

FORMS PACKET

N0821, A Phase II First-Line Study of a Combination of Pemetrexed, Carboplatin and Bevacizumab in Advanced Nonsquamous NSCLC Evaluating Efficacy and Tolerability in Elderly Patients (Age ≥ 70 yrs) with Good Performance Status (PS < 2)

- Contents:
- ✓ Eligibility checklist (12/18/09)
 - * Forms completion instructions
 - On-study form (11/28/08)
 - Baseline adverse events form (11/28/08)
 - Nadir/adverse event form (11/28/08)
 - Baseline concurrent treatment form (11/28/08)
 - Concurrent treatment form (11/28/08)
 - Pretreatment measurement form (11/28/08)
 - Measurement form (11/28/08)
 - Evaluation/treatment form- Cycles 1-6 (10/13/09)
 - Evaluation/treatment form- Cycles ≥ 7 (11/28/08)
 - Evaluation/observation form (11/28/08)
 - Patient Questionnaire Booklet Compliance Form (11/28/08)
 - Baseline blood specimen submission form (11/28/08)
 - Pathology submission form (11/28/08)
 - Pathology reporting form (11/28/08)
 - Baseline tissue specimen submission form (11/28/08)
 - End of active treatment/cancel notification form (11/28/08)
 - Event monitoring form (11/28/08)
 - Grade 4 or 5 non-AER reportable events/hospitalization form (11/28/08)
 - Booklet order form (12/12/08)
 - N0821 kit fax supply order form (1/8/09)

✓ 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

12/18/2009

Page 1 of 5

N0821: A phase II first-line study of a combination of pemetrexed, carboplatin and bevacizumab in advanced nonsquamous NSCLC evaluating efficacy and tolerability in elderly patients (age ≥ 70 yrs) with good performance status (PS < 2)

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) _____	Race (check all that apply)
Gender (check one) ___ Male ___ Female ___ Unknown	___ White
Date of birth (mm/dd/yyyy) ___/___/_____	___ Black or African American
ZIP code _____	___ Native Hawaiian or Other Pacific Islander
Country of Residence _____	___ Asian
	___ American Indian or Alaska Native
	___ Not reported: Patient refused or not available
	___ Unknown: Patient unsure
Method of payment (check one)	Ethnicity (check one)
___ PI (Private Insurance)	___ Not Hispanic or Latino
___ MR (Medicare)	___ Hispanic or Latino
___ MRP (Medicare and Private Insurance)	___ Not reported: Refused or data not available
___ MD (Medicaid)	___ Unknown: Unsure of their ethnicity
___ 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)	

NCCTG Eligibility Checklist N0821

12/18/2009
Page 2 of 5

Patient study ID number _____

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

Inclusion Criteria

Yes No

≥70 years of age. Age = _____.	___ ___
Histologic or cytologic confirmation of nonsquamous NSCLC. Patient should have stage IV or stage IIIB disease (AJCC TNM sixth edition; symptomatic pleural effusions should be drained prior to registration). • Although patients with squamous cell carcinomas are not eligible, adenosquamous histology is allowed.	___ ___
ECOG performance status (PS) 0, 1. PS = _____.	___ ___
Clinically significant effusions must be drained prior to treatment (e.g., symptomatic pleural effusion or ascites; if effusion produces clinically significant measurable objective changes such as hypoxia or estimated volume >500 ml effusion should be drained even if patient is asymptomatic).	___ ___
Measurable disease as defined in Section 11.0 with at least one lesion whose longest diameter can be accurately measured as ≥2.0 cm with conventional techniques or as ≥1.0 cm with spiral CT. If spiral CT is used, it must be used for both pre- and post-treatment tumor assessments.	___ ___
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 μL. ANC = _____.	___ ___
• PLT ≥100,000 μL. PLT = _____.	___ ___
• Hgb ≥9 g/dL. Hgb = _____.	___ ___
• Total bilirubin ≤1.5 x upper limit of normal (ULN) or direct bilirubin ≤ULN Which was done? ___ Total bilirubin → Total bilirubin = _____; ULN = _____. ___ Direct bilirubin → Direct bilirubin = _____; ULN = _____. ___ Both total and direct bilirubin (<i>enter values in above spaces.</i>)	___ ___
• AST and ALT ≤3 x ULN or AST and ALT ≤5 x ULN is acceptable if liver has tumor involvement. Is there liver tumor involvement? (This question may be answered yes or no). ___ Yes → AST (≤5 x ULN) = _____; ULN = _____. ALT (≤5 x ULN) = _____; ULN = _____. ___ No → AST (≤3 x ULN) = _____; ULN = _____. ALT (≤3 x ULN) = _____; ULN = _____.	___ ___
• Creatinine clearance must be ≥45 ml/min. Creatinine clearance is either measured with 24-hour urine collection or calculated using the Cockcroft-Gault formula (see Sect. 3.16). Creatinine clearance = _____.	___ ___
Prior radiation therapy is permitted as long as: • >2 weeks since last fraction of radiation administered and patient has recovered from the toxic effects of radiation treatment before study entry, except for alopecia. • ≤25% of bone marrow radiated. • Presence of measurable disease whether in-field disease progression/recurrence or disease outside the treatment fields of radiation port. • For patients receiving radiation for brain metastases, see Section 3.22.	___ ___
Ability to interrupt NSAIDs 2 days before (5 days for long-acting NSAIDs) the day of, and 2 days following administration of protocol treatment.	___ ___
Willingness to provide the biologic specimens as required by the protocol (see Sections 6.2, 14.0, 17.0).	___ ___
Able to take folic acid, vitamin B ₁₂ supplementation, or dexamethasone.	___ ___
Willingness to return to NCCTG enrolling institution for follow-up.	___ ___
Ability to provide informed consent.	___ ___
Life expectancy ≥12 weeks.	___ ___
Ability to complete questionnaire(s) by themselves or with assistance.	___ ___
Willingness to enroll in N0392. Note: Participation in N0392 is mandatory for this study.	___ ___

