NCI COOPERATIVE GROUP PRE-REGISTRATION ELIGIBILITY CHECKLIST

N0574: **Phase III Randomized Trial of the Role of Whole Brain Radiation Therapy in Addition to Radiosurgery in Patients with One to Three Cerebral Metastases**

Has the patient ever been on a prior study entered through this Registration Office? ____ Yes ____ No

If yes: Prior protocol number _________________; prior study patient ID number ________________________

NCCTG Patient ID *(provided at time of Pre-Registration)* ________________________

Patient Medical Record Number ___________________

Participating Group Code (Cooperative Group where credit will be applied) ____________________________________

Pre-Registering Institution Name (treating location/performance site) ____

Credentialed SRS Institution Name ____

Institution Code (CTEP assigned number) *(not required for NCCTG Members)* _____ _____ _____ _____ _____

Physician of Record _____________________________ RT Physician of Record _____________________________

IRB/REB approval date *(mm/dd/yyyy)* __ __/__ __/__ __ __ __

Date of Pre-Registration *(mm/dd/yyyy)* __ __/__ __/__ __ __ __

Person Completing Form:
Last Name: ______________________________
First Name: ______________________________
Phone: ______________________________
Fax: ______________________________
Email: ______________________________

Patient initials *(last, first, middle)* _______________________
(For Mayo Rochester patients, include first four letters of last name.)

Gender *(check one)* ____Male ____Female ____Unknown

Patient's Date of Birth *(mm/dd/yyyy)* __ __/__ __/__ __ __ __

Patient's Zip code *(USA)* _________________________

Country of Residence *(if not USA)* _________________________

Method of payment *(check one)*
___ PI *(Private Insurance)*
___ MR *(Medicare)*
___ MRP *(Medicare and Private Insurance)*
___ MD *(Medicaid)*
___ MM *(Medicaid and Medicare)*
___ MVA *(Military or Veterans Sponsored, Not Otherwise Specified (NOS))*
___ MS *(Military Sponsored [including CHAMPUS & TRCARE])*
___ MV *(Veterans Sponsored)*
___ SP *(Self pay [no insurance])*
___ NP *(No means of payment [no insurance])*
___ OTH *(Other)*
___ UNK *(Unknown)*

Race *(check all that apply)*
___ White
___ Black or African American
___ Native Hawaiian or Other Pacific Islander
___ Asian
___ American Indian or Alaska Native
___ Not reported: *Patient refused or data not available*
___ Unknown: *Patient is unsure of race*

Ethnicity *(check one)*
___ Not Hispanic or Latino
___ Hispanic or Latino
___ Not reported: *Patient refused or data not available*
___ Unknown: *Patient is unsure of their ethnicity*

Weight *(kg)* ____ ____ ____ . ____

Performance Status _____
0=fully active (Karnofsky 90-100)
1=ambulatory, capable of light work (K 70-80)
2=in bed <50% of time, capable of self care but not work activities (K 50-60)

NCCTG Patient ID ____________________________

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

Required Characteristics	Yes No NA
One to three presumed brain metastases from a pathologically confirmed extra-cerebral tumor site (e.g. lung, breast, prostate, etc.). The pathologic confirmation may have been from primary tumor site, from another metastatic site (e.g. an osseous metastasis, adrenal metastasis, etc.), or from the metastatic brain lesion(s). **NOTE:** Each lesion must measure <3.0 cm in maximal extent on the contrasted pre-treatment MRI brain scan obtained ≤28 days prior to randomization (see *Magnetic Resonance Imaging (MRI) Guidelines* section 11.2).	____ ____
All standard tumor-staging procedures necessary to define baseline extracranial disease status completed ≤42 days prior to pre-registration.	____ ____
Ability to be treated with either a gamma knife or a linear accelerator-based radiosurgery system. Note: A treating center must have completed stereotactic radiosurgery credentialing (see Section 6.1).	____ ____
≥18 years of age. Age = _____.	____ ____
Ability to complete questionnaire(s) by themselves or with assistance.	____ ____
ECOG performance status 0, 1, or 2.	____ ____
Grooved peg board available for Neurocognitive Testing (See Section 6.29 for further details). Note: The examiner must have credentialing confirming completion of the neurocognitive testing training (see section 6.1).	____ ____
SRS facility is RPC approved (see Section 6.1).	____ ____

All responses in above section must be "Yes."

Contraindications	Yes No NA
Any of the following: • Pregnant women • Men or women of childbearing potential who are unwilling to employ adequate contraception	____ ____
Pacemaker or other MRI non-compatible metal in the body.	____ ____
Known allergy to gadolinium.	____ ____
Prior resection of cerebral metastasis.	____ ____
A lesion that is located ≤5 mm of the optic chiasm or within the brainstem.	____ ____
Prior chemotherapy ≤7 days prior to pre-registration. No prior chemotherapy *(check NA)* vs. Last day of chemotherapy __ __/__ __/__ __ __ __.	____ ____ ____
Planned chemotherapy during the SRS and WBRT.	____ ____
Prior cranial radiation therapy.	____ ____
Primary germ cell tumor, small cell carcinoma, or lymphoma.	____ ____
Leptomeningeal metastasis.	____ ____

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
Consent form signed and dated. Date of consent _____-_____-_____.	____ ____
Authorization for use and disclosure of protected health information signed and dated. **Non-USA institution only** *(check NA)* vs. Date of authorization _____-_____-_____.	____ ____ ____
Pre-registration tests/procedures must be completed ≤21 days prior to pre-registration (see Section 4.0). Earliest pre-registration test date _____-_____-_____; latest pre-registration test date _____-_____-_____. NOTE: The earliest pre-registration test date must be less than or equal to the latest pre-registration test date. The above dates **DO NOT** include footnote 7 of the test schedule that reads "All standard tumor-staging procedures necessary to define baseline extracranial status (as deemed appropriate by the treating oncology physician) completed ≤42 days prior to pre-registration."	____ ____

NCCTG Patient ID ____________________________

Registration Check – *(continued)*

	Yes	No	NA
All required baseline symptoms (see Section 10.3) must be documented and graded.	____	____	
A radiation oncologist has seen the patient and confirms the patient is a suitable candidate for this study.	____	____	
Patient questionnaire booklet availability checked. Note: copies of the Appendices are not acceptable for this submission.	____	____	
Site booklets ({1} QOL: FACT-BR Booklet; {2} Neurocognitive Patient Completed Booklet and {3} Neurocognitive Examiners Booklets) are available.	____	____	
Grooved peg board available for Neurocognitive testing. **NOTE:** If site has a psychology department, they may use their peg boards and not have to purchase them.	____	____	

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

Assigned Treatment

_____ Pre-Registration

Person registering ______________________________ Registration Office specialist _______
Signature initials

Physician _____________________________________ _____-_____-_____
Signature M D Y