

FORMS PACKET

N0724, A Randomized Phase II Study of Oligometastatic Stage IV Non-Small Cell Lung Cancer (NSCLC) Treated with Systemic Therapy plus Either Radiotherapy to all Sites of Gross Disease or No Radiotherapy

- Contents:
- ✓ Pre-registration (Step 1) eligibility checklist (4/30/10)
 - ✓ Randomization (Step 2) eligibility checklist (4/30/10)
 - * Forms completion instructions
 - Preregistration screening failure form (10/27/08)
 - ✓ On-study form (4/13/10)
 - Baseline adverse events form (10/1/08)
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 - Radiation therapy reporting form (3/20/09)

✓ 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.

**NCI COOPERATIVE GROUP
Pre-Registration Form and Eligibility Checklist**

04/302010
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Coordinating Group Protocol Number <u> N0724 </u>	Coordinating Group Code <u> NCCTG </u>
Protocol Title <u>A Randomized Phase II Study of Oligometastatic Stage IV Non-Small Cell Lung Cancer (NSCLC) Treated with Systemic Therapy plus Radiotherapy to all Sites of Gross Residual Disease or No Radiotherapy</u>	
Patient Study ID _____	Patient Medical Record Number _____
Participating Group Code (Cooperative Group where credit will be applied) (RT) _____	
Institution Name (treating location/performance site) (RT) _____	
Institution Code (CTEP assigned number) (RT) _____	
Physician of Record (RT) _____	

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

SWOG Institutions: Pre-registration must be done through the SWOG Data Operations Center in Seattle by phoning 206/652-2267, 6:30 a.m. to 1:30 p.m. Pacific Time, Monday through Friday, excluding holidays. The SWOG Data Operations Center will then contact the NCCTG Registration Office at (507-284-4130) to pre-register the patient.

Protocol Administration

Date Informed Consent Signed: (mm/dd/yyyy) __/__/____ _____ Date of Pre-Registration: (mm/dd/yyyy) __/__/____ _____	Person Completing Form (Please Print) Last Name _____ First Name _____ Phone (____) _____ Fax (____) _____ Email _____
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Patient Demographics/Pre-Treatment Characteristics

Patient Initials (L, F, M) _____			
Patient Birth Date: (mm/dd/yyyy) __/__/____		Patient Gender: ___ Male ___ Female	
Patient Race (<i>check all that apply</i>) (U.S. and Canada only)	<input type="checkbox"/> White <input type="checkbox"/> Native Hawaiian or other Pacific Islander <input type="checkbox"/> Asian	<input type="checkbox"/> Black or African American <input type="checkbox"/> American Indian or Alaska Native	<input type="checkbox"/> Unknown: Patient is unsure of race <input type="checkbox"/> Not Reported: Patient refused or data not available
Patient Ethnicity (<i>check one</i>)	<input type="checkbox"/> Hispanic or Latino <input type="checkbox"/> Not Reported: Patient refused or data not available	<input type="checkbox"/> Non-hispanic	<input type="checkbox"/> Unknown: Patient is unsure of ethnicity
Patient's ZIP Code (USA) _____ - _____		Country of Residence (if not USA) _____	
Method of Payment (check one) (U.S. only)			
<input type="checkbox"/> Private Insurance (PI) <input type="checkbox"/> Medicare (MR) <input type="checkbox"/> Medicare & Private Insurance (MRP) <input type="checkbox"/> Medicaid (MD) <input type="checkbox"/> Medicaid and Medicare (MM) <input type="checkbox"/> Military or Veterans Sponsored, Not Otherwise Specified (NOS) (MVA)		<input type="checkbox"/> Military Sponsored (including CHAMPUS & TRICARE) (MS) <input type="checkbox"/> Veterans Sponsored (MV) <input type="checkbox"/> Self pay (no insurance) (SP) <input type="checkbox"/> No means of payment (no insurance) (NP) <input type="checkbox"/> Other (OTH) <input type="checkbox"/> Unknown (UNK)	

NCCTG Pre-Registration (Step 1) Eligibility Checklist N0724

04/302010
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Patient study ID number _____

