

August 25, 2011

FORMS PACKET

N064B, Randomized Phase II Trial of Panitumumab, Erlotinib, and Gemcitabine vs. Erlotinib and Gemcitabine in Patients with Untreated, Metastatic Pancreatic Adenocarcinoma

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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.

NORTH CENTRAL CANCER TREATMENT GROUP
Eligibility Checklist

4/2/2010
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N064B: Randomized Phase II Trial of Panitumumab, Erlotinib, and Gemcitabine vs. Erlotinib and Gemcitabine
in Patients with Untreated, Metastatic Pancreatic Adenocarcinoma

For the first 6-12 patients enrolled on study: Prior to discussing protocol entry with the patient, call the Registration Office (507/284-4130) to insure that a place on the protocol is open to the patient.

First 6-12 patients: To register a patient, call (507/284-4130) or fax (507/284-0885) a completed eligibility checklist to the Registration Office between 8 a.m. and 4:30 p.m. central time Monday through Friday.

Following first 6-12 patients: To register a patient, access the NCCTG web page at <https://ncctg.mayo.edu/training> and enter the remote registration/randomization application.

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

Patient study ID number _____

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

Registration – Inclusion Criteria

	Yes	No	NA
Histologically or cytologically confirmed metastatic adenocarcinoma of the pancreas (ductal or undifferentiated).	___	___	___
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.	___	___	___
• ANC ≥1500/uL. ANC = _____.	___	___	___
• PLT ≥100,000/uL. PLT = _____.	___	___	___
• Total Bilirubin ≤2 x institutional upper limits (patient may be stented) Total Bilirubin = _____; Total Bilirubin UNL = _____.	___	___	___
• AST (SGOT) ≤ 2.5 x institutional upper limit of normal (UNL). AST (SGOT) = _____; AST (SGOT) UNL = _____.	___	___	___
• Creatinine ≤2.0 x UNL. Creatinine = _____; Creatinine UNL = _____.	___	___	___
• Magnesium ≥ LOWER limit of normal (LNL). Magnesium = _____. Magnesium LNL = _____.	___	___	___
ECOG performance status (PS) of 0 or 1. ECOG Performance Status = _____.	___	___	___
Life expectancy ≥3 months.	___	___	___
≥18 years of age. Age = _____.	___	___	___
Ability to understand and the willingness to sign a written informed consent document.	___	___	___
Negative serum pregnancy test done ≤ 7 days prior to registration, for women of childbearing potential only. Not a woman of childbearing potential (<i>check NA</i>) vs. negative pregnancy test date ___/___/_____. _____	___	___	___
Willingness to provide mandatory stool specimen for translational studies (see Sections 6.12 and 14.3).	___	___	___

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

Registration – Exclusion Criteria

	Yes	No
Islet cell, acinar cell, or cystadenocarcinomas.	___	___
Locally advanced disease.	___	___
Prior cytotoxic chemotherapy for metastatic disease. <u>Exceptions:</u> • Prior adjuvant chemotherapy for completely resected disease or chemoradiotherapy for locally advanced disease is allowed but must have been administered >6 months prior to registration. Treatment-related adverse events must have resolved. • Gemcitabine used as either a radiosensitizer or as maintenance therapy is allowed provided >6 months have elapsed since the last day of treatment and adverse events have resolved. • The prior adjuvant chemotherapy must not have contained an EGFR inhibitor.	___	___
Prior anti-EGFR antibody therapy (e.g., cetuximab) or treatment with small molecule EGFR inhibitors (e.g., gefitinib, erlotinib, lapatinib).	___	___
Radiation therapy, immunotherapy or biologic therapy ≤4 months prior to registration.	___	___
Major surgery ≤28 days.	___	___

NCCTG Eligibility Checklist N064B

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Patient study ID number _____

Registration – Exclusion Criteria continued

Yes No

Any of the following: <ul style="list-style-type: none"> • Pregnant women • Nursing women • Men or women of childbearing potential who are unwilling to employ adequate contraception. 	____	____
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 (including myocardial infarction, unstable angina, symptomatic congestive heart failure, serious uncontrolled cardiac arrhythmia) ≤1 year before registration.	____	____
Pre-existent liver dysfunction from cirrhosis or viral hepatitis.	____	____
Known positive test(s) for human immunodeficiency virus (HIV) infection or acute or chronic active hepatitis B or C infection.	____	____
Enteral hyperalimentation.	____	____

