving Surgery
- 3  Post-Mastectomy Chest Wall Radiotherapy
- 4  Post-Mastectomy Chest Wall Radiotherapy plus Regional Lymphatic Radiotherapy

			Beam Energy	Total Dose (cGy)	Fraction No.	Elapsed Days
Primary	Breast/chest wall	photons	---	-----	---	---
		electrons	---	-----	---	---
Regional	Supraclavicular	photons	---	-----	---	---
	Axillary	photons	---	-----	---	---
Boost(s)	Breast/chest wall	photons	---	-----	---	---
		electrons	---	-----	---	---
		brachytherapy		-----		
Other (specify) _____		photons	---	-----	---	---
		electrons	---	-----	---	---
Other (specify) _____		photons	---	-----	---	---
		electrons	---	-----	---	---

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP**

**ADJUVANT BREAST CANCER RADIOTHERAPY  
REPORT FORM**

**ALL ITEMS MUST BE COMPLETED**

pg 2 of 2

**Are data amended? (check one)  Yes  No**

*(if data are amended, please circle in red when using paper form)*

Protocol Number: N083E

Patient ID: \_\_\_\_\_ Patient Initials: \_\_\_\_\_  
L F M

Institution Number: \_\_\_\_\_

Institution: \_\_\_\_\_

Discontinued early (*check one*)    2  No    1  Yes. If Yes, reason \_\_\_\_\_

Therapy Interruption?    2  No    1  Yes. If Yes, for each interruption indicate:

	# days	Reason
1st Interruption	__ __	_____
2nd Interruption	__ __	_____
3rd Interruption		_____

**NOTE: Report RT adverse events on the Adverse Event Log.**

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP**

Protocol Number: N083E

**END OF ACTIVE TREATMENT/CANCEL NOTIFICATION FORM**

Patient ID: \_\_\_\_\_ Patient Initials: \_\_\_\_\_

**Submit Once Per Patient**

Institution Number: \_\_\_\_\_ L F M

**ALL ITEMS MUST BE COMPLETED**

Institution: \_\_\_\_\_

**Are data amended? (check one)**  Yes  No  
*(if data are amended, please circle in red when using paper form)*

Last Date (any modality of) protocol therapy was given: (mm/dd/yyyy) \_\_\_/\_\_\_/\_\_\_\_\_  
*(date of last treatment dose on this study or date decision made not to initiate protocol treatment)*

Off Treatment Date: (mm/dd/yyyy) \_\_\_/\_\_\_/\_\_\_\_\_  
*(date decision was made to end active treatment or not to initiate protocol treatment)*

This patient will now go to: (check one)  
*(See Schema and Section 13.0 of the protocol)*

- 2  Event Monitoring (follow Event Monitoring schedule)
- 9  Off Study (cancels only)

Reason Treatment Ended <i>(check one)</i>	COMMENTS
1 <input type="checkbox"/> Treatment Completed Per Protocol Criteria	
2 <input type="checkbox"/> Patient Withdrawal/Refusal <b>After</b> Beginning Protocol Therapy	Specify:
24 <input type="checkbox"/> Patient Withdrawal/Refusal <b>Prior To</b> Beginning Protocol Therapy <i>(cancel)</i>	Specify:
3 <input type="checkbox"/> Adverse Event/Side Effects/Complications	Specify:
4 <input type="checkbox"/> Disease Progression, Relapse During Active Treatment*	Complete Event Monitoring Form
10 <input type="checkbox"/> Disease Progression Before Active Treatment	
5 <input type="checkbox"/> Alternative Therapy	Specify:
6 <input type="checkbox"/> Patient Off-Treatment For Other Complicating Disease	Specify:
7 <input type="checkbox"/> Death On Study	Complete Event Monitoring Form
8 <input type="checkbox"/> Other	Specify:

\* Submit documentation to verify progression. See Section 11.0 and Section 18.0 of protocol.