All responses in above section must be "Yes."

Patient study ID number _____

Exclusion Criteria

Yes No NA

Any of the following because this study involves an agent that has known genotoxic, mutagenic and teratogenic effects: <ul style="list-style-type: none"> Men or women of childbearing potential who are unwilling to employ adequate contraception 	___	___	
Symptomatic, untreated, or uncontrolled CNS metastases or seizure disorder. Patients with CNS metastases treated with whole brain radiation (WBRT) may be enrolled after completion of WBRT. Patients may begin chemotherapy as early as 2 weeks after WBRT. Patients treated with gamma-knife radiosurgery only for brain metastases (without WBRT) may begin chemotherapy as early as 3 days after the procedure.	___	___	
Prior chemotherapy for advanced lung cancer (except neoadjuvant or adjuvant therapy for lung cancer >12 months prior to registration).	___	___	
Symptomatic pleural and/or peritoneal effusion (\geq CTCAE v3.0 grade 2 dyspnea) that is not amenable to drainage prior to registration.	___	___	
Any clinically significant infection.	___	___	
Second primary malignancy <5 years at the time of registration with the following exceptions who are eligible regardless of date of diagnosis: <ul style="list-style-type: none"> Carcinoma in situ of the cervix. Non-melanomatous skin cancer. History of melanoma allowed only if it was diagnosed and definitively treated at least 5 years previously with no subsequent evidence of recurrence. History of low-grade (Gleason score \leq6) localized prostate cancer (no nodal involvement). Treated stage I breast cancer, 	___	___	
History of abdominal fistula, gastrointestinal perforation, or intra-abdominal abscess \leq 12 months prior to registration.	___	___	
History of diverticulitis \leq 12 months prior to registration.	___	___	
Any of the following prior therapies:			
<ul style="list-style-type: none"> Systemic chemotherapy \leq12 months prior to registration. If no prior chemotherapy (<i>check NA</i>); If prior chemotherapy - Last day of chemotherapy ___/___/_____ 	___	___	___
<ul style="list-style-type: none"> Immunotherapy \leq12 months prior to registration. If no prior immunotherapy (<i>check NA</i>); If prior immunotherapy - Last day of immunotherapy ___/___/_____ 	___	___	___
<ul style="list-style-type: none"> Biologic therapy \leq12 months prior to registration. If no prior biologic therapy (<i>check NA</i>); If prior biologic therapy - Last day of biologic therapy ___/___/_____ 	___	___	___
<ul style="list-style-type: none"> Radiation therapy \leq2 weeks prior to registration. The site of previous radiotherapy should have evidence of progressive disease if this is the only site of disease. If no prior radiation therapy (<i>check NA</i>); If prior radiation therapy - Last day of radiation therapy ___/___/_____ 	___	___	___
<ul style="list-style-type: none"> Radiation to \geq25% of bone marrow 	___	___	
<ul style="list-style-type: none"> Major surgery (i.e., laparotomy), open biopsy, or significant traumatic injury \leq8 weeks prior to registration. Minor surgery \leq4 weeks prior to registration. Insertion of a vascular access device is not considered major or minor surgery in this regard (patient is thus eligible). 	___	___	
<ul style="list-style-type: none"> Administration of live or attenuated viral vaccine <4 weeks prior to registration. If no prior viral vaccine (<i>check NA</i>); If prior viral vaccine – Last day of viral vaccine ___/___/_____ 	___	___	___

Patient study ID number _____

Exclusion Criteria – (continued)

