

**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*) ____/____/____