

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

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> <i>(U.S. and Canada only)</i>	<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"/> Non-hispanic <input type="checkbox"/> Unknown: Patient is unsure of ethnicity <input type="checkbox"/> Not Reported: Patient refused or data not available			
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)		

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*) ___/___/_____