Pre-Registering Group: (*check one*) ___ NCCTG ___ SWOG

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

Inclusion Criteria

Yes No NA

≥18 years of age. Age = _____	___	___	___
Histologic or cytologic confirmation of Stage IV NSCLC Note: Mixed histology allowed if all components consistent with NSCLC. In addition, patients whose tumors have squamous cell histology/feature are eligible.	___	___	___
Previously untreated disease or SD or PR ≤8 weeks following one previous regimen of a standard platinum-based chemotherapy given every 3-4 weeks for a total of 2-6 cycles.	___	___	___
Ability to provide informed consent.	___	___	___
Life expectancy ≥12 weeks.	___	___	___
M1 with 1-3 non-brain metastases but not more. Note: Patients with M1 disease that is other intrapulmonary metastases can be treated as long as the lung V20 is ≤40%.	___	___	___
Patients who have had up to 3 brain metastases can participate if these have been treated prior to registration and there are no signs of progression at the time of registration.	___	___	___

All responses in above section must be “Yes.”

Exclusion Criteria

Yes No NA

History of or current brain metastases.	___	___	___
Secondary primary malignancy with the following exceptions: <ul style="list-style-type: none"> • Carcinoma in situ of the cervix. • Non-melanomatous skin cancer, unless that prior malignancy was diagnosed and definitively treated at least 5 years previously with no subsequent evidence of recurrence. • History of low-grade (Gleason score ≤6) localized prostate cancer even if diagnosed <5 years prior to pre-registration. • Treated stage I breast cancer even if diagnosed ≤5 years prior to pre-registration. (The lung tumor in this case would have to be a different histology or TTF1 positive.) 	___	___	___
Any prior therapies for this cancer other than 2-6 cycles of platinum-based chemotherapy. Note: bevacizumab is allowed.	___	___	___
Prior radiation therapy to the sites which need to be treated (primary lesion, clinically involved nodes, and metastatic lesions).	___	___	___

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.	___	___	___
Authorization for use and disclosure of protected health information (<i>USA institutions only</i>) signed and dated. If not a USA institution (<i>check NA</i>); If a USA institution - Date of authorization ___/___/_____	___	___	___

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

Person pre-registering Signature _____ Registration Office specialist initials _____

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

**NCI COOPERATIVE GROUP
Registration Form and Eligibility Checklist**

04/302010
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NCCTG Institutions only: *To register a patient, access the NCCTG web page at <https://ncctg.mayo.edu/training> and enter the remote registration/randomization application.*

SWOG Institutions: *Registration of patients must be done through the SWOG Data Operations Center in Seattle by phoning 206/652-2267, 6:30 a.m. to 1:30 p.m. Pacific Time, Monday through Friday, excluding holidays. The SWOG Data Operations Center will then contact the NCCTG Registration Office at (507-284-4130) to register and randomize the patient.*

Coordinating Group Protocol Number <u> N0724 </u>	Coordinating Group Code <u> NCCTG </u>
Protocol Title <u>A Randomized Phase II Study of Oligometastatic Stage IV Non-Small Cell Lung Cancer (NSCLC) Treated with Systemic Therapy plus Radiotherapy to all Sites of Gross Residual Disease or No Radiotherapy</u>	
Patient Study ID _____	Patient Medical Record Number _____
Participating Group Code (Cooperative Group where credit will be applied) (RT) _____	
Institution Name (treating location/performance site) (RT) _____	
Institution Code (CTEP assigned number) (RT) _____	
Physician of Record (RT) _____	

Protocol Administration

Date of Registration/Randomization: (mm/dd/yyyy) <u> </u> / <u> </u> / <u> </u>	Person Completing Form (Please Print) Last Name _____ First Name _____ Phone (____) _____ Fax (____) _____ Email _____
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Patient Demographics/Pre-Treatment Characteristics