	Yes	No	NA
Any of the following concurrent severe and/or uncontrolled medical conditions: <ul style="list-style-type: none"> • Hypertension, labile hypertension, or history of poor compliance with antihypertensive medication • Angina pectoris • History of congestive heart failure ≤3 months, unless ejection fraction >40% • Myocardial infarction ≤6 months prior to registration • Cardiac arrhythmia • Diabetes mellitus • Interstitial pneumonia or extensive and symptomatic interstitial fibrosis of the lung • Active or recent history of hemoptysis >1/2 teaspoon per event. • Ongoing or active infection • Psychiatric illness/social situations that would limit compliance with study requirements. 	_____	_____	
Serious, nonhealing wounds, ulcers, or bone fractures.	_____	_____	
Patient who is at greater than normal risk of bleeding or on any anticoagulant except those receiving low-dose warfarin or heparin for deep venous thrombosis prophylaxis (not treatment).	_____	_____	
Prior systemic therapy for stage IIIB or stage IV disease. Note: History of chemoradiation, neoadjuvant or adjuvant chemotherapy allowed if last administered dose was >12 months prior to registration.	_____	_____	
History of stroke ≤6 months prior to registration.	_____	_____	
Unwilling to, or unable to, comply with the protocol.	_____	_____	

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
A mandatory translational research component is available for your patient; the patient will be automatically registered onto this component (Sections 3.19a, 14.0, and 17.0).	_____	_____	
Consent form signed and dated. Date informed consent signed ___/___/_____.	_____	_____	
Authorization for use and disclosure of protected health information (<i>U.S.A. institutions only</i>) signed and dated. If not a USA institution (<i>check NA</i>); If a USA institution - 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 ≤14 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.	_____	_____	
<u>Exceptions to the above dates:</u> <ul style="list-style-type: none"> • Tumor assessment (such as chest x-ray, CT scans, PET-CT scans, MRI) must be performed ≤28 days prior to registration (see Section 4.0). Earliest exception test date ___/___/_____; latest exception test date ___/___/_____ 	_____	_____	
All required baseline symptoms (see Section 10.3) must be documented and graded.	_____	_____	
Study drug availability checked.	_____	_____	
Blood draw kit availability checked.	_____	_____	
Patient questionnaire booklet availability checked; copies are not acceptable for this submission.	_____	_____	
Patient has agreed to be enrolled on N0392. Note: Participation in N0392 is mandatory for this study.	_____	_____	

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

NCCTG Eligibility Checklist N0821

12/18/2009
Page 5 of 5

Patient study ID number _____

Registration Check (continued)

Yes No

At the time of registration/randomization, the following will also be recorded:	
• Patient has given permission to store and use blood samples for future research to learn about, prevent, or treat cancer.	___ ___
• Patient has given permission to store and use blood samples for future research to learn about, prevent, or treat other health problems (for example: diabetes, Alzheimer’s disease, or heart disease).	___ ___
• Patient has given permission to store and use tissue samples for future research to learn about, prevent, or treat cancer.	___ ___
• Patient has given permission to store and use tissue samples for future research to learn about, prevent, or treat other health problems (for example: diabetes, Alzheimer’s disease, or heart disease).	___ ___
• Patient has given permission to give their samples to outside researchers.	___ ___

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

Assigned Treatment

___ A) ALIMTA + CBDCA + AVASTN

Person registering Signature _____ Registration Office specialist initials _____

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

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N0821

ON-STUDY FORM

Patient ID: _____ Patient Initials: _____

ALL ITEMS MUST BE COMPLETED pg 1 of 2

L F M

Institution Number: _____

Are data amended? (check one) Yes No

Institution: _____

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

Description of Primary Disease

MedDRA code: 10029514 [Non-small cell lung cancer, NOS]

Histologic Type (check one)

- 2 Bronchoalveolar carcinoma (BAC)
- 3 Adenocarcinoma
- 4 Non-small cell lung cancer (NSCLC), NOS
- 5 Large Cell undifferentiated
- 6 Other, specify other histologic type: _____

Descriptive Factor: NSCLC stage: (check one) 1 Stage IIIB 2 Stage IV

Histologic Grade (Differentiation): (check one)

1 Grade I (well) 3 Grade III (poor)

2 Grade II (moderate) 4 Grade IV (undifferentiated, anaplastic)

Status of Primary Tumor (check one)

1 Resected with no residual 3 Unresected

2 Resected with known residual 4 Recurrent

Disease Status

Method of Evaluation* Date (mm/dd/yyyy)

Primary ___/___/___

Recurrence (of Primary) ___/___/___

First Metastasis ___/___/___

* (1=Evaluated but no disease found (can only be used for first Metastasis) 2=Biopsy 3=Cytology 4=Clinical 6=Not evaluated)

Metastatic Site(s) (Method of Evaluation)*

- Hilar nodes Contralateral lung Bone
- Ipsilateral lung Adrenal(s) Skin
- Liver Brain Other, specify _____
- Bone marrow Supraclavicular/scalene nodes
- Mediastinal nodes Pleura

* (1=Evaluated but no disease found; 2=Biopsy 3=Cytology 4=Clinical 6=Not evaluated)

