

## FORMS PACKET

N064A, Phase II Study of Panitumumab, Chemotherapy, and External Beam Radiation  
in Patients with Locally Advanced Pancreatic Cancer

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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).”

The specific forms instructions take precedence over the generic forms instructions, so it is very important to review them in addition to the generic forms instructions.

Eligibility Checklist

03/19/2010  
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N064A: Phase II Study of Panitumumab, Chemotherapy, and External Beam Radiation in Patients with Locally Advanced Pancreatic Cancer

**To register a patient, access the NCCTG web page at <https://ncctg.mayo.edu/training> and enter the remote registration/randomization application.**

Has the patient ever been on a prior study entered through this Registration Office?  Yes  No

If yes: Prior study number \_\_\_\_\_; prior patient study ID number \_\_\_\_\_

Registration date (date on) (mm/dd/yyyy) ___/___/_____
Patient study ID number (provided at time of Reg/Random) _____
NCCTG member (participant sponsor) _____
NCCTG treating location (chemo) _____
(RT) _____
NCCTG treating physician (chemo) _____
(RT) _____
Institution patient number (local subject number) _____
IRB approval date (chemo) (mm/dd/yyyy) ___/___/_____ IRB approval date (RT) (mm/dd/yyyy) ___/___/_____
<b>Person Completing Form:</b>
Last Name: <b>(print)</b> _____ First Name: <b>(print)</b> _____
Phone: _____ Fax: _____ Email: _____

Patient initials (last, first, middle) _____ (For Mayo Rochester patients, include first four letters of last name.)	Race (check all that apply)
Gender (check one) <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Unknown	<input type="checkbox"/> White
Date of birth (mm/dd/yyyy) ___/___/_____	<input type="checkbox"/> Black or African American
Zip code _____	<input type="checkbox"/> Native Hawaiian or Other Pacific Islander
Country of Residence _____	<input type="checkbox"/> Asian
	<input type="checkbox"/> American Indian or Alaska Native
	<input type="checkbox"/> Not reported: Patient refused or not available
	<input type="checkbox"/> Unknown: Patient unsure
Method of payment (check one)	Ethnicity (check one)
<input type="checkbox"/> PI (Private Insurance)	<input type="checkbox"/> Not Hispanic or Latino
<input type="checkbox"/> MR (Medicare)	<input type="checkbox"/> Hispanic or Latino
<input type="checkbox"/> MRP (Medicare and Private Insurance)	<input type="checkbox"/> Not reported: Refused or data not available
<input type="checkbox"/> MD (Medicaid)	<input type="checkbox"/> Unknown: Unsure of their ethnicity
<input type="checkbox"/> MM (Medicaid and Medicare)	
<input type="checkbox"/> MVA (Military or Veterans Sponsored, Not Otherwise Specified (NOS))	
<input type="checkbox"/> MS (Military Sponsored [including CHAMPUS & TRCARE])	
<input type="checkbox"/> MV (Veterans Sponsored)	
<input type="checkbox"/> SP (Self pay [no insurance])	
<input type="checkbox"/> NP (No means of payment [no insurance])	
<input type="checkbox"/> OTH (Other)	
<input type="checkbox"/> UNK (Unknown)	

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

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

**Required Characteristics**

Yes No NA

Histologically or cytology confirmed unresectable adenocarcinoma of the pancreas (includes subtotal resection and gross residual disease). Measurable disease is not required (see Sections 11.0 and 11.2).	___	___	___
Disease that is encompassable within standard RT fields for pancreatic cancer.	___	___	___
Adequate oral nutrition.	___	___	___
Age ≥18 years. Age = _____.	___	___	___
The following laboratory values obtained ≤14 days prior to registration. Earliest laboratory test date ___/___/_____; latest laboratory test date ___/___/_____. NOTE: These dates pertain to the following labs only.	___	___	___
• <b>ANC ≥1500/mm<sup>3</sup></b> . ANC = _____.	___	___	___
• <b>Hgb ≥9 g/dL</b> . Hgb = _____.	___	___	___
• <b>PLT ≥100,000/mm<sup>3</sup></b> . PLT = _____.	___	___	___
• <b>Total bilirubin ≤3 x upper limit normal (UNL)</b> . Bilirubin = _____; UNL = _____. NOTE: Biliary stent placement or surgical bypass should be considered prior to treatment if impending bile duct obstruction by tumor.	___	___	___
• <b>AST ≤3 x UNL</b> . AST = _____; UNL = _____.	___	___	___
• <b>Creatinine ≤2.0 x UNL</b> . Creatinine = _____; UNL = _____.	___	___	___
• <b>Magnesium ≥LOWER limit of normal (LNL)</b> . Magnesium = _____; LNL = _____.	___	___	___
Ability and willingness to provide informed consent.	___	___	___
Willingness to return to an NCCTG institution for follow-up.	___	___	___
ECOG performance status (PS) 0 or 1. PS = _____.	___	___	___
Negative serum pregnancy test done ≤7 days prior to registration, for women of childbearing potential only. Not a woman of childbearing potential or male (check NA) vs. negative pregnancy test date ___/___/_____.	___	___	___