Patient Initials (L, F, M) _____			
Patient Birth Date: (mm/dd/yyyy) <u> </u> / <u> </u> / <u> </u>		Patient Gender: <u> </u> Male <u> </u> Female	
Patient Race (<i>check all that apply</i>) (U.S. and Canada only)	<input type="checkbox"/> White <input type="checkbox"/> Native Hawaiian or other Pacific Islander <input type="checkbox"/> Asian	<input type="checkbox"/> Black or African American <input type="checkbox"/> American Indian or Alaska Native	<input type="checkbox"/> Unknown: Patient is unsure of race <input type="checkbox"/> Not Reported: Patient refused or data not available
Patient Ethnicity (<i>check one</i>)	<input type="checkbox"/> Hispanic or Latino <input type="checkbox"/> Not Reported: Patient refused or data not available	<input type="checkbox"/> Non-hispanic	<input type="checkbox"/> Unknown: Patient is unsure of ethnicity
Patient's ZIP Code (USA) _____ - _____		Country of Residence (if not USA) _____	
Method of Payment (<i>check one</i>) (U.S. only)			
<input type="checkbox"/> Private Insurance (PI) <input type="checkbox"/> Medicare (MR) <input type="checkbox"/> Medicare & Private Insurance (MRP) <input type="checkbox"/> Medicaid (MD) <input type="checkbox"/> Medicaid and Medicare (MM) <input type="checkbox"/> Military or Veterans Sponsored, Not Otherwise Specified (NOS) (MVA)		<input type="checkbox"/> Military Sponsored (including CHAMPUS & TRICARE) (MS) <input type="checkbox"/> Veterans Sponsored (MV) <input type="checkbox"/> Self pay (no insurance) (SP) <input type="checkbox"/> No means of payment (no insurance) (NP) <input type="checkbox"/> Other (OTH) <input type="checkbox"/> Unknown (UNK)	

Patient study ID number _____

Randomization Group: (check one) ____ NCCTG ____ SWOG

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

Inclusion Criteria

Yes No NA

ECOG performance status (PS) 0 or 1. (This form is now on the NCCTG website.) ECOG performance status = _____	____	____	____
Negative pregnancy test done ≤7 days prior to randomization, for women of childbearing potential only. If not a woman of childbearing potential or male (check NA) If a woman of childbearing potential - Negative pregnancy test date ____/____/____	____	____	____
Able to receive radiation therapy based on radiation oncology consultation.	____	____	____
Received at least 2-6 cycles of standard chemotherapy during or before pre-registration.	____	____	____
The following laboratory values obtained ≤21 days prior to randomization. Earliest laboratory test date ____/____/____; latest laboratory test date ____/____/____. NOTE: These dates pertain to the following labs only.	____	____	____
• PLT ≥100,000 µL PLT (≥100000) = _____	____	____	____
• Hgb ≥9 g/dL Hgb (≥9) = _____	____	____	____
• WBC ≥2.0 WBC (≥2.0) = _____	____	____	____
• Creatinine ≤2 x UNL Creatinine (≤2 x UNL) = _____; Creatinine UNL = _____	____	____	____
Stable Disease (SD) or Partial Response (PR).	____	____	____

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

Exclusion Criteria

Yes No NA

History of >3 or current brain metastases or progressive brain metastases if fewer than 3.	____	____	____
More than a minimal pleural effusion.	____	____	____
FEV1 <1 Liter.	____	____	____
Use of supplemental oxygen on a daily basis.	____	____	____
Any clinically significant infection.	____	____	____
Unwilling to, or unable to, comply with the protocol.	____	____	____
Any prior therapies for this cancer other than 2-6 cycles of platinum-based chemotherapy. Note: Prior to RT, bevacizumab is allowed until unacceptable toxicity during chemotherapy. Bevacizumab or other maintenance systemic therapy is not administered during the radiotherapy. Bevacizumab may not be administered < 4 weeks following radiotherapy (See Section 7.11). Bevacizumab or other maintenance systemic therapy may be administered again after this time until progression of disease or unacceptable toxicity.	____	____	____
Psychiatric illness/social situations that would limit compliance with study requirements.	____	____	____
Any of the following concurrent severe and/or uncontrolled medical conditions: • Angina pectoris • History of congestive heart failure ≤3 months, unless ejection fraction >40% • Myocardial infarction ≤6 months prior to registration • Cardiac arrhythmia	____	____	____
Receiving any other investigational agent which would be considered as a treatment for the primary neoplasm during RT.	____	____	____
Any of the following: • Pregnant women • Nursing women • Men or women of childbearing potential who are unwilling to employ adequate contraception	____	____	____
Prior radiation therapy to the sites which need to be treated (primary lesion, clinically involved nodes, and metastatic lesions).	____	____	____

All responses in above section must be “No.”