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. Non-USA institution only (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 cannot begin prior to registration and 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 __/__/____. Note: The earliest pretreatment test date must be less than or equal to the earliest laboratory test date and the latest pretreatment test date must be greater than or equal to the latest laboratory test date.	____	____	____
Exceptions to the above dates: <ul style="list-style-type: none"> • Exception test/procedures must be completed ≤ 28 days prior to registration (see Section 4.0). Earliest exception test date __/__/____; latest exception test date __/__/____. 	____	____	____
A mandatory translational research component is part of this study; the patient will be automatically registered onto this component (Sections 3.18 and 14.3).	____	____	____
All required baseline symptoms (see Section 10.3) must be documented and graded.	____	____	____
Study drug availability checked.	____	____	____
Blood draw kit availability checked.	____	____	____
Stool kit availability checked.	____	____	____

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

Patient study ID number _____

Registration Check continued

Yes No

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). <ul style="list-style-type: none"> • Patient has given permission to give blood samples for research testing planned as part of this study. 	_____
<ul style="list-style-type: none"> • Patient has given permission to give tissue sample for research testing planned as part of this study. 	_____
At the time of registration, the following will also be recorded: <ul style="list-style-type: none"> • Patient has given permission to keep blood sample(s) for use in future research to learn about, prevent, or treat cancer. 	_____
<ul style="list-style-type: none"> • 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). 	_____
<ul style="list-style-type: none"> • Patient has given permission to keep tissue sample(s) for use in future research to learn about, prevent, or treat cancer. 	_____
<ul style="list-style-type: none"> • 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). 	_____
<ul style="list-style-type: none"> • Patient has given permission to keep stool sample(s) for use in future research to learn about, prevent, or treat cancer. 	_____
<ul style="list-style-type: none"> • Patient has given permission to keep stool 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). 	_____
<ul style="list-style-type: none"> • Patient has given NCCTG permission to give blood sample(s) to outside researchers. 	_____
<ul style="list-style-type: none"> • Patient has given NCCTG permission to give tissue sample(s) to outside researchers. 	_____
<ul style="list-style-type: none"> • Patient has given NCCTG permission to give stool sample(s) to outside researchers. 	_____
<ul style="list-style-type: none"> • 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 section may be “Yes” or “No”.

Stratification Factors

ECOG Performance score:

____ 0
____ 1

Prior adjuvant chemotherapy:

____ Yes
____ No

Assigned Treatment

_____ A) GEMZAR + OS1774
_____ B) GEMZAR + OS1774 + ABXEGF

Person registering Signature _____ Registration Office specialist initials _____

Physician Signature _____ Date (mm/dd/yyyy) ____/____/____

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N064B

ON-STUDY FORM

Patient ID: _____ 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 code: 10052747 (*Adenocarcinoma - 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*)

- 1 Resected with no residual 3 Unresected
- 2 Resected with known residual 4 Recurrent

Chronology Of Diagnoses

Distant Metastases (*Method of Diagnosis*)*

Method of Diagnosis*	Dates (mm/dd/yyyy)	<input type="checkbox"/> Nodal	<input type="checkbox"/> Subcutaneous	<input type="checkbox"/> Bone	<input type="checkbox"/> Lung
<input type="checkbox"/> Primary	___/___/___	<input type="checkbox"/> Liver	<input type="checkbox"/> Abdominal	<input type="checkbox"/> Brain	
<input type="checkbox"/> Recurrence of Primary	___/___/___	<input type="checkbox"/> Other, specify _____			
<input type="checkbox"/> First Metastasis	___/___/___	_____			

* (1-None 2-Yes, biopsy 3-Yes, cytology 4-Yes, clinical)

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

DATE (mm/dd/yyyy)

Operative Procedure (*Biopsies, Resections, Bypass, Explorations, etc.*)

___/___/___	
___/___/___	
___/___/___	
___/___/___	

Previous Radiotherapy (*check one*) 1 Yes 2 No

Site	Field Size (cGy)	Total Dose (cGy)	Number of Fractions	From Date (mm/dd/yyyy)	To
				___/___/___	___/___/___
				___/___/___	___/___/___
				___/___/___	___/___/___

Previous Systemic Cancer Therapy (*check one*) 1 Yes 2 No

Therapy	Date (mm/dd/yyyy)		Response (NED, CR, PR, REGR, SD, PD)
	From	To	
	___/___/___	___/___/___	
	___/___/___	___/___/___	
	___/___/___	___/___/___	

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N064B

ON-STUDY FORM

Patient ID: _____ 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)

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

Current Symptom/Disease	
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:

Site of metastases: (check one) 1 Liver 2 Other 3 Both (liver plus other)

Number of metastatic sites: (check one) 1 1 2 2 3 3 4 ≥4

Measurable disease: (check one) 1 Yes 2 No

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

Prior chemotherapy as a radiosensitizing therapy: (check one) 1 Yes 2 No

Smoking Status: (check one)
1 Current (or quit <6 months ago)
2 Former (quit ≥6 months ago)
3 Never

Height (cm): ___ .