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

**Contraindications**

Yes No NA

Evidence of metastatic disease outside of the planned radiation therapy field.	___	___	___
Distant metastases (liver or lung metastases or peritoneal spread).	___	___	___
Microscopic residual disease only.	___	___	___
Laparotomy ≤21 days prior to registration. Laparotomy not done (check NA) vs. date of Laparotomy: ___/___/_____.	___	___	___
Any of the following: • Prior anti-EGFR antibody therapy (e.g., cetuximab) or treatment with small molecule EGFR inhibitors (e.g., gefitinib, erlotinib, lapatinib) • Prior or planned concurrent systemic chemotherapy other than that included in this study or biologic therapy, or in the context of a clinical trial. • Concurrent or prior malignancy unless disease-free ≥3 years except for non-melanoma skin cancer, carcinoma in situ of the cervix, Gleason Grade <7 organ confined prostate cancer. • Any previous treatment with radiation therapy that would overlap with planned RT fields.	___	___	___
Nausea or vomiting >Grade 1.	___	___	___
Chronic use of immunosuppressive agents (e.g., methotrexate, cyclosporine, corticosteroids).	___	___	___

NCCTG Eligibility Checklist N064A

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

Any of the following: <ul style="list-style-type: none"> <li>• Pregnant women</li> <li>• Nursing women</li> <li>• Men or women of childbearing potential who are unwilling to employ adequate contraception during the study and for 6 months after the last treatment with panitumumab.</li> </ul> <b>This study involves an investigational agent whose genotoxic, mutagenic, and teratogenic effects on the developing fetus and newborn are unknown.</b>	___ ___
Cystadenocarcinoma of the pancreas or pancreatic tumors of neuroendocrine origin.	___ ___
Uncontrolled intercurrent illness including, but not limited to, ongoing or active infection, or psychiatric illness/social situations that would limit compliance with study requirements.	___ ___
History or known presence of central nervous system (CNS) metastases.	___ ___
Clinically significant cardiovascular disease (New York Heart Association >Grade 2) including myocardial infarction, unstable angina, symptomatic congestive heart failure, serious uncontrolled cardiac arrhythmia ≤1 year before registration. New York Heart association classifications are provided on the NCCTG website at <a href="https://ncctg.mayo.edu/ncctg/forms/NonProtocolSpecificForms/">https://ncctg.mayo.edu/ncctg/forms/NonProtocolSpecificForms/</a>	___ ___
Known positive test(s) for human immunodeficiency virus infection, hepatitis C virus, acute, or chronic active hepatitis B infection.	___ ___
Enteral hyperalimentation	___ ___
Current, recent (≤4 weeks prior to registration), or planned participation in an experimental drug study other than this study with the exception of studies with specific interventions intended to treat rashes associated with EGFR (e.g., N05C4).	___ ___

**All responses in above section must be “No” unless specified as “NA.”**

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. <b>Non-USA institution only</b> (check NA) vs. Date of authorization ___/___/____.	___ ___ ___
Treatment on this protocol must commence at the accruing membership under the supervision of an NCCTG member physician.	___ ___
Treatment must begin ≤7 days after registration.	___ ___
Pretreatment tests/procedures must be completed ≤14 days prior to registration (see Section 4.0). Earliest pretreatment test date ___/___/____; latest pretreatment test date ___/___/____. <b>Note:</b> 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> <ul style="list-style-type: none"> <li>• <b>CT or MRI of abdomen</b> must be done ≤ 28 days prior to registration (see Section 4.0). Earliest exception test date (mm/dd/yyyy): ___/___/____. Latest exception test date (mm/dd/yyyy): ___/___/____.</li> </ul>	___ ___
All required baseline symptoms must be documented and graded.	___ ___
Study drug availability checked.	___ ___
A NCCTG radiation oncologist has seen the patient and confirms the patient is a suitable candidate for this study.	___ ___

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

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

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

**An optional translational research component is part of this study. There will be an option to select if the patient is to be registered onto this component (Sections 14.0 and 17.0).**

	Yes	No
• Patient has given permission to give blood samples for research testing planned as part of this study.	___	___
• Patient has given permission to give tissue sample for research testing planned as part of this study.	___	___

**At the time of registration/randomization, the following will also be recorded:**

	Yes	No
• Patient has given permission to keep blood sample(s) for use in future research to learn about, prevent, or treat cancer.	___	___
• Patient has given permission to keep blood 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).	___	___
• Patient has given NCCTG permission to give blood sample(s) to outside researchers.	___	___
• Patient has given permission to keep tissue sample(s) for use in future research to learn about, prevent, or treat cancer.	___	___
• Patient has given permission to keep tissue 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).	___	___
• Patient has given NCCTG permission to give tissue sample(s) to outside researchers.	___	___
• Patient has agreed to be enrolled on N0392, Assessment of Patient Satisfaction with Participation in Phase II/III NCCTG Clinical Trials.	___	___

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

Assigned Treatment:

\_\_\_ A) 5FU (or CAPCIT) + ABXEGF + GEMZAR + RT

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

Physician \_\_\_\_\_ Signature  
M - D - Y

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP**

Protocol Number: N064A

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

L F M

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

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

**ON-STUDY 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)*

**Description Of Primary Disease**

MedDRA codes: 10033612 [Pancreatic cancer (excluding Islets) NOS]  
10052747 [Adenocarcinoma of the pancreas]