Patient study ID number _____

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

Yes No NA

Treatment on this protocol must commence at the accruing membership under the supervision of an NCCTG or SWOG member physician.	____
Treatment (protocol radiotherapy) cannot begin prior to randomization and must begin ≤14 days after randomization.	____
Pretreatment tests/procedures (see Section 4.0) must be completed ≤21 days prior to randomization. Earliest pretreatment test/procedure date ___/___/____; latest pretreatment test/procedure date ___/___/____. NOTE: The earliest pretreatment test/procedure date must be less than or equal to the earliest laboratory test date and the latest pretreatment test/procedure date must be greater than or equal to the latest laboratory test date.	____
<p><u>Exceptions to the above dates:</u></p> <ul style="list-style-type: none"> Tumor assessment: Imaging studies such as chest x-ray, CT scans, PET/CT and MRIs are to be completed ≤28 days prior to randomization (see Section 4.0). Use same imaging throughout the study. Radiographic tests [Chest CT (preferably with IV contrast) and CT at site of metastases; Positron Emission Tomography (PET) preferably with CT; MRI or CT of the head (if CT must be with contrast, contrast preferable for MRI)] are to be completed ≤28 days prior to randomization (see Section 4.0). Earliest exception (imaging studies/radiographic) test date ___/___/____; latest exception (imaging studies/radiographic) test date ___/___/____. <p>NOTE: The CT scans of the chest and mets can be eliminated if the PET is a combined PET/CT scan. CT is used for tumor measurements.</p>	
All required baseline symptoms (see Section 10.3) must be documented and graded.	____
A NCCTG or SWOG radiation oncologist has seen the patient and confirms the patient is a suitable candidate for this study prior to randomization.	____

All responses in above section must be “Yes.”

Stratification Factor

Prior 1st line chemotherapy received
 ___ Bevacizumab
 ___ No bevacizumab

Cycles of standard chemotherapy received
 ___ 2-3
 ___ 4-6

Linear Analog Self Assessment value
 ___ ≤ 7
 ___ >7

Histology
 ___ Predominantly squamous cell
 ___ Not predominantly squamous cell NSCLC

Assigned Treatment

___ A) No Radiation Therapy
 ___ B) Radiation Therapy

Person registering Signature _____ Registration Office specialist initials _____

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

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

**PREREGISTRATION
SCREENING FAILURE 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: N0724

Patient ID: _____ Patient Initials: _____
L F M

Institution Number: _____

Institution: _____

Date aware of preregistration screening failure: (mm/dd/yyyy) ___/___/___

Primary reason screening failed? (check one)

- 3 Did not meet eligibility criteria
- 1 Investigator decision
- 2 Patient decision
- 4 Other reason, specify _____

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

ON-STUDY FORM

Protocol Number: N0724
Patient ID Number: Patient Initials: L F M
Institution Number:
Institution:

ALL ITEMS MUST BE COMPLETED

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

Description of Primary Disease

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

Histologic Type (check one)

- 1 Squamous cell (or if mixed, predominantly squamous cell) carcinoma
2 Bronchoalveolar carcinoma (BAC)
3 Adenocarcinoma
4 Non-small cell lung cancer (NSCLC) NOS
5 Large cell undifferentiated
6 Other, Specify Other Histologic Type:

Histologic Grade (Differentiation) (check one)

- 1 Grade I (well) 2 Grade II (moderate) 3 Grade III (poor) 4 Grade IV (undifferentiated, anaplastic)

Status of Primary Tumor (check one)

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

Disease Status

Method of Evaluation* Date (mm/dd/yyyy)
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 Bone marrow Adrenal(s) Pleura
Ipsilateral Lung Mediastinal nodes Brain Bone
Liver Contralateral Lung Supraclavicular/scalene nodes Skin
Other, specify

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

Previous Surgery Related To The Tumor

Table with 4 columns: Surgical Approach, Surgery Results (Positive, Negative, Not Done), and Date of prior surgery (mm/dd/yyyy). Rows include Mediastinoscopy, Bronchoscopy, Supraclavicular biopsy, Thoracoscopy, Fine Needle Aspirate, and Other.