Previous Surgery Related to the Tumor

<u>Surgical Approach</u>	<u>Surgery Results</u>			<u>Date of prior surgery</u> (mm/dd/yyyy)
Mediastinoscopy (check one)	1 <input type="checkbox"/> Positive	2 <input type="checkbox"/> Negative	3 <input type="checkbox"/> Not Done	___/___/___
Bronchoscopy (check one)	1 <input type="checkbox"/> Positive	2 <input type="checkbox"/> Negative	3 <input type="checkbox"/> Not Done	___/___/___
Supraclavicular biopsy (check one)	1 <input type="checkbox"/> Positive	2 <input type="checkbox"/> Negative	3 <input type="checkbox"/> Not Done	___/___/___
Thoracoscopy (check one)	1 <input type="checkbox"/> Positive	2 <input type="checkbox"/> Negative	3 <input type="checkbox"/> Not Done	___/___/___
Fine Needle Aspirate (check one)	1 <input type="checkbox"/> Positive	2 <input type="checkbox"/> Negative	3 <input type="checkbox"/> Not Done	___/___/___
Other, specify (check one)	1 <input type="checkbox"/> Positive	2 <input type="checkbox"/> Negative	3 <input type="checkbox"/> Not Done	___/___/___

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N0821

ON-STUDY FORM

Patient ID: _____ Patient Initials: _____

ALL ITEMS MUST BE COMPLETED pg 2 of 2

L F M

Institution Number: _____

Are data amended? (check one) Yes No

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

Institution: _____

Prior Radiation Therapy (including other previous malignancies)? (check one) 1 Yes 2 No

If Yes:

Prior RT Site	Total Dose (cGy)	Prior radiation therapy start date (mm/dd/yyyy)	Prior radiation therapy stop date (date of completion) (mm/dd/yyyy)
		___/___/_____	___/___/_____
		___/___/_____	___/___/_____
		___/___/_____	___/___/_____

Descriptive Factor:

Treatment History: (check one) 1 Prior Chemotherapy (chemoradiation/adjuvant or neoadjuvant chemotherapy)

2 None

If Prior Chemotherapy (chemoradiation adjuvant or neoadjuvant chemotherapy):

Prior Treatment Name	Prior chemotherapy start date (mm/dd/yyyy)	Prior chemotherapy stop date (mm/dd/yyyy)
	___/___/_____	___/___/_____
	___/___/_____	___/___/_____
	___/___/_____	___/___/_____

Has the patient had any prior cancer diagnosed: (check one) 1 Yes 2 No

If Yes: Site of prior cancer: _____

Prior Cancer Diagnosis Date: (mm/dd/yyyy) ___/___/_____

Prior Treatment Regimen Type: _____

Height (cm): _____ .

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N0821

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	MedDRA Code (v. 10.0)	CTC Adverse Event Grade
Baseline number of stools per day: _____		
Hypertension	10020772	<input type="text" value="0"/> <input type="text" value="1"/> <input type="text" value="2"/> <input type="text" value="3"/> <input type="text" value="4"/>
Cardiac ischemia/infarction	10028601	<input type="text" value="0"/> <input type="text" value="1"/> <input type="text" value="2"/> <input type="text" value="3"/> <input type="text" value="4"/>
Rash/desquamation	10037853	<input type="text" value="0"/> <input type="text" value="1"/> <input type="text" value="2"/> <input type="text" value="3"/> <input type="text" value="4"/>
Wound complication, non-infectious	10048031	<input type="text" value="0"/> <input type="text" value="1"/> <input type="text" value="2"/> <input type="text" value="3"/> <input type="text" value="4"/>
Mucositis/stomatitis (clinical exam) - <i>Selects</i>		
- Oral cavity	10056848	<input type="text" value="0"/> <input type="text" value="1"/> <input type="text" value="2"/> <input type="text" value="3"/> <input type="text" value="4"/>
- Pharynx	10065717	<input type="text" value="0"/> <input type="text" value="1"/> <input type="text" value="2"/> <input type="text" value="3"/> <input type="text" value="4"/>
Mucositis/stomatitis (functional/symptomatic) - <i>Selects</i>		
- Oral cavity	10028130	<input type="text" value="0"/> <input type="text" value="1"/> <input type="text" value="2"/> <input type="text" value="3"/> <input type="text" value="4"/>
- Pharynx	10065881	<input type="text" value="0"/> <input type="text" value="1"/> <input type="text" value="2"/> <input type="text" value="3"/> <input type="text" value="4"/>
Nausea	10028813	<input type="text" value="0"/> <input type="text" value="1"/> <input type="text" value="2"/> <input type="text" value="3"/> <input type="text" value="4"/>
Vomiting	10047700	<input type="text" value="0"/> <input type="text" value="1"/> <input type="text" value="2"/> <input type="text" value="3"/> <input type="text" value="4"/>
Hemorrhage, pulmonary/upper respiratory - <i>Selects</i>		
- Bronchus	10065757	<input type="text" value="0"/> <input type="text" value="1"/> <input type="text" value="2"/> <input type="text" value="3"/> <input type="text" value="4"/>
- Lung	10037397	<input type="text" value="0"/> <input type="text" value="1"/> <input type="text" value="2"/> <input type="text" value="3"/> <input type="text" value="4"/>
Proteinuria	10037020	<input type="text" value="0"/> <input type="text" value="1"/> <input type="text" value="2"/> <input type="text" value="3"/> <input type="text" value="4"/>
CNS cerebrovascular ischemia	10023030	<input type="text" value="0"/> <input type="text" value="2"/> <input type="text" value="3"/> <input type="text" value="4"/>
Pain - <i>Select</i>		
- Abdomen NOS	10000081	<input type="text" value="0"/> <input type="text" value="1"/> <input type="text" value="2"/> <input type="text" value="3"/> <input type="text" value="4"/>
Thrombosis/thrombus/embolism	10043607	<input type="text" value="0"/> <input type="text" value="2"/> <input type="text" value="3"/> <input type="text" value="4"/>
Fatigue (asthenia, lethargy, malaise)	10016256	<input type="text" value="0"/> <input type="text" value="1"/> <input type="text" value="2"/> <input type="text" value="3"/> <input type="text" value="4"/>
Neuropathy - sensory	10034620	<input type="text" value="0"/> <input type="text" value="1"/> <input type="text" value="2"/> <input type="text" value="3"/> <input type="text" value="4"/>