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP**

Protocol Number: N083E

Patient ID: \_\_\_\_\_ Patient Initials: \_\_\_\_\_

L F M

Institution Number: \_\_\_\_\_

Institution: \_\_\_\_\_

**EVENT MONITORING FORM**

**ALL ITEMS MUST BE COMPLETED**

Pg. 1 of 2

**Are data amended? (check one)**  Yes  No  
*(if data are amended, please circle in red when using paper form)*

**Were you able to obtain any information about the patient since the last report?\***

- 1  Yes. If Yes, complete rest of form.
- 2  No. If No, date of last attempt to contact patient: (mm/dd/yyyy) \_\_\_/\_\_\_/\_\_\_\_\_ (End form)

**Vital Status**

- 1  Alive Date of last contact or death: (mm/dd/yyyy) \_\_\_/\_\_\_/\_\_\_\_\_
- 2  Dead  
Primary Cause of Death: (check one) 1  Due to this disease 2  Due to other cause, specify \_\_\_\_\_  
4  Due to protocol treatment  
*(adverse event related to treatment)*

**Disease Follow-up Status**

- Has the patient had a documented clinical assessment for this cancer *(since submission of the last event monitoring form)?\**
- 2  No. If No, Go to Notice of New Primary.
- 1  Yes. If Yes, Cancer Follow-up Status Date: (mm/dd/yyyy) \_\_\_/\_\_\_/\_\_\_\_\_

**Notice of First Relapse or Progression in the Event Monitoring Phase**

Has the patient developed a first relapse or progression **that has not been previously reported** *(in event monitoring phase)?*

- 2  No 1  Yes. If Yes, Date of Relapse or Progression:\*\* (mm/dd/yyyy) \_\_\_/\_\_\_/\_\_\_\_\_

- Site(s) of Relapse or Progression: (check all that apply)
- |                                 |   |   |
|---------------------------------|---|---|
| <input type="checkbox"/> Bone   | <input type="checkbox"/> Axillary Nodes | <input type="checkbox"/> Intraclavicular nodes  |
| <input type="checkbox"/> Liver  | <input type="checkbox"/> Brain          | <input type="checkbox"/> Internal mammary nodes |
| <input type="checkbox"/> Lung   | <input type="checkbox"/> Skin           | <input type="checkbox"/> Ipsilateral breast     |
| <input type="checkbox"/> Axilla | <input type="checkbox"/> Chestwall      | <input type="checkbox"/> Other, specify _____   |

- Method(s) of Diagnosis:
- |  |                              |   |
|--|------------------------------|---|
| <input type="checkbox"/> Physical Exam | <input type="checkbox"/> MRI | <input type="checkbox"/> Chest x-ray            |
| <input type="checkbox"/> CT            | <input type="checkbox"/> ULT | <input type="checkbox"/> Patient correspondence |
|  |                              | <input type="checkbox"/> Other, specify _____   |

**Notice of First Subsequent Treatment**

Has the patient received subsequent treatment for this cancer **that has not been previously reported?**

- 2  No 3  Unknown 1  Yes. If Yes, (Start) Date of subsequent treatment: (mm/dd/yyyy) \_\_\_/\_\_\_/\_\_\_\_\_
- Subsequent Treatment Type: \_\_\_\_\_

**Notice of New Primary**

Has a new primary cancer or MDS (*myelodysplastic syndrome*) been diagnosed **that has not been previously reported?**

- 2  No 3  Unknown 1  Yes. If Yes, New Primary Cancer Date: (mm/dd/yyyy) \_\_\_/\_\_\_/\_\_\_\_\_
- Site of New Primary: \_\_\_\_\_

**Late Adverse Event (post completion of active monitoring)**

Has the patient experienced (prior to treatment for progression or relapse or a second primary, and prior to non-protocol treatment) any severe (grade  $\geq 3$ ) long term toxicity that has not been previously reported:

- Adverse events at least possibly attributed to treatment on this study.
- Death within 30 days of treatment.
- Death any time at least **possibly** treatment related.
- 2  No 3  Unknown 1  Yes. If Yes, Submit page 2 of the Event Monitoring Form for Late Adverse Event Reporting.