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

ON-STUDY FORM

Protocol Number: N0724

Patient ID Number: Patient Initials: L F M

Institution Number:

Institution:

ALL ITEMS MUST BE COMPLETED pg 2 of 2

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

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

Table with 4 columns: Prior RT Site, Total (Dose) cGy Administered, Prior radiation therapy start date, Prior radiation therapy stop date.

Prior systemic (cancer) therapy (other previous malignancies) (check one) Yes No

Table with 4 columns: Prior Treatment Name, Prior systemic therapy start date, Prior systemic therapy stop date, Response (NED, CR, PR, REGR, SD, PD).

Has the patient had any prior cancer diagnosed? (check one) Yes No

If Yes: Site of prior cancer: Prior Cancer Diagnosis Date (mm/dd/yyyy) Prior Treatment Regimen Type:

Descriptive Factors:

Number of metastatic sites at on-study: (check one) 1 2 3 Response to initial standard chemotherapy: (check one) PR SD Measurable disease: (check one) Yes No Brain metastases: (check one) Yes No

Height (cm):

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N0724

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

**BASELINE
ADVERSE EVENTS FORM**

ALL ITEMS MUST BE COMPLETED

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

Required Baseline Adverse Events from Section 10.0 of Protocol		
CTC Adverse Event Term	MedDRA Code (v. 10.0)	CTC Adverse Event Grade
Baseline number of stools per day: _____		
Hemoglobin	10019483	<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"/>
Platelets	10035528	<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"/>
Leukocytes (total WBC)	10048552	<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"/>
Pericarditis	10034484	<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: dermatitis associated with radiation - <i>Select</i>		
- Radiation	10061103	<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"/>
Esophagitis	10015461	<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"/>
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"/>
Creatinine	10011368	<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"/>
AST, SGOT (serum glutamic oxaloacetic transaminase)	10003481	<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"/>
Bilirubin (hyperbilirubinemia)	10004690	<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="1"/> <input type="text" value="2"/> <input type="text" value="3"/> <input type="text" value="4"/>
Myelitis	10028524	<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"/>
Pneumonitis/pulmonary infiltrates	10035742	<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: N0724

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

NADIR/ADVERSE EVENT FORM

ALL ITEMS MUST BE COMPLETED

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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 <i>(Date of lab test)</i> (mm/dd/yyyy)	Nadir/Worst Value <i>(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.)</i>	Is nadir below LLN? <i>(check one)</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?*
Platelets (PLT) K/uL or 10 ⁹ /L	___/___/_____	_____	1 <input type="checkbox"/> Yes → 2 <input type="checkbox"/> No → <i>(Go to WBC)</i>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	_____
Leukocytes (total WBC) K/uL or 10 ⁹ /L	___/___/_____	_____	1 <input type="checkbox"/> Yes → 2 <input type="checkbox"/> No → <i>(Go to Hgb)</i>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	_____
Hemoglobin (Hgb) g/dL	___/___/_____	_____	1 <input type="checkbox"/> Yes → 2 <input type="checkbox"/> No → <i>(Go to ANC)</i>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	_____
Absolute Neutrophil Count (ANC) K/uL or 10 ⁹ /L	___/___/_____	_____	1 <input type="checkbox"/> Yes → 2 <input type="checkbox"/> No → <i>(Go to Adverse Event)</i>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	_____

CTC Adverse Event Term	MedDRA Code <i>(v. 10.0)</i> <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?*
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Required Adverse Events from Section 10.0 of Protocol

Cardiac ischemia/infarction	10028601	<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"/>	_____
Pericarditis	10034484	<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"/>	_____
Rash: dermatitis associated with radiation - <i>Select</i>				
- Radiation	10061103	<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"/>	_____
Diarrhea	10012727	<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"/>	_____

* See Section 10.0 of the protocol.