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N0821

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): _____

Date of Evaluation: (mm/dd/yyyy) ___/___/_____

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

CTC Adverse Event Term	MedDRA Code (v. 10.0) (must be completed)	CTC Adverse Event Grade (highest grade this cycle) 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

Hypertension	10020772	<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	_____
Cardiac ischemia/infarction	10028601	<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	_____
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	_____
Wound complication, non-infectious	10048031	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	_____
Diarrhea	10012727	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	_____
Mucositis/stomatitis (clinical exam) - Selects				
- 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	_____

* 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: N0821

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

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

CTC Adverse Event Term	MedDRA Code (v. 10.0) (must be completed)	CTC Adverse Event Grade (highest grade this cycle) 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

Mucositis/stomatitis (functional/symptomatic) - *Selects*

- Oral cavity	10028130	0 1 2 3 4 5 (death)	1 2 3 4 5	___
- Pharynx	10065881	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	___

Hemorrhage, pulmonary/upper respiratory - *Selects*

- Bronchus	10065757	0 1 2 3 4 5 (death)	1 2 3 4 5	___
- Lung	10037397	0 1 2 3 4 5 (death)	1 2 3 4 5	___

Infection (documented clinically or microbiologically) with grade 3 or 4 neutrophils (ANC <1.0 x 10e9/L) - *Select*

- Lung (pneumonia)	90030220	0 2 3 4 5 (death)	1 2 3 4 5	___
--------------------	----------	-------------------	-----------	-----

Infection with normal ANC or Grade 1 or 2 neutrophils - *Select*

- Lung (pneumonia)	90031074	0 2 3 4 5 (death)	1 2 3 4 5	___
Proteinuria	10037020	0 1 2 3 4 5 (death)	1 2 3 4 5	___
CNS cerebrovascular ischemia	10023030	0 2 3 4 5 (death)	1 2 3 4 5	___
Leukoencephalopathy (radiographic findings)	10024382	0 1 2 3	1 2 3 4 5	___

Pain - *Select*

- Abdomen NOS	10000081	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

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)

Protocol Number: N0821

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

Current Cycle Number (*nadir/adverse events associated with this cycle*): _____

CTC Adverse Event Term	MedDRA Code (v. 10.0) <i>(must be completed)</i>	CTC Adverse Event Grade <i>(highest grade this cycle)</i> INCLUDE GRADE 0's	CTC AE Attribution Code <i>(If Grade > 0)</i> 1 = Unrelated 2 = Unlikely 3 = Possible 4 = Probable 5 = Definite	Has an adverse event expedited report been submitted?*
Required Adverse Events from Section 10.0 of Protocol				
Thrombosis/thrombus/embolism	10043607	0 2 3 4 5 (death)	1 2 3 4 5	_____
Fatigue (asthenia, lethargy, malaise)	10016256	0 1 2 3 4	1 2 3 4 5	_____
Neuropathy - sensory	10034620	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

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: N0821

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	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 > 0)</i> 1 = Unrelated 2 = Unlikely 3 = Possible 4 = Probable 5 = Definite	Has an adverse event expedited report been submitted?*
	<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	_____
	<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

**CONCURRENT TREATMENT FORM
(BASELINE)**

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: N0821

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

Date of Evaluation: (mm/dd/yyyy) ___/___/_____

Is patient taking any concomitant medications? (check one) 1 Yes 2 No (Stop here)

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

Concomitant Medication	Dose	Schedule

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

**CONCURRENT TREATMENT FORM
(ACTIVE MONITORING PHASE)**

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: N0821

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

Current Cycle Number: _____

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

Has there been any change in medications since the previous visit? (check one) 1 Yes 2 No

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

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

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N0821

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 non-target lesions at baseline, thereafter record the status of non-target lesions at each required evaluation.