Primary Tumor Site: Pancreas

Cell Type: \_\_\_\_\_

Differentiation (Grade) (check one) 1  Well 2  Moderate 3  Poor 4  Undifferentiated, anaplastic

Status of Primary Tumor (check one): 2  Resected with known residual 3  Unresected 4  Recurrent

**Chronology of Diagnoses:**

Dates (mm/dd/yyyy)

Primary \_\_\_\_\_

Recurrence of Primary \_\_\_\_\_

Previous Surgery Related to Tumor (check one) 1  Yes 2  No

If Yes:	DATE (mm/dd/yyyy)	Operative Procedure (Biopsies, Resections, Bypass, Explorations, etc.)
	____/____/____	
	____/____/____	
	____/____/____	
	____/____/____	

Current Symptoms and Diseases (check one) 1  Yes 2  No

If Yes:	Current Symptom/Disease	1 <input type="checkbox"/> Yes	2 <input type="checkbox"/> No
	Pain	1 <input type="checkbox"/> Yes	2 <input type="checkbox"/> No
	Diabetes	1 <input type="checkbox"/> Yes	2 <input type="checkbox"/> No

Any Previous Cancer: (check one) 1  Yes 2  No

If Yes: Site: \_\_\_\_\_

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

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

**Descriptive Factors**

Method of diagnosis (check one): 1  Percutaneous biopsy  
2  Endoscopic biopsy  
3  Open biopsy at laparotomy

Nodal status: (check one) 1  Positive 2  Negative

Nodal status method: (check one) 1  Clinical 2  Pathologic

Treatment regimen: (check one) 1  5FU 2  Capecitabine

Weight loss in preceding 6 months: (check one) 1  <5% 2  5 - 10% 3  >10%

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

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP**

Protocol Number: N064A

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

L F M

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

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

**PRETREATMENT  
RECIST MEASUREMENT 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**

1. Record the target lesions (per Section 11 of the protocol).
2. Measure target lesions in cm. using longest diameter (one dimension only).
3. Record measurements at pretreatment.
4. Maintain same type of assessment throughout study.
5. Record presence or absence of nontarget lesions at baseline, thereafter record the status of nontarget lesions at each required evaluation.

**Assessment Date** (mm/dd/yyyy) \_\_\_/\_\_\_/\_\_\_

(Assessment date is the date reflecting type of assessment, not the physician interpretation date).

Does the patient have measurable disease (per Section 11.0 of the protocol)? (check one)

- 1  Yes. If Yes, complete Target and Nontarget Lesions  
2  No. If No, go to Nontarget Lesions

Target Lesion Site(s)	Method of Evaluation				Longest Diameter of Lesion(s) (cm)
	CT <sup>2</sup>	Spiral CT <sup>3</sup>	MRI	CXR <sup>5</sup>	
1	2 <input type="checkbox"/>	13 <input type="checkbox"/>	3 <input type="checkbox"/>	5 <input type="checkbox"/>	
2	2 <input type="checkbox"/>	13 <input type="checkbox"/>	3 <input type="checkbox"/>	5 <input type="checkbox"/>	
3	2 <input type="checkbox"/>	13 <input type="checkbox"/>	3 <input type="checkbox"/>	5 <input type="checkbox"/>	
4	2 <input type="checkbox"/>	13 <input type="checkbox"/>	3 <input type="checkbox"/>	5 <input type="checkbox"/>	
5	2 <input type="checkbox"/>	13 <input type="checkbox"/>	3 <input type="checkbox"/>	5 <input type="checkbox"/>	
6	2 <input type="checkbox"/>	13 <input type="checkbox"/>	3 <input type="checkbox"/>	5 <input type="checkbox"/>	
7	2 <input type="checkbox"/>	13 <input type="checkbox"/>	3 <input type="checkbox"/>	5 <input type="checkbox"/>	
8	2 <input type="checkbox"/>	13 <input type="checkbox"/>	3 <input type="checkbox"/>	5 <input type="checkbox"/>	
9	2 <input type="checkbox"/>	13 <input type="checkbox"/>	3 <input type="checkbox"/>	5 <input type="checkbox"/>	
10	2 <input type="checkbox"/>	13 <input type="checkbox"/>	3 <input type="checkbox"/>	5 <input type="checkbox"/>	
<b>Sum of Longest Diameters of All Target Lesions:</b>					

<b>Nontarget Lesion</b> (check one)	1 <input type="checkbox"/> Yes (Present)	2 <input type="checkbox"/> No (Absent)
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2=CT scan  
3=Spiral CT scan  
5=Chest x-ray



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: N064A  
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).