Height (cm): ___ .

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N064B

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 Events Term (CTCAE v.3.0)	MedDRA Code (v. 10.0)	CTC Adverse Event Grade
Neutrophils/granulocytes (ANC/AGC)	10029366	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Platelets	10035528	<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
Diarrhea	10012727	<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 clinically or microbiologically documented infection) (ANC <1.0 x 10 ⁹ /L, fever ≥38.5° C)	10016288	<input type="checkbox"/> 0 <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
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"/> 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

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N064B

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

ADVERSE EVENT FORM

ALL ITEMS MUST BE COMPLETED

Pg. 1 of 3

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): _____

Is this: (check one) 1 Initial Treatment 2 Retreatment after PD (CR patients only)

Evaluation Date: (mm/dd/yyyy) ____ / ____ / ____

CTC Adverse Event Term (CTCAE v.3.0)	MedDRA Code (v. 10.0) (must be completed)	CTC Adverse Event Grade (highest grade this cycle) INCLUDE GRADE 0's	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				
Neutrophils/granulocytes (ANC/AGC)	10029366	0 1 2 3 4 5 (death)	1 2 3 4 5	___
Platelets	10035528	0 1 2 3 4 5 (death)	1 2 3 4 5	___
Nail changes	10028694	0 1 2 3	1 2 3 4 5	___
Pruritis/itching	10037087	0 1 2 3 5 (death)	1 2 3 4 5	___
Rash: Acne/acneiform	10037847	0 1 2 3 5 (death)	1 2 3 4 5	___
Rash: Erythema multiforme (e.g. Stevens-Johnson syndrome, toxic epidermal necrolysis)	10015218	0 3 4 5 (death)	1 2 3 4 5	___
Rash/desquamation	10037853	0 1 2 3 4 5 (death)	1 2 3 4 5	___
Ulceration	10040947	0 2 3 4 5 (death)	1 2 3 4 5	___
Diarrhea	10012727	0 1 2 3 4 5 (death)	1 2 3 4 5	___
Nausea	10028813	0 1 2 3 4 5 (death)	1 2 3 4 5	___
Vomiting	10047700	0 1 2 3 4 5 (death)	1 2 3 4 5	___
Febrile neutropenia (fever of unknown origin without clinically or microbiologically documented infection) (ANC <1.0 x 10 ⁹ /L fever ≥38.5° C)	10016288	0 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: N064B

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

ADVERSE EVENT FORM

ALL ITEMS MUST BE COMPLETED

Pg. 2 of 3

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 (CTCAE v.3.0)	MedDRA Code (v. 10.0) (must be completed)	CTC Adverse Event Grade (highest grade this cycle) INCLUDE GRADE 0's	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

Magnesium, serum-low (hypomagnesemia)	10040336	0 1 2 3 4 5 (death)	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	_____
Hypoxia	10021143	0 2 3 4 5 (death)	1 2 3 4 5	_____
Pneumonitis/pulmonary infiltrates	10035742	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

ADVERSE EVENT FORM

ALL ITEMS MUST BE COMPLETED

Pg. 3 of 3

Are data amended? (check one) Yes No

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

Protocol Number: N064B

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 Terms not listed (CTCAE v.3.0)	MedDRA Code (v. 10.0) (must be completed)	CTC Adverse Event Grade (highest grade this cycle)	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)
	<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"/>	<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"/>	<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"/>	<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"/>	<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"/>	<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"/>	<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"/>	<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"/>	<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"/>	<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"/>	<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"/>	<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 and nonhematologic Adverse Events must be graded on this form as applicable.

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N064B

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

(Total) Number of Target Lesions (as reported on Pretreatment Measurement Form) (1-10): _____

Target Lesion Site(s)	Method of Evaluation				Longest Diameter of Lesion(s) (cm)
	CT ²	Spiral CT ³	MRI	CXR ⁵	
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"/>	
Sum of Longest Diameters of All Target Lesions:					

Nontarget Lesion (check one)	1 <input type="checkbox"/> Yes (Present) 2 <input type="checkbox"/> No (Absent)
--	--

2=CT scan
 3=Spiral CT scan
 5=Chest x-ray

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

ACTIVE MONITORING
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)

Protocol Number: N064B

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

Current Cycle Number: _____

INSTRUCTIONS

1. Record the target lesions in the same order as recorded at pretreatment (refer to Section 11 of the protocol).
2. Measure target lesions in cm. using longest diameter (one dimension only).
3. Record measurements at scheduled evaluations and progression (refer to protocol Section 4).
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.
6. Overall objective status is determined by combining status of target lesions, nontarget lesions and new lesions (refer to protocol Section 11).