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

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

Target Lesion Site(s)	Method of Evaluation						Longest Diameter of Lesion(s) (cm)
	PE ¹	CT ²	Spiral CT ³	PET/CT ⁴	MRI	CXR ⁵	
1	1 <input type="checkbox"/>	2 <input type="checkbox"/>	13 <input type="checkbox"/>	15 <input type="checkbox"/>	3 <input type="checkbox"/>	5 <input type="checkbox"/>	
2	1 <input type="checkbox"/>	2 <input type="checkbox"/>	13 <input type="checkbox"/>	15 <input type="checkbox"/>	3 <input type="checkbox"/>	5 <input type="checkbox"/>	
3	1 <input type="checkbox"/>	2 <input type="checkbox"/>	13 <input type="checkbox"/>	15 <input type="checkbox"/>	3 <input type="checkbox"/>	5 <input type="checkbox"/>	
4	1 <input type="checkbox"/>	2 <input type="checkbox"/>	13 <input type="checkbox"/>	15 <input type="checkbox"/>	3 <input type="checkbox"/>	5 <input type="checkbox"/>	
5	1 <input type="checkbox"/>	2 <input type="checkbox"/>	13 <input type="checkbox"/>	15 <input type="checkbox"/>	3 <input type="checkbox"/>	5 <input type="checkbox"/>	
6	1 <input type="checkbox"/>	2 <input type="checkbox"/>	13 <input type="checkbox"/>	15 <input type="checkbox"/>	3 <input type="checkbox"/>	5 <input type="checkbox"/>	
7	1 <input type="checkbox"/>	2 <input type="checkbox"/>	13 <input type="checkbox"/>	15 <input type="checkbox"/>	3 <input type="checkbox"/>	5 <input type="checkbox"/>	
8	1 <input type="checkbox"/>	2 <input type="checkbox"/>	13 <input type="checkbox"/>	15 <input type="checkbox"/>	3 <input type="checkbox"/>	5 <input type="checkbox"/>	
9	1 <input type="checkbox"/>	2 <input type="checkbox"/>	13 <input type="checkbox"/>	15 <input type="checkbox"/>	3 <input type="checkbox"/>	5 <input type="checkbox"/>	
10	1 <input type="checkbox"/>	2 <input type="checkbox"/>	13 <input type="checkbox"/>	15 <input type="checkbox"/>	3 <input type="checkbox"/>	5 <input type="checkbox"/>	
Sum of Longest Diameters of all Target Lesions							

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

1=Physical exam

2=CT scan

3=Spiral CT scan

4=PET/CT (a CT image from a PET/CT is an acceptable tool for tumor assessments if the original tumor is FDG-avid, and if a nonenhanced CT is sufficient to image the lesion)

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: N0821
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 non-target lesions at baseline, thereafter record the status of non-target lesions at each required evaluation.
6. Overall objective status is determined by combining status of target lesions, non-target lesions and new lesions (refer to protocol Section 11).

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)

Overall Objective Status at this Assessment: (check one) 19 Mark an "X" if NA (not applicable this cycle) - End Form
1 CR*
2 PR*
5 SD
6 PD* (Complete End of Active Treatment and Event Monitoring Forms)

Was the appearance of any new lesions documented? (check one) 1 Yes 2 No

Symptomatic Deterioration? (check one) 1 Yes 2 No

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

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

Sum of Longest Diameters all Target Lesions:	
Nontarget Lesion Site	Follow-Up Status of Lesion: (check one) 1 <input type="checkbox"/> CR 2 <input type="checkbox"/> SD 3 <input type="checkbox"/> PD 5 <input type="checkbox"/> Not Done 9 <input type="checkbox"/> Mark on "X" if NA (Not Applicable) (NonCR/NonPD)

*Submit documentation to verify CR, PR, PD.

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

**EVALUATION/TREATMENT FORM
CYCLES 1 - 6**

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: N0821

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) _____ . _____

Creatinine Clearance = _____

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

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

- | | | |
|---|---|---|
| 35 <input type="checkbox"/> Hematologic | 70 <input type="checkbox"/> Neurologic | 38 <input type="checkbox"/> Other non-hematologic |
| 60 <input type="checkbox"/> Gastrointestinal | 59 <input type="checkbox"/> Renal/Genitourinary | 99 <input type="checkbox"/> Other (not per protocol), specify _____ |
| 129 <input type="checkbox"/> Hemorrhage/bleeding | 110 <input type="checkbox"/> Vascular | |
| 154 <input type="checkbox"/> Metabolic/laboratory | 45 <input type="checkbox"/> Dermatology/skin | |