Patient's Initial Consent given for tissue specimen use for research on the patient's cancer? (check one)

1  Yes. If Yes, complete rest of form.

2  No. If No, end form.

Was sample obtained? (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**

**ACTIVE MONITORING  
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)*

Protocol Number: N064A  
Patient ID: \_\_\_\_\_ Patient Initials: \_\_\_\_\_  
L F M  
Institution Number: \_\_\_\_\_  
Institution: \_\_\_\_\_

- Time point: (check one)
- 1  Cycle 1, Day 8
  - 2  Prior to Cycle 3, Day 1
  - 3  Prior to Treatment on Cycle 4, Day 15
  - 4  Prior to Cycle 6, Day 1
  - 5  At Recurrence
  - 6  Prior to Cycle 7, Day 15
  - 7  Prior to Cycle 9, Day 1
  - 8  Prior to Cycle 10, Day 15

**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.

Patient's Initial Consent given for blood specimen use for research on the patient's cancer? (check one)

- 1  Yes. If Yes, complete rest of form
- 2  No. If No, end form

Was sample obtained? (check one)

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

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

PATHOLOGY SUBMISSION FORM

(NOTE: This form is used to update the Outstanding Materials Report)

Protocol Number: N064A

Patient ID: Patient Initials: L F M

Institution Number:

Institution:

\*\* This form must be submitted to the NCCTG Operations Office at the time slides/blocks are sent to the NCCTG reviewer (see Pathology section of the protocol) \*\*

Date specimen shipped: (mm/dd/yyyy) \_ \_ / \_ \_ / \_ \_ \_ \_

Reviewer: (check one) [ ] Laurie Hauge, RN, OCN (see Section 17 for mailing address) [ ] Thomas Smyrk, M.D., Mayo Clinic Rochester - Rochester, MN

Number of slides sent: \_ \_ \_ \_

Accession number(s) (on the slides sent):

Grid for accession numbers on slides sent

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

Accession number(s) (on the blocks sent):

Grid for accession numbers on blocks sent

COMMENTS:

Comments section with horizontal lines

Institution Contact Information: (Please Print)

Contact Person at Institution (CRA/Nurse):

Contact information fields: Institution Name, Street Address, City, State, Zip Code, Phone Number, Fax Number, E-mail Address

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP**

**PATHOLOGY REPORTING FORM**

**PANCREAS CARCINOMA**

Protocol Number: N064A

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

L F M

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

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

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

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

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

I. CRA/RN

1. DATE OF OPERATIVE PROCEDURE

/   /      
m m d d y y y y

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

2. OPERATIVE PROCEDURE

- 1. Open biopsy
- 2. Biliary bypass only
- 3. Gastrointestinal bypass only
- 4. Biliary bypass plus gastroenterostomy
- 5. Resection (total pancreatectomy)
- 6. Resection (whipple procedure)
- 7. No surgery, percutaneous biopsy only

II. Completed by the NCCTG Pathology reviewer

3. LOCATION OF PRIMARY NEOPLASM

- LOBE
- 1. Head
- 2. Body
- 3. Tail
- 4. Periapillary region
- 5. Extensive (combined)

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

mm x    mm x    mm

5. GROSS FEATURES OF PRIMARY NEOPLASM

- 1. Circumscribed
- 2. Diffuse
- 3. Other (specify): \_\_\_\_\_

6. HISTOLOGIC FEATURES OF PRIMARY NEOPLASM

HISTOLOGIC TYPE

- 1. Ductal adenocarcinoma
- 2. Acinar
- 3. Undifferentiated
- 4. Papillary
- 5. Other (specify): \_\_\_\_\_

DEGREE OF DIFFERENTIATION

- 1. Grade 1
- 2. Grade 2
- 3. Grade 3
- 4. Grade 4

7. EXTENT OF LOCAL SPREAD

- 1. Confined to pancreas
- 2. Direct extension to peripancreatic tissues (specify): \_\_\_\_\_
- 3. Indeterminate

8. REGIONAL LYMPH NODE STATUS

Number of nodes positive (specify location): \_\_\_\_\_  
  Number of nodes negative

9. SOURCE(S) OF SPECIMEN (specify location)

- 1. Primary tumor
  - 2. Primary and metastatic tumor
  - 3. Metastatic tumor with clinical evidence of primary tumor in pancreas
- (specify metastatic site[s]): \_\_\_\_\_

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

III. Signatures

NCCTG Pathology Reviewer

Date

- 1. Agree with original local diagnosis
- 2. Minor disagreement with original local diagnosis
- 3. Substantial disagreement with original local diagnosis

Comments: \_\_\_\_\_

Research base Advisor

Date

- 1. Agree with original local diagnosis
- 2. Minor disagreement with original local diagnosis
- 3. Substantial disagreement with original local diagnosis

Comments: \_\_\_\_\_

Committee Chairperson

Date

- 1. Agree with original local diagnosis
- 2. Minor disagreement with original local diagnosis
- 3. Substantial disagreement with original local diagnosis

Comments: \_\_\_\_\_

Block/Slide number(s) to be used for research/banking: \_\_\_\_\_

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP**

Protocol Number:   N064A  

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)

<b>Required Baseline Adverse Events from Section 10.0 of Protocol</b>		
<b>CTC Adverse Events Term (CTCAE v3.0)</b>	<b>MedDRA Code (v. 10.0)</b>	<b>CTC Adverse Event Grade</b>
<b>Baseline number of stools per day:</b> _____		
Fatigue (lethargy, malaise, asthenia)	10016256	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Fever (in the absence of neutropenia, where neutropenia is defined as ANC <1.0 X 10 <sup>9</sup> /L)	10016558	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Nail changes	10028694	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3
Pruritis/itching	10037087	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3
Rash: acne/acneiform	10037847	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3
Rash: erythema multiforme (e.g. Stevens-Johnson syndrome, toxic epidermal necrolysis)	10015218	<input type="checkbox"/> 0 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Rash/desquamation	10037853	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Ulceration	10040947	<input type="checkbox"/> 0 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Anorexia	10002646	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Nausea	10028813	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Vomiting	10047700	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Febrile neutropenia (fever of unknown origin without clinical or microbiologically documented infections) (ANC <1.0 x 10 <sup>9</sup> /L, fever ≤38.5° C)	10016288	<input type="checkbox"/> 0 <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
Hypoxia	10021143	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Pneumonitis/pulmonary infiltrates	10035742	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Creatinine	10011368	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Magnesium serum-low (hypomagnesemia)	10040336	<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**