\*If this is the first event monitoring form check yes, enter cancer follow-up status date and complete the rest of the form. 12/17/2008  
 \*\*Submit documentation to verify PD. CDE

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP**

**EVENT MONITORING FORM  
(LATE ADVERSE EVENT REPORTING)**

**ALL ITEMS MUST BE COMPLETED**

Pg. 2 of 2

**Are data amended? (check one)**  Yes  No  
(if data are amended, please circle in red when using paper form)

Protocol Number: N083E

Patient ID: \_\_\_\_\_ Patient Initials: \_\_\_\_\_

L F M

Institution Number: \_\_\_\_\_

Institution: \_\_\_\_\_

The CTC AE v.3.0 will be used to evaluate the following adverse events:

CTC Adverse Event Term	MedDRA Code (v. 10.0) (must be completed)	CTC Adverse Event Grade (Highest Grade)	CTC AE Attribution Code 1 = Unrelated 2 = Unlikely 3 = Possible 4 = Probable 5 = Definite	Late Adverse Event Onset Date (mm/dd/yyyy)
	<input type="text"/>	<input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5 (death)	<input type="text"/> 1 <input type="text"/> 2 <input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5	___/___/___
	<input type="text"/>	<input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5 (death)	<input type="text"/> 1 <input type="text"/> 2 <input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5	___/___/___
	<input type="text"/>	<input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5 (death)	<input type="text"/> 1 <input type="text"/> 2 <input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5	___/___/___
	<input type="text"/>	<input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5 (death)	<input type="text"/> 1 <input type="text"/> 2 <input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5	___/___/___
	<input type="text"/>	<input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5 (death)	<input type="text"/> 1 <input type="text"/> 2 <input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5	___/___/___
	<input type="text"/>	<input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5 (death)	<input type="text"/> 1 <input type="text"/> 2 <input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5	___/___/___
	<input type="text"/>	<input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5 (death)	<input type="text"/> 1 <input type="text"/> 2 <input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5	___/___/___
	<input type="text"/>	<input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5 (death)	<input type="text"/> 1 <input type="text"/> 2 <input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5	___/___/___
	<input type="text"/>	<input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5 (death)	<input type="text"/> 1 <input type="text"/> 2 <input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5	___/___/___
	<input type="text"/>	<input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5 (death)	<input type="text"/> 1 <input type="text"/> 2 <input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5	___/___/___
	<input type="text"/>	<input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5 (death)	<input type="text"/> 1 <input type="text"/> 2 <input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5	___/___/___
	<input type="text"/>	<input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5 (death)	<input type="text"/> 1 <input type="text"/> 2 <input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5	___/___/___
	<input type="text"/>	<input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5 (death)	<input type="text"/> 1 <input type="text"/> 2 <input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5	___/___/___
	<input type="text"/>	<input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5 (death)	<input type="text"/> 1 <input type="text"/> 2 <input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5	___/___/___
	<input type="text"/>	<input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5 (death)	<input type="text"/> 1 <input type="text"/> 2 <input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5	___/___/___
	<input type="text"/>	<input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5 (death)	<input type="text"/> 1 <input type="text"/> 2 <input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5	___/___/___
	<input type="text"/>	<input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5 (death)	<input type="text"/> 1 <input type="text"/> 2 <input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5	___/___/___

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP**

Protocol Number: N083E

Patient ID: \_\_\_\_\_ Patient Initials: \_\_\_\_\_

L F M

Institution Number: \_\_\_\_\_

Institution: \_\_\_\_\_

**NOTIFICATION FORM**  
**Grade 4 or 5 Non-AER Reportable Events/Hospitalization**  
**ALL ITEMS MUST BE COMPLETED**

**INSTRUCTIONS:**

- Use this form to report all known information on non-AER reportable grade 4 or 5 adverse events or any hospitalization during active treatment.
- Verify reporting requirements listed within the study protocol, prior to entering into the remote data entry system.
- If AER has been submitted for this event do not enter this form.
- Fill out all information known.
- Enter into the remote data entry system within 5 working days of notification.
- These events must also be reported on the Nadir/Adverse Event Form.