Is this: (check one) Initial Treatment Retreatment after PD (CR patients only)

Overall Response Status at This Assessment
(check one)

19 Mark an "X" if N/A (not applicable this cycle) → End Form

1 CR*

2 PR*

5 SD

6 PD* (Complete End of Active Treatment and Event Monitoring Forms.)

Note: If PD is selected for Overall Response Status, and Yes is selected for "Was the appearance of any new lesions documented" go to Nontarget Lesions.

• Was the appearance of any new lesions documented? 1 Yes 2 No
• Symptomatic Deterioration? 1 Yes 2 No

Assessment Date (mm/dd/yyyy) ___/___/___

(Assessment date is the date reflecting type of assessment, not the physician interpretation date. If tumor measurements are not required this cycle per Section 4.0, Assessment Date is the date the patient was evaluated.)

Did the patient have measurable disease at baseline? (check one) 1 Yes. If Yes, complete Target and Nontarget Lesions
2 No. If No, go to Nontarget Lesions

(Total) Number of Target Lesions (as reported on Pretreatment Measurement Form) (1-10): _____

Target Lesion Site(s)	Longest Diameter of Lesion(s) (cm)
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	
9.	
10.	
Sum of Longest Diameters of All Target Lesions:	

Nontarget Lesion Site	Follow-up Status of Lesion: (check one)			
	1 <input type="checkbox"/> CR	2 <input type="checkbox"/> SD (NonPD)	3 <input type="checkbox"/> PD	9 <input type="checkbox"/> Mark an "X" if N/A (Not Applicable)

*Submit documentation to verify CR, PR, PD.

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: N064B

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

Current Cycle Number: _____

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, Specify: _____

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: N064B
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).

Did this patient provide written consent to give tissue specimen (s) for research? (check one)

1 Yes. If Yes, complete rest of form.

2 No. If No, end form.

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
STOOL 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: N064B
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 14 days of study entry.
- See Section 14 of the protocol for specimen requirements and shipment.

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
PATHOLOGY REPORTING FORM
PANCREAS CARCINOMA**

Protocol # N064B

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. 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

PATHOLOGY SUBMISSION FORM

Protocol Number: N064B

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

(NOTE: This form is used to update the Outstanding Materials Report)
(DMS: Refer to Section 17 - if no outside NCCTG reviewer, remove the above statement).

**** 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) Linnea Loserth, NCCTG reviewer - Scottsdale, AZ

Thomas C. Smyrk, M.D., Mayo Clinic Rochester - Rochester, MN

Number of slides sent: ___

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

_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

Number of blocks sent: ___

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

_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

COMMENTS:

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

EVALUATION/TREATMENT FORM (ARM A)

Protocol Number: N064B

Patient ID: Patient Initials: L F M

Institution Number:

Institution:

ALL ITEMS MUST BE COMPLETED

page 1 of 2

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 (m²): (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 181 Pain
60 Gastrointestinal 196 Pulmonary/Upper Respiratory
97 Infection 38 Other nonhematologic adverse event
190 Dermatology/Skin 201 Vascular
154 Metabolic/Laboratory 99 Other (not per protocol), specify
130 Ocular/Visual

Table with 2 columns: Agent, Gemcitabine (GEMZAR). Rows include Agent Start Date, Initial Dose, Total Dose, Dose modification, Reason Modified, Was agent omitted, and omitted days.