Protocol Number: N064A

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

L F M

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

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

**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)

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

Evaluation Date: (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 WBC)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	_____
Leukocytes (total WBC) 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 (CTCAE v3.0)	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**

Fatigue (lethargy, malaise, asthenia)	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	_____
Fever (in the absence of neutropenia, where neutropenia is defined as ANC <1.0 X 10 <sup>9</sup> /L)	10016558	<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	_____
Cytokine release syndrome/infusion reaction	10052015	<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	_____
Nail changes	10028694	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	_____
Pruritis/itching	10037087	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <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

**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: N064A

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

L F M

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

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

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

CTC Adverse Event Term (CTCAE v3.0)	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)
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**Required Adverse Events from Section 10.0 of Protocol**

Rash: acne/acneiform	10037847	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <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	_____
Rash: erythema multiforme (e.g. Stevens-Johnson syndrome, toxic epidermal necrolysis)	10015218	<input type="checkbox"/> 0 <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	_____
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	_____
Ulceration	10040947	<input type="checkbox"/> 0 <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	_____
Anorexia	10002646	<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	_____
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	_____
<b>Mucositis/stomatitis (clinical exam) - Selects</b>				
- 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	_____
<b>Mucositis/stomatitis (functional/symptomatic) - Selects</b>				
- 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	_____
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	_____
Febrile neutropenia (fever of unknown origin without clinical or microbiologically documented infections) (ANC <1.0 x 10 <sup>9</sup> /L, fever ≤38.5° C)	10016288	<input type="checkbox"/> 0 <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

**NORTH CENTRAL CANCER TREATMENT GROUP**

Protocol Number: N064A

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

L F M

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

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

**NADIR/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 (nadir/adverse events associated with this cycle): \_\_\_\_\_

CTC Adverse Event Term (CTCAE v3.0)	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)
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**Required Adverse Events from Section 10.0 of Protocol**

Infection (documented clinically or microbiologically) with grade 3 or 4 neutrophils (ANC < 1.0 x 10<sup>9</sup>/L) - *Selects*

- Skin (cellulitis)	90030270	<input type="checkbox"/> 0 <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	___
- Abdomen NOS	90030154	<input type="checkbox"/> 0 <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	___
- Catheter-related	90030174	<input type="checkbox"/> 0 <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	___
- Wound	90030304	<input type="checkbox"/> 0 <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	___
- Biliary tree	90030162	<input type="checkbox"/> 0 <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	___

Infection - *Selects*

- Skin (cellulitis)	10040872	<input type="checkbox"/> 0 <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	___
- Abdomen NOS	10056519	<input type="checkbox"/> 0 <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	___
- Catheter-related	10007810	<input type="checkbox"/> 0 <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	___
- Wound	10048038	<input type="checkbox"/> 0 <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	___
- Biliary tree	10061695	<input type="checkbox"/> 0 <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	___
Cough	10011224	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	___
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 <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	___
Hypoxia	10021143	<input type="checkbox"/> 0 <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	___
Pneumonitis/pulmonary infiltrates	10035742	<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	___
Creatinine	10011368	<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	___
Magnesium serum-low (hypomagnesemia)	10040336	<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

**NORTH CENTRAL CANCER TREATMENT GROUP**

**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)

Protocol Number: N064A

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

L F M

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

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

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 (CTCAE v3.0)	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: N064A

EVALUATION/TREATMENT FORM
CHEMOTHERAPY CONCURRENT WITH RADIATION
CYCLE 1 (Days 1-28)

page 1 of 2

Patient ID: Patient Initials: L F M

Institution Number:

Institution:

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^2): (used for this cycle)

Radiation Start Date: (mm/dd/yyyy)

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)

- 45 Dermatology/skin 140 Pulmonary/upper respiratory
154 Metabolic/Laboratory 38 Other non-hematologic
186 Blood/bone marrow 99 Other (not per protocol)
60 Gastrointestinal

Is patient taking: (check one) 1 5FU 2 CAPECIT

Table with 3 columns: Agent, 5FU, CAPECIT. Rows include Agent Start Date, Dose Level day one, Total Dose, DOSE LEVEL adjustment, and Primary Reason for Dose Adjustment.