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

NADIR/ADVERSE EVENT FORM

ALL ITEMS MUST BE COMPLETED

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

Protocol Number: N0724

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)
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Required Adverse Events from Section 10.0 of Protocol

Esophagitis	10015461	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	___
Nausea	10028813	0 1 2 3 4 5 (death)	1 2 3 4 5	___
Hepatobiliary / pancreas - Other (liver injury due to RT)	10062000	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 10⁹/L) - Selects

- Skin (cellulitis)	90030270	0 2 3 4 5 (death)	1 2 3 4 5	___
- Catheter-related	90030174	0 2 3 4 5 (death)	1 2 3 4 5	___
- Wound	90030304	0 2 3 4 5 (death)	1 2 3 4 5	___
- Lung (pneumonia)	90030220	0 2 3 4 5 (death)	1 2 3 4 5	___
- Bladder (urinary)	90030164	0 2 3 4 5 (death)	1 2 3 4 5	___
- Urinary tract NOS	90030294	0 2 3 4 5 (death)	1 2 3 4 5	___

Infection with normal ANC or Grade 1 or 2 neutrophils - Selects

- Skin (cellulitis)	90031178	0 2 3 4 5 (death)	1 2 3 4 5	___
- Catheter-related	90030309	0 2 3 4 5 (death)	1 2 3 4 5	___
- Wound	90030351	0 2 3 4 5 (death)	1 2 3 4 5	___
- Lung (pneumonia)	90031074	0 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: N0724

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

Infection with normal ANC or Grade 1 or 2 neutrophils - *Selects (continued)*

- Bladder (urinary)	90031010	<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	___
- Urinary tract NOS	90031102	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	___
Creatinine	10011368	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	___
AST, SGOT (serum glutamic oxaloacetic transaminase)	10003481	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	___
Bilirubin (hyperbilirubinemia)	10004690	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	___
CNS cerebrovascular ischemia	10023030	<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	___
Myelitis	10028524	<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	___
Pneumonitis/pulmonary infiltrates	10035742	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	___

* 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

Protocol Number: N0724

Patient ID: Patient Initials: L F M

Institution Number:

Institution:

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

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

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

- 1 Yes, and reportable adverse events occurred
3 Yes, but no reportable adverse events occurred (Stop here)
2 No (Stop here)

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

Table with 5 columns: Other CTC Adverse Event Term not listed, MedDRA Code (v. 10.0) (must be completed), CTC Adverse Event Grade (highest grade this cycle), CTC AE Attribution Code (If Grade > 0), Has an adverse event expedited report been submitted?*

* 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

Protocol Number: N0724

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

NORTH CENTRAL CANCER TREATMENT GROUP

EVALUATION 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: 1

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)

Evaluation Date this cycle (Arm A) / Radiation Therapy Start Date this cycle (Arm B): *(mm/dd/yyyy)* ___/___/___

PLACE LABEL HERE

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)

Protocol Number: N0724
Patient ID: _____ Patient Initials: _____
L F M
Institution Number: _____
Institution: _____

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)* ____/____/____

Has the patient received subsequent *(maintenance)* treatment for this cancer that has not been previously reported? *(check one)*

1 Yes 2 No

If Yes, Subsequent Treatment Type: *(check all that apply)*

- Bevacizumab
- Pemetrexed
- Erlotinib
- Other, specify _____

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

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

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N0724

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 target lesions (per Section 11 of the protocol).
2. Measure target lesions in cm. using longest diameter (one dimension only).
- 3 Record measurement 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.)