Agent	Pemetrexed (ALIMTA)	Bevacizumab (AVASTN)	Carboplatin (CBDCA)
Agent Start Date (this cycle) (mm/dd/yyyy)	___/___/___	___/___/___	___/___/___
Initial Dose (Dose Level day one this cycle) (If agent was not given this cycle, enter the dose level received on last day of treatment.)	mg/m ²	mg/kg	AUC <u>6</u>
Total Dose of Agents/Drugs for this cycle (If agent was not given this cycle, enter 0 for total dose.)	mg	mg	
Were there any dose modifica- tions or additions/omissions to protocol treatment? (from previous cycle)	1 <input type="checkbox"/> Yes, planned 2 <input type="checkbox"/> No 3 <input type="checkbox"/> Yes, unplanned	1 <input type="checkbox"/> Yes, planned 2 <input type="checkbox"/> No 3 <input type="checkbox"/> Yes, unplanned	1 <input type="checkbox"/> Yes, planned 2 <input type="checkbox"/> No 3 <input type="checkbox"/> Yes, unplanned
Reason Modified (If Yes, planned or unplanned, PRIMARY REA- SON for Dose modification per Section 8.0. Not BSA changes). (Check one)	35 <input type="checkbox"/> Hematologic 60 <input type="checkbox"/> Gastrointestinal 45 <input type="checkbox"/> Dermatology/skin 38 <input type="checkbox"/> Other non-hematologic 99 <input type="checkbox"/> Other (not per protocol), specify _____ 500 <input type="checkbox"/> Increased per protocol	38 <input type="checkbox"/> Other non-hematologic 99 <input type="checkbox"/> Other (not per protocol), specify _____	35 <input type="checkbox"/> Hematologic 38 <input type="checkbox"/> Other non-hematologic 99 <input type="checkbox"/> Other (not per protocol), specify _____

Was Dexamethasone administered (and taken for this cycle)? (check one) 1 Yes 2 No

Was Vitamin B12 administered (for this cycle)? (check one) 1 Yes 2 No

If Yes, date Vitamin B12 administered? (mm/dd/yyyy) ___/___/___

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

EVALUATION/TREATMENT FORM
CYCLE ≥ 7

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: N0821

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? (check one) 1 Yes, planned 2 No 3 Yes, unplanned

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

- 35 Hematologic
- 60 Gastrointestinal
- 129 Hemorrhage/bleeding
- 154 Metabolic/laboratory
- 70 Neurologic
- 59 Renal/Genitourinary
- 110 Vascular
- 45 Dermatology/skin
- 38 Other non-hematologic
- 99 Other (not per protocol), specify _____

Agent	Pemetrexed (ALIMTA)	Bevacizumab (AVASTN)
Agent Start Date (this cycle) (mm/dd/yyyy)	____/____/____	____/____/____
Initial Dose (Dose Level day one this cycle) (If agent was not given this cycle, enter the dose level received on last day of treatment.)	mg/m ²	mg/kg
Total Dose of Agents/Drugs for this cycle (If agent was not given this cycle, enter 0 for total dose.)	mg	mg
Were there any dose modifications or additions/omissions to protocol treatment? (from previous cycle)	1 <input type="checkbox"/> Yes, planned 2 <input type="checkbox"/> No 3 <input type="checkbox"/> Yes, unplanned	1 <input type="checkbox"/> Yes, planned 2 <input type="checkbox"/> No 3 <input type="checkbox"/> Yes, unplanned
Reason Modified (If Yes, planned or unplanned, PRIMARY REASON for Dose modification per Section 8.0. Not BSA changes) (Check one)	35 <input type="checkbox"/> Hematologic 60 <input type="checkbox"/> Gastrointestinal 45 <input type="checkbox"/> Dermatology/skin 38 <input type="checkbox"/> Other non-hematologic 99 <input type="checkbox"/> Other (not per protocol), specify _____ 500 <input type="checkbox"/> Increased per protocol	38 <input type="checkbox"/> Other non-hematologic 99 <input type="checkbox"/> Other (not per protocol), specify _____

Was Dexamethasone administered (and taken for this cycle)? (check one) 1 Yes 2 No

Was Vitamin B12 administered (for this cycle)? (check one) 1 Yes 2 No

If Yes, date Vitamin B12 administered? (mm/dd/yyyy) ____/____/____

PLACE LABEL HERE

Protocol Number: N0821

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

Protocol Number: N0821

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: _____

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
- 7 Other reason, specify _____

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N0821

Patient ID: _____ Patient Initials: _____
L F M

Institution Number: _____

Institution: _____

PATHOLOGY SUBMISSION FORM

**** 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) ___/___/_____

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

PATHOLOGY REPORTING FORM

LUNG CARCINOMA

Protocol Number: N0821

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. Biopsy
- 2. Resection (lung)
- 3. Resection (lobes)
- 4. Resection (segmental)

II. Completed by the NCCTG Pathology reviewer

3. LOCATION OF PRIMARY NEOPLASM

- LOBE
 - 1. Right upper
 - 2. Right middle
 - 3. Right lower
 - 4. Left upper
 - 5. Left lower
 - 6. Right mainstem
 - 7. Left mainstem
 - 8. Carina
 - 9. Multiple