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N064A

EVALUATION/TREATMENT FORM  
CHEMOTHERAPY CONCURRENT WITH RADIATION  
CYCLE 1 (Days 1-28)

page 2 of 2

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

L F M

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

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

ALL ITEMS MUST BE COMPLETED

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

Agent	Panitumumab (ABXEGF) Days 1, 15
Agent Start Date this cycle (mm/dd/yyyy)	___/___/_____
Dose Level day one this cycle (If agent was not given this cycle, enter the dose level received on last day of treatment.)	mg/kg
Total Dose this cycle (If agent was not given this cycle, enter 0 for total dose.)	mg
Was DOSE LEVEL adjusted (Day 15) from day 1 of this cycle? (kg)	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No
If Yes, PRIMARY REASON for Dose Adjustment per Section 8.0. Not BSA (weight) changes. (Check one)	45 <input type="checkbox"/> Dermatology/skin 60 <input type="checkbox"/> Gastrointestinal 154 <input type="checkbox"/> Metabolic/Laboratory 140 <input type="checkbox"/> Pulmonary/upper respiratory 38 <input type="checkbox"/> Other non-hematologic 99 <input type="checkbox"/> Other (not per protocol), specify _____

Agent: Panitumumab

Was dose omitted (day 1)? (check one)

1  Yes (dose was missed)

2  No

Was dose omitted (day 15)? (check one)

1  Yes (dose was missed)

2  No

Agent: 5 FU

Was dose omitted this cycle? (check one) 1  Yes 2  No

If Yes, how many days? \_\_\_\_\_

Agent: CAPECIT

Was dose omitted this cycle? (check one) 1  Yes 2  No

If Yes, how many days? \_\_\_\_\_

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N064A

EVALUATION/TREATMENT FORM
CHEMOTHERAPY CONCURRENT WITH RADIATION
CYCLE 2 (Day 29 - End of RT)

page 1 of 2

Patient ID: Patient Initials: L F M

Institution Number:

Institution:

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^2): (used for this cycle)

Was this cycle of treatment held (Day 29)? (check one)
1 Yes, planned 2 No 3 Yes, unplanned

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

- 45 Dermatology/skin 140 Pulmonary/upper respiratory
154 Metabolic/Laboratory 38 Other non-hematologic
186 Blood/bone marrow 99 Other (not per protocol)
60 Gastrointestinal

Table with 3 columns: Agent, 5FU, CAPECIT. Rows include Agent Start Date, Dose Level day one, Total Dose, Was DOSE LEVEL adjusted, and Primary Reason for Dose Adjustment.

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N064A

EVALUATION/TREATMENT FORM  
CHEMOTHERAPY CONCURRENT WITH RADIATION  
CYCLE 2 (Day 29 - End of RT)

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

L F M

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

ALL ITEMS MUST BE COMPLETED

page 2 of 2

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

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

Agent	Panitumumab (ABXEGF) Day 29
Agent Start Date this cycle (mm/dd/yyyy)	___/___/___
Dose Level day one this cycle (If agent was not given this cycle, enter the dose level received on last day of treatment.)	mg/kg
Total Dose this cycle (If agent was not given this cycle, enter 0 for total dose.)	mg
Was DOSE LEVEL adjusted from previous cycle? (kg)	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No
If Yes, PRIMARY REASON for Dose Adjustment per Section 8.0. Not BSA (weight) changes. (Check one)	45 <input type="checkbox"/> Dermatology/skin 60 <input type="checkbox"/> Gastrointestinal 154 <input type="checkbox"/> Metabolic/Laboratory 140 <input type="checkbox"/> Pulmonary/upper respiratory 38 <input type="checkbox"/> Other non-hematologic 99 <input type="checkbox"/> Other (not per protocol), specify _____

Agent: Panitumumab

Was dose omitted (day 29)? (check one)

1  Yes (dose was missed)

2  No

Agent: 5 FU

Was dose omitted this cycle? (check one) 1  Yes 2  No

If Yes, how many days? \_\_\_\_\_

Agent: CAPECIT

Was dose omitted this cycle? (check one) 1  Yes 2  No

If Yes, how many days? \_\_\_\_\_

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP**

Protocol Number: N064A

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

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

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

**EVALUATION/TREATMENT FORM**  
**4-6 WEEKS AFTER COMPLETION OF RADIATION THERAPY**  
**CYCLES 3, 4, 5** page 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.**

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 <input type="checkbox"/> Blood/bone marrow           | 154 <input type="checkbox"/> Metabolic/Laboratory          |
| 45 <input type="checkbox"/> Dermatology/skin             | 38 <input type="checkbox"/> Other non-hematologic          |
| 60 <input type="checkbox"/> Gastrointestinal             | 99 <input type="checkbox"/> Other (not per protocol) _____ |
| 140 <input type="checkbox"/> Pulmonary/upper respiratory |  |

Agent	Gemcitabine (GEMZAR) Days 1, 8, 15	Panitumumab (ABXEGF) Days 1, 15
Agent Start Date this cycle ( <i>mm/dd/yyyy</i> )	___/___/____	___/___/____
Dose Level day one this cycle <i>(If agent was not given this cycle, enter the dose level received on last day of treatment.)</i>	mg/m <sup>2</sup>	mg/kg
Total Dose this cycle <i>(If agent was not given this cycle, enter 0 for total dose.)</i>	mg	mg
Was <b>DOSE LEVEL</b> adjusted ( <i>Day 1, 8, or 15</i> ) this cycle?	1 <input type="checkbox"/> Yes    2 <input type="checkbox"/> No	1 <input type="checkbox"/> Yes    2 <input type="checkbox"/> No
<b>If Yes, PRIMARY REASON</b> for Dose Adjustment per Section 8.0. Not BSA ( <i>weight</i> ) changes.  <i>(Check one)</i>	186 <input type="checkbox"/> Blood/bone marrow 38 <input type="checkbox"/> Other non-hematologic 99 <input type="checkbox"/> Other (not per protocol), specify _____	45 <input type="checkbox"/> Dermatology/skin 60 <input type="checkbox"/> Gastrointestinal 154 <input type="checkbox"/> Metabolic/Laboratory 140 <input type="checkbox"/> Pulmonary/upper respiratory 186 <input type="checkbox"/> Blood/bone marrow 38 <input type="checkbox"/> Other non-hematologic 99 <input type="checkbox"/> Other (not per protocol), specify _____