Did patient have measurable disease per Section 11.0 of the protocol? Yes. If Yes, complete Target and Nontarget Lesions
 No. If No, go to Nontarget Lesions

Target Lesion Site(s)	Method of Evaluation					Longest Diameter of Lesion(s) (cm)
	CT ¹	Spiral CT ²	PET/CT ³	MRI	CXR ⁴	
1	2 <input type="checkbox"/>	13 <input type="checkbox"/>	15 <input type="checkbox"/>	3 <input type="checkbox"/>	5 <input type="checkbox"/>	
2	2 <input type="checkbox"/>	13 <input type="checkbox"/>	15 <input type="checkbox"/>	3 <input type="checkbox"/>	5 <input type="checkbox"/>	
3	2 <input type="checkbox"/>	13 <input type="checkbox"/>	15 <input type="checkbox"/>	3 <input type="checkbox"/>	5 <input type="checkbox"/>	
4	2 <input type="checkbox"/>	13 <input type="checkbox"/>	15 <input type="checkbox"/>	3 <input type="checkbox"/>	5 <input type="checkbox"/>	
5	2 <input type="checkbox"/>	13 <input type="checkbox"/>	15 <input type="checkbox"/>	3 <input type="checkbox"/>	5 <input type="checkbox"/>	
6	2 <input type="checkbox"/>	13 <input type="checkbox"/>	15 <input type="checkbox"/>	3 <input type="checkbox"/>	5 <input type="checkbox"/>	
7	2 <input type="checkbox"/>	13 <input type="checkbox"/>	15 <input type="checkbox"/>	3 <input type="checkbox"/>	5 <input type="checkbox"/>	
8	2 <input type="checkbox"/>	13 <input type="checkbox"/>	15 <input type="checkbox"/>	3 <input type="checkbox"/>	5 <input type="checkbox"/>	
9	2 <input type="checkbox"/>	13 <input type="checkbox"/>	15 <input type="checkbox"/>	3 <input type="checkbox"/>	5 <input type="checkbox"/>	
10	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 (check one) Yes (Present) No (Absent)

- 1=CT scan
- 2=Spiral CT scan
- 3=PET/CT - Only CT portion of scan can be used for measurement
- 4=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: N0724

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 Day (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 Response Status at This Assessment
(check one)

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.

- 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.)
- Was the appearance of any new lesions documented? 1 Yes 2 No
 - Symptomatic Deterioration? 1 Yes 2 No

Did patient have measurable disease at study entry?

- 1 Yes → Complete Target and Nontarget Lesions
- 2 No → Go to Nontarget 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 of All Target Lesions:

Nontarget Lesions

- Change: (check one)**
- 1 CR 2 SD (NonCR/NonPD) 3 PD 9 Mark an "X" if NA (Not Applicable)

*Submit documentation to verify CR,PR, PD.

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N0724

END OF ACTIVE TREATMENT/CANCEL NOTIFICATION FORM

Patient ID: _____ Patient Initials: _____

Submit Once Per Patient

Institution Number: _____ L F M

ALL ITEMS MUST BE COMPLETED

Institution: _____

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

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

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

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

- 1 Observation *(follow test schedule and enter cycle data)*
- 2 Event Monitoring *(follow Event Monitoring schedule)*
- 9 Off Study *(cancels only)*

Reason Treatment Ended <i>(check one)</i>	COMMENTS
1 <input type="checkbox"/> Treatment Completed Per Protocol Criteria	
2 <input type="checkbox"/> Patient Withdrawal/Refusal 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
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: N0724

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/Progression: (check all that apply)

<input type="checkbox"/> Hilar nodes	<input type="checkbox"/> Brain
<input type="checkbox"/> Ipsilateral Lung	<input type="checkbox"/> Supraclavicular/scalene nodes
<input type="checkbox"/> Liver	<input type="checkbox"/> Pleura
<input type="checkbox"/> Bone marrow	<input type="checkbox"/> Bone
<input type="checkbox"/> Mediastinal nodes	<input type="checkbox"/> Skin
<input type="checkbox"/> Contralateral Lung	<input type="checkbox"/> Other, specify _____
<input type="checkbox"/> Adrenal(s)	

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: (check all that apply)

<input type="checkbox"/> Bevacizumab	<input type="checkbox"/> Erlotinib
<input type="checkbox"/> Pemetrexed	<input type="checkbox"/> Other, specify _____