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

**EVALUATION/TREATMENT FORM
(ARM A)**

Protocol Number: N064B

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

ALL ITEMS MUST BE COMPLETED

page 2 of 2

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

Agent	Erlotinib (OS1774)
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 (<i>Days 1-28</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.</i>) (<i>Check one</i>)	190 <input type="checkbox"/> Dermatology/skin 60 <input type="checkbox"/> Gastrointestinal 154 <input type="checkbox"/> Metabolic/Laboratory 130 <input type="checkbox"/> Ocular/Visual 181 <input type="checkbox"/> Pain 38 <input type="checkbox"/> Other nonhematologic adverse event 201 <input type="checkbox"/> Vascular 99 <input type="checkbox"/> Other (not per protocol), specify _____ 500 <input type="checkbox"/> Increased per protocol
Was (agent) omitted this cycle?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

EVALUATION/TREATMENT FORM (ARM B)

ALL ITEMS MUST BE COMPLETED

Pg. 1 of 3

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

Protocol Number: N064B

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 (m²): (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
60 [] Gastrointestinal
97 [] Infection
190 [] Dermatology/Skin
154 [] Metabolic/Laboratory
130 [] Ocular/Visual

- 181 [] Pain
196 [] Pulmonary/Upper Respiratory
38 [] Other nonhematologic adverse event
201 [] Vascular
99 [] Other (not per protocol), specify

Table with 2 columns: Agent, Gemcitabine (GEMZAR). Rows include Agent Start Date, Initial Dose, Total Dose, Dose modification, Reason Modified, Was agent omitted, and If Yes, which days were omitted.

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

**EVALUATION/TREATMENT FORM
(ARM B)**

Protocol Number: N064B

Patient ID: _____ Patient Initials: _____
L F M

Institution Number: _____

Institution: _____

ALL ITEMS MUST BE COMPLETED page 2 of 3

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

Agent	Panitumumab (ABXEGF)
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, 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, Primary Reason for Dose (Level) modification per Section 8.0.</i>) (<i>Check one</i>)	190 <input type="checkbox"/> Dermatology/skin 60 <input type="checkbox"/> Gastrointestinal 38 <input type="checkbox"/> Other nonhematologic adverse event 201 <input type="checkbox"/> Vascular 99 <input type="checkbox"/> Other (not per protocol), specify _____ 500 <input type="checkbox"/> Increased per protocol
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"/> 15

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

**EVALUATION/TREATMENT FORM
(ARM B)**

ALL ITEMS MUST BE COMPLETED

page 3 of 3

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

Protocol Number: N064B

Patient ID: _____ Patient Initials: _____
L F M

Institution Number: _____

Institution: _____

Agent	Erlotinib (OS1774)
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 (<i>Days 1-28</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.</i>) (<i>Check one</i>)	190 <input type="checkbox"/> Dermatology/skin 60 <input type="checkbox"/> Gastrointestinal 154 <input type="checkbox"/> Metabolic/Laboratory 130 <input type="checkbox"/> Ocular/Visual 181 <input type="checkbox"/> Pain 38 <input type="checkbox"/> Other nonhematologic adverse event 201 <input type="checkbox"/> Vascular 99 <input type="checkbox"/> Other (not per protocol), specify _____ 500 <input type="checkbox"/> Increased per protocol
Was (agent) omitted this cycle?	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N064B

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: Liver Pancreas
(check all that apply) Lung Other, specify _____
- Method (s) of Diagnosis: CT Spiral CT
(check all that apply) MRI Chest x-ray
 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 ≥ 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.

**Submit documentation to verify PD.

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N064B

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

**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)

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: N064B

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
2 <input type="checkbox"/> Patient Withdrawal/Refusal After Beginning Protocol Therapy	Specify:
24 <input type="checkbox"/> Patient Withdrawal/Refusal Prior To 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: N064B

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 _____



NCCTG

NORTH CENTRAL CANCER TREATMENT GROUP

May 15, 2009

Order Form

Quality-of-Life Booklets

N064B, Randomized Phase II Trial of Panitumumab, Erlotinib, and Gemcitabine vs. Erlotinib and Gemcitabine in Patients with Untreated, Metastatic Pancreatic Adenocarcinoma

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: _____

PLACE LABEL HERE

Protocol Number: N064B

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 _____

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: N064B

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) _____

<u>Type of Kits</u>	<u># of Kits Needed</u>
N064B Research Kit	_____
_____	_____
	Total Kits _____

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

STOOL Fax Supply Order Form

No Cover Sheet Necessary

Fax to Julie Simonson: 1-507-266-0350

SPONSOR COMPANY: North Central Cancer Treatment Group (NCCTG)

PROTOCOL: N064B

Investigator: _____

Order placed by _____ Phone #: (____) _____

Fax #: (____) _____

Name of Main Member investigator: _____
(required)

Name and address kits should be sent to:

Today's Date: _____

YOU WILL RECEIVE YOUR SUPPLIES WITHIN 2 WEEKS OF TODAY'S DATE.

Please call 1-507-538-2155 or e-mail simonson.julie@mayo.edu if you have questions about this order.

Lab Supplies:

Quantity:

Stool Collection Kit

_____ each