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP**

Protocol Number: N064A

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

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

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

**EVALUATION/TREATMENT FORM**  
**4-6 WEEKS AFTER COMPLETION OF RADIATION THERAPY**  
**CYCLES 3, 4, 5** page 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)*

Agent: Gemcitabine

Was dose omitted (*day 1*)? (*check one*)

1  Yes (*dose was missed*)

2  No

Was dose omitted (*day 8*)? (*check one*)

1  Yes (*dose was missed*)

2  No

Was dose omitted (*day 15*)? (*check one*)

1  Yes (*dose was missed*)

2  No

Agent: Panitumumab

Was dose omitted (*day 1*)? (*check one*)

1  Yes (*dose was missed*)

2  No

Was dose omitted (*day 15*)? (*check one*)

1  Yes (*dose was missed*)

2  No

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

EVALUATION/TREATMENT FORM  
MAINTENANCE THERAPY  
CYCLE 6-11  
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: N064A  
Patient ID: \_\_\_\_\_ Patient Initials: \_\_\_\_\_  
L F M  
Institution Number: \_\_\_\_\_  
Institution: \_\_\_\_\_

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
- 45  Dermatology/skin
- 60  Gastrointestinal
- 140  Pulmonary/upper respiratory
- 154  Metabolic/Laboratory
- 38  Other non-hematologic
- 99  Other (not per protocol) \_\_\_\_\_

Agent	Panitumumab (ABXEGF) Days 1, 15
Agent Start Date this cycle (mm/dd/yyyy)	___/___/___
Dose Level day one this cycle (If agent was not given this cycle, enter the dose level received on last day of treatment.)	mg/kg
Total Dose this cycle (If agent was not given this cycle, enter 0 for total dose.)	mg
Was DOSE LEVEL adjusted (Day 1 or 15) from previous cycle?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No
If Yes, PRIMARY REASON for Dose Adjustment per Section 8.0. Not BSA (weight) changes.  (Check one)	186 <input type="checkbox"/> Blood/bone marrow 45 <input type="checkbox"/> Dermatology/skin 60 <input type="checkbox"/> Gastrointestinal 154 <input type="checkbox"/> Metabolic/Laboratory 140 <input type="checkbox"/> Pulmonary/upper respiratory 38 <input type="checkbox"/> Other non-hematologic 99 <input type="checkbox"/> Other (not per protocol), specify _____

Agent: Panitumumab

Was dose omitted (day 1)? (check one)  
1  Yes (dose was missed)  
2  No

Was dose omitted (day 15)? (check one)  
1  Yes (dose was missed)  
2  No

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

RADIATION THERAPY 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: N064A
Patient ID: Patient Initials: L F M
Institution Number:
Institution:

PANCREAS

Date Start Radiotherapy [ ][ ] / [ ][ ] / [ ][ ][ ][ ]
m m d d y y y y
Date End Radiotherapy [ ][ ] / [ ][ ] / [ ][ ][ ][ ]
m m d d y y y y

Please Enclose a Copy of:

- 1. Daily treatment records.
2. Dosimetry calculations and isodose curves.
3. All simulation and portal films.

TECHNIQUE

Modality

[ ] 1-Linear Accel. FIELD: GTV= cc, CTV1= cc, CTV2= cc, PTV1= cc, PTV2= cc
MV
[ ] 2-Other BOOST: GTV= cc, CTV1= cc, CTV2= cc, PTV1= cc, PTV2= cc
MV
MV

Treatment Areas, Dose and Time

Table with 4 columns: Site, Tumor Dose (rad), # of Fractions, Elapsed Days. Rows include Central Axis Midplane - Large Field, Central Axis Midplane - Boost Field, Central Axis Midplane - Total, and Maximum Dose to Spinal Cord.

Right Kidney V20= %, Left Kidney V20= %, Spinal cord max. dose= cGy, Liver D50= cGy, Small bowel max dose= cGy

Total Initial Dose Given: cGy
Total number of initial fractions given:
Total Boost Dose Given: cGy
Total number of boost fractions given:
Total RT Dose Given: cGy
Total number of RT fractions given:

Unscheduled Interruptions? [ ] 1 = Yes, 2 = No -> (Go to Comments)

- (Enter Days and Reasons)
1 = Social
2 = Local reaction
3 = Systemic reaction
4 = Machine down
7 = ANC
8 = Platelets
6 = Unknown
5 = Other, specify

Grid for Days (3x3) and Reasons (3x1)

Radiation Oncologist's Comments:

Radiation Oncologist's Signature

OPERATIONS OFFICE

Date 6/10/2009

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP**

Protocol Number: N064A

**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)*

- 1  Observation *(follow test schedule and enter cycle data)*
- 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
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