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: N0724

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"/>	___/___/_____
	<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: N0724

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
NCCTG INSTITUTIONS ONLY

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 _____

PLACE LABEL HERE

Protocol Number: N0724

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

NORTH CENTRAL CANCER TREATMENT GROUP

PATHOLOGY SUBMISSION FORM

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

**** 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) Dr. James Quesenberry, NCCTG and SWOG reviewer - Sioux City, IA

Dr. Marie Christine Aubry, Mayo Clinic Rochester - Rochester, MN

(Note: For Mayo Clinic Rochester only)

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: N0724

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

RADIATION THERAPY REPORTING FORM

Protocol Number: N0724

Patient ID Number: _____ Patient Initials: _____
L F M

Institution Number: _____

Institution: _____

Treating Institution: _____ pg 1 of 2

Radiation Oncologist: _____

LUNG

Lung

Treating Radiation Oncologist's preference: (check one)

1 60 Gy in 30 fractions

2 45 Gy in 15 fractions

RT Start Date: (mm/dd/yyyy) ___/___/_____

RT End Date: (mm/dd/yyyy) ___/___/_____

Technique

Definition of prescription point (check one):
 1 Isocenter
 2 Isodose line, specify _____
 3 Volume, specify _____

Inhomogeneity corrections? (check one) 1 Yes 2 No

Field (from list below)	Total Dose to Prescription Point	Energy (Photon)	Number of Treatment Fields
Lung	_____	_____	___ __
Metastatic Site (1):* _____	_____	_____	___ __
Metastatic Site (2):* _____	_____	_____	___ __
Metastatic Site (3):* _____	_____	_____	___ __

Treatment Areas, Dose, and Time

Field (from list below)	Daily Dose (Gy)	Total Tumor Dose (Gy)	Daily Number of Fractions	Total Number of Fractions	Elapsed Days
Lung	_____	_____	___ __	_____	___ __
Metastatic Site (1):* _____	_____	_____	___ __	_____	___ __
Metastatic Site (2):* _____	_____	_____	___ __	_____	___ __
Metastatic Site (3):* _____	_____	_____	___ __	_____	___ __

*Metastatic Site(s):
 Hilar nodes Mediastinal nodes Supraclavicular/scalene nodes
 Ipsilateral Lung Contralateral Lung Pleura
 Liver Adrenal(s) Bone
 Bone marrow Brain Skin
 Other, specify _____

Lung: V₂₀: _____ % V₅: _____ % Mean lung dose: _____

Spinal cord: Max spinal cord dose: _____

RADIATION THERAPY REPORTING FORM

Protocol Number: N0724

Patient ID Number: _____ Patient Initials: _____
 L F M

Institution Number: _____

Institution: _____

Treating Institution: _____

Radiation Oncologist: _____

Unscheduled Interruptions

Were there any unscheduled interruptions to the radiation therapy? (check one) 1 Yes 2 No

If Yes:

	<u>Dates</u>	<u>Number of Days</u>	<u>Reason</u>	<u>Due To</u>
<u>Lung:</u>	___/___/___ thru ___/___/___	___	_____	_____
<u>Metastatic Site 1:</u>	___/___/___ thru ___/___/___	___	_____	_____
<u>Metastatic Site 2:</u>	___/___/___ thru ___/___/___	___	_____	_____
<u>Metastatic Site 3:</u>	___/___/___ thru ___/___/___	___	_____	_____

- | | |
|--------------------------------------|-------------------|
| 1. Social | 1. Chemotherapy |
| 2. Skin reaction | 2. Radiotherapy |
| 3. Systemic reaction | 3. Combination |
| 4. Machine down | 4. None of above |
| 6. Unknown | 5. Other, specify |
| 7. ANC | _____ |
| 8. Platelets | 9. Unknown |
| 9. Febrile neutropenia | |
| 12. Dysphagia | |
| 13. Other non-hematologic | |
| 5. Other (not per protocol), specify | |
| _____ | |

Radiation Oncologist's Comments:

 Radiation Oncologist's Signature

 Date