- LOCATION WITHIN LUNG
 - 1. Central (perihilar)
 - 2. Peripheral
 - 3. Mid zone

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

mm x mm x mm

5. HISTOLOGIC FEATURES OF PRIMARY NEOPLASM

HISTOLOGIC TYPE

- 1. Squamous cell
- 2. Large cell undifferentiated
- 3. Small cell undifferentiated
- 4. Adenocarcinoma
- 5. Alveolar carcinoma
- 6. Combined (mixed pattern) (specify): _____
- 7. Other (specify): _____

DEGREE OF DIFFERENTIATION

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

6. EXTENT OF LOCAL SPREAD

- 1. Confined to lung parenchyma
- 2. Involvement of bronchial margin of resection
- 3. Involvement of pleura

7. REGIONAL LYMPH NODE STATUS

Number of positive nodes (specify location): _____
(intrapulmonary peribronchial, hilar, mediastinal)

Number of negative nodes

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

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

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

**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: N0821
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 60 days of study entry.
- See Section 17 of the protocol for specimen requirements and shipment.
- Include a copy of this form with tissue submission (see Section 17).

Was (research tissue) 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: _____

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

Protocol Number: N0821

END OF ACTIVE TREATMENT/CANCEL NOTIFICATION FORM

Patient ID: _____ Patient Initials: _____

Submit Once Per Patient

Institution Number: _____

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 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: N0821

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: Brain Adrenal
(check all that apply) Liver Other, specify _____
 Bone Unknown
- Method (s) of Diagnosis: Imaging (i.e., CT scan, MRI, etc.) Other, specify _____
(check all that apply) PE Unknown
 Biopsy

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 ≥ 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

**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: N0821

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"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5 (death)	<input type="text"/> 1 <input type="text"/> 2 <input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5	___/___/_____
	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5 (death)	<input type="text"/> 1 <input type="text"/> 2 <input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5	___/___/_____
	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5 (death)	<input type="text"/> 1 <input type="text"/> 2 <input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5	___/___/_____
	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5 (death)	<input type="text"/> 1 <input type="text"/> 2 <input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5	___/___/_____
	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5 (death)	<input type="text"/> 1 <input type="text"/> 2 <input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5	___/___/_____
	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5 (death)	<input type="text"/> 1 <input type="text"/> 2 <input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5	___/___/_____
	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5 (death)	<input type="text"/> 1 <input type="text"/> 2 <input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5	___/___/_____
	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5 (death)	<input type="text"/> 1 <input type="text"/> 2 <input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5	___/___/_____
	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5 (death)	<input type="text"/> 1 <input type="text"/> 2 <input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5	___/___/_____
	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5 (death)	<input type="text"/> 1 <input type="text"/> 2 <input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5	___/___/_____
	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5 (death)	<input type="text"/> 1 <input type="text"/> 2 <input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5	___/___/_____
	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5 (death)	<input type="text"/> 1 <input type="text"/> 2 <input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5	___/___/_____
	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5 (death)	<input type="text"/> 1 <input type="text"/> 2 <input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5	___/___/_____
	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5 (death)	<input type="text"/> 1 <input type="text"/> 2 <input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5	___/___/_____
	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5 (death)	<input type="text"/> 1 <input type="text"/> 2 <input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5	___/___/_____
	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5 (death)	<input type="text"/> 1 <input type="text"/> 2 <input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5	___/___/_____
	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5 (death)	<input type="text"/> 1 <input type="text"/> 2 <input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5	___/___/_____
	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5 (death)	<input type="text"/> 1 <input type="text"/> 2 <input type="text"/> 3 <input type="text"/> 4 <input type="text"/> 5	___/___/_____

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N0821

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 _____

December 12, 2008

Order Form

Quality-of-Life Booklets

Protocol # and Title: N0821, A Phase II First-Line Study of a Combination of Pemetrexed, Carboplatin and Bevacizumab in Advanced Nonsquamous NSCLC Evaluating Efficacy and Tolerability in Elderly Patients (Age \geq 70 yrs) with Good Performance Status (PS $<$ 2)

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: _____

Mayo Medical Laboratories
Fax Supply Order Form – No Cover Sheet Necessary
Fax to Kit Building @ 507-538-4103

Study ID: N0821

Investigator: _____

Order Placed By: _____ Phone #: () _____

Email: _____ Fax #: () _____

<u>Type of Kits</u>	<u># of Kits Needed</u>
----------------------------	--------------------------------

Generic Research Kit	_____
----------------------	-------

_____	_____
-------	-------

_____	_____
-------	-------

_____	_____
-------	-------

Total Kits	_____
-------------------	-------

Date Needed: _____
(Please be specific)

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.**

Fed Ex account number (Rush deliveries only) _____

Address (kits sent to):

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