Protocol Number: N064A

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

L F M

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

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

**NORTH CENTRAL CANCER TREATMENT GROUP**

**PATIENT QUESTIONNAIRE BOOKLET COMPLIANCE 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)*

***Complete this form only if the entire Patient Questionnaire booklet contains absolutely NO patient provided assessment information.***

Baseline: \_\_\_\_\_ or Current Cycle Number: \_\_\_\_\_ *(prefill if possible)*

Date this form completed: (mm/dd/yyyy) \_\_\_\_/\_\_\_\_/\_\_\_\_

***Reason Patient Questionnaire booklet was not completed. (check one)***

- 1  Patient refusal
- 2  Unable to accommodate disability or language needs
- 3  Staff unavailable
- 4  Patient not given form by staff
- 5  Patient did not like content of questions
- 6  Site did not like content of questions
- 99  Other reason, specify \_\_\_\_\_

PLACE LABEL HERE

Protocol Number: N064A

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

L F M

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

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

**NORTH CENTRAL CANCER TREATMENT GROUP**

**EVALUATION/OBSERVATION 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)*

**Use one form per cycle.**

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)*

**Observation\***

Day 1 of this observation cycle: *(mm/dd/yyyy)* \_\_\_\_/\_\_\_\_/\_\_\_\_



End of observation? *(check one)*    1  Yes    2  No

\*When observation ends amend the last existing Evaluation/Observation Form by checking "Yes" for the End of observation question above.

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP**

Protocol Number: N064A

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 date of 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/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/Progression:\*\* (mm/dd/yyyy) \_\_\_/\_\_\_/\_\_\_\_\_
- Site(s) of Relapse/Progression: (check all that apply)
  - Local/Regional  Other distant
  - Liver  Other, specify \_\_\_\_\_
  - Peritoneal
- Method (s) of Diagnosis: (check all that apply)
  - Clinical  Radiographic
  - Biopsy  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) \_\_\_/\_\_\_/\_\_\_\_\_
- Specify subsequent treatment: \_\_\_\_\_

**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/Not evaluated 1  Yes. If Yes, Submit page 2 of the Event Monitoring Form for Late Adverse Event Reporting.

\*If this is the first event monitoring check yes, enter cancer follow-up status date and complete the rest of the form.

\*\*Submit documentation to verify PD.

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: N064A

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"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____
	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____
	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____
	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____
	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____
	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____
	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____
	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____
	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____
	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____
	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____
	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____
	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____
	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____
	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____
	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____
	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____
	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____
	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP**

Protocol Number: N064A

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.
- 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      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? <sup>1</sup>
___/___/_____		<input type="checkbox"/> 4 <input type="checkbox"/> 5	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 3 <input type="checkbox"/> Unknown
___/___/_____		<input type="checkbox"/> 4 <input type="checkbox"/> 5	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 3 <input type="checkbox"/> Unknown
___/___/_____		<input type="checkbox"/> 4 <input type="checkbox"/> 5	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 3 <input type="checkbox"/> Unknown
___/___/_____		<input type="checkbox"/> 4 <input type="checkbox"/> 5	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 3 <input type="checkbox"/> Unknown
___/___/_____		<input type="checkbox"/> 4 <input type="checkbox"/> 5	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 3 <input type="checkbox"/> Unknown

1. Answer YES if attribution is unlikely, possible, probable or definite; answer NO if unrelated; answer UNKNOWN if you are not sure.

**Hospitalization:**      1  Yes      2  No

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

Reason(s) for Hospitalization:

1  Adverse Event, specify type and grade: \_\_\_\_\_

2  Prophylactic, specify: \_\_\_\_\_

3  Other reason, specify \_\_\_\_\_

PLACE LABEL HERE

Protocol Number: N064A

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

L F M

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

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

**NORTH CENTRAL CANCER TREATMENT GROUP**

**PATIENT QUESTIONNAIRE BOOKLET COMPLIANCE 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)*

***Complete this form only if the entire Patient Questionnaire booklet contains absolutely NO patient provided assessment information.***

Baseline: \_\_\_\_\_ or Current Cycle Number: \_\_\_\_\_ *(prefill if possible)*

Date this form completed: (mm/dd/yyyy) \_\_\_\_/\_\_\_\_/\_\_\_\_

***Reason Patient Questionnaire booklet was not completed. (check one)***

- 1  Patient refusal
- 2  Unable to accommodate disability or language needs
- 3  Staff unavailable
- 4  Patient not given form by staff
- 5  Patient did not like content of questions
- 6  Site did not like content of questions
- 99  Other reason, specify \_\_\_\_\_

June 19, 2009

**Order Form**

**Quality-of-Life Booklets**

**N064A, Phase II Study of Panitumumab, Chemotherapy, and External Beam Radiation in Patients with Locally Advanced Pancreatic Cancer**

**Patient Questionnaire**

Number of booklets needed: \_\_\_\_\_

Fax form to: 507-284-1902

Attention of NCCTG Operational Support Clerk

Requestor: \_\_\_\_\_ Phone: \_\_\_\_\_

Affiliate/Membership: \_\_\_\_\_/\_\_\_\_\_

Shipping address: \_\_\_\_\_

\_\_\_\_\_

Date: \_\_\_\_\_

**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:   N064A  

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**

Kit # 1 to be used for all visits \_\_\_\_\_

\_\_\_\_\_

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

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