Date membership CRA aware of event(s): (mm/dd/yyyy) \_\_\_/\_\_\_/\_\_\_\_\_

Name of Person Completing Form: \_\_\_\_\_ Phone: (\_\_\_\_\_) \_\_\_\_\_ - \_\_\_\_\_

Current Cycle Number: \_\_\_\_\_ Assigned Treatment Arm: \_\_\_\_\_

Event ≥ Grade 4: (check one) 1  Yes 2  No

Date of First Occurrence of Adverse Event (mm/dd/yyyy)	CTC Adverse Event Term (only one event per line)	CTC Adverse Event Grade	In your opinion, is this related to the study medication?*
___/___/_____		<input type="checkbox"/> 4 <input type="checkbox"/> 5	4 <input type="checkbox"/> Yes: Unlikely 1 <input type="checkbox"/> Yes: Possible, probable, or definite 2 <input type="checkbox"/> No 3 <input type="checkbox"/> Unknown
___/___/_____		<input type="checkbox"/> 4 <input type="checkbox"/> 5	4 <input type="checkbox"/> Yes: Unlikely 1 <input type="checkbox"/> Yes: Possible, probable, or definite 2 <input type="checkbox"/> No 3 <input type="checkbox"/> Unknown
___/___/_____		<input type="checkbox"/> 4 <input type="checkbox"/> 5	4 <input type="checkbox"/> Yes: Unlikely 1 <input type="checkbox"/> Yes: Possible, probable, or definite 2 <input type="checkbox"/> No 3 <input type="checkbox"/> Unknown
___/___/_____		<input type="checkbox"/> 4 <input type="checkbox"/> 5	4 <input type="checkbox"/> Yes: Unlikely 1 <input type="checkbox"/> Yes: Possible, probable, or definite 2 <input type="checkbox"/> No 3 <input type="checkbox"/> Unknown
___/___/_____		<input type="checkbox"/> 4 <input type="checkbox"/> 5	4 <input type="checkbox"/> Yes: Unlikely 1 <input type="checkbox"/> Yes: Possible, probable, or definite 2 <input type="checkbox"/> No 3 <input type="checkbox"/> Unknown

\*Answer YES if attribution is unlikely, possible, probable or definite; answer NO if unrelated; answer UNKNOWN if you are not sure. Verify if expedited reporting (e.g. ADEERS) is required (see protocol), based on relationship to study treatment.

**Hospitalization:** (check one) 1  Yes 2  No

If Yes: Hospital Admission Date: (mm/dd/yyyy) \_\_\_/\_\_\_/\_\_\_\_\_

Reason(s) for Hospitalization:

- 1  Adverse Event, specify type and grade: \_\_\_\_\_
- 2  Prophylactic, specify: \_\_\_\_\_
- 3  Other reason, specify \_\_\_\_\_

**Biospecimen Accessioning Processing**  
**Fax Supply Order Form – No Cover Sheet Necessary**  
Fax to Research Kit Building @ 507-538-4103

**NOTE: Form must be either typed or printed legibly and filled out completely.**

**Study ID:**   N083E  

**Investigator:** \_\_\_\_\_

**Order Placed By:** \_\_\_\_\_ **Phone #:** (    ) \_\_\_\_\_

**Email:** \_\_\_\_\_ **Fax #:** (    ) \_\_\_\_\_

**Complete Address (kits sent to):**

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**ALLOW AT LEAST TWO WEEKS TO RECEIVE THE KITS.**

**NOTE:** Kits will be sent via FedEx® Ground at no additional cost to the participating institutions. Kits will not be sent via rush delivery service unless the participating institution provides their own FedEx® account number or alternate billing number for express service. **The study will not cover the cost for rush delivery of kits.**

**Date Needed:** \_\_\_\_\_  
**(Please be specific)**

**Fed Ex account number (Rush deliveries only)** \_\_\_\_\_

**Type of Kits**

**# of Kits Needed**

N083E Custom Research Kit \_\_\_\_\_

\_\_\_\_\_

**Total Kits** \_\_\_\_\_

**Questions?** Contact the Biospecimen Resource Manager listed on the Protocol Resource page of the protocol.