

FORMS PACKET COVER SHEET

N0574, “A Phase III Randomized Trial of the Role of Whole Brain Radiation Therapy in Addition to Radiosurgery in the Management of Patients with One to Three Cerebral Metastases”

- Contents:
- Forms completion instructions (05/08/2006)
 - Pre-Registration Eligibility checklist (10/24/2008)
 - Randomization Eligibility checklist (4/17/2009)
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 - On-study form (01/15/2007)
 - ✓ Baseline adverse events form (09/22/2011)
 - Evaluation/treatment form (08/14/2007)
 - Evaluation/observation form (08/21/2007)
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 - Event monitoring form (02/12/2008)
 - Arm B radiation therapy reporting form (06/15/2007)
 - Radiosurgery reporting form (08/28/2007)
 - Notification form [Grade 4 or 5 Non-AER Reportable Events] (06/20/2006)
 - Neurocognitive testing booklet compliance form (06/19/2006)
 - Booklet Order Form (6/12/2007)
 - Neurocognitive testing verification form (11/8/2006)

✓ designates revised/new forms

(N0574) Forms Completion Instructions

General Information

- All forms are protocol specific and contain the data that is pertinent to the protocol's analysis.
- It is important to comply with the protocol's test schedule (Section 4.0). Not all protocol test schedule requirements will be captured/recorded on the forms; however, the tests/procedures are required for patient management.
- All data items on the forms must be completed unless there are specific instructions on the form indicating that only one choice must be marked.
- Place an "x" over the appropriate AE value on the toxicity forms, it is difficult to discern when boxes are blackened.
- Sites will be queried if any required fields are not completed.
- All forms completed and submitted must include all patient identifiers. Please note initials must be supplied in the correct order (last, first, middle).
- The header on all forms requires **NCCTG patient ID number** which will be the 90_____ number that the patient received at random.
- The **Institution Number** is your local internal patient number.
- Refer to Section 18.0 for submission of all forms.

Pre-registration Screening Failure Form

- Complete and submit only when the patient has been pre-registered but is not randomized.

Quality-of-Life

- ***Fact-BR***
- **Functional Independence**
- **Barthel ADL Index**
- **Neurocognitive Boklets**

- Refer to Appendices III, IV, V, VI, and VIII.
- Make sure all booklets and forms are properly identified to include the patient's initials (last, first, middle), the patient's assigned identification number, and the date of administration.
- **DO NOT** duplicate QOL forms. Must always send originals.

(N0574) Forms Completion Instructions Continued

**Notification Form
Grade 4 or 5 Non-AER
Reportable Events/
Hospitalization (NCCTG
sites only)**

- The Notification Form is used to report all grade 4 or 5 events that do not meet the criteria for an AdEERS report. This form is also used for any hospitalization during active treatment that does not meet the criteria for an AdEERS report.
- If an AdEERS report is required per protocol, do not submit the Notification Form in addition to AdEERS or in place of AdEERS.
- The following items must be completed:
 - Date membership notified of the event (this date **cannot** be before the date of the actual event)
 - Cycle number
 - Event \geq grade 4
 - Name and phone number of person completing the form
- If 'yes' is selected for event \geq grade 4, the following information must be provided:
 - Date of first occurrence of the event
 - Event type, only one event per line
 - Grade
 - Relationship to study medication
- 'Yes' or 'no' **must** be marked for 'hospitalization.' If 'yes' is selected, the following information must be provided:
 - Date of admission
 - Reason(s) for hospitalization

*Note: Many hospitalizations involve a grade 3 event. Please check the protocol Section 10.0 for the proper reporting process (e.g., AdEERS reporting). The events listed on this form **must** also be reported on the Nadir/Adverse Event Form.*

Event Monitoring Form

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**Event Monitoring
Continuation Form (Late
Adverse Event Reporting)**

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NCI COOPERATIVE GROUP PRE-REGISTRATION ELIGIBILITY CHECKLIST

10/24/2008

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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 (<i>provided at time of Pre-Registration</i>) _____	
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) (<i>not required for NCCTG Members</i>) _____	
Physician of Record _____	RT Physician of Record _____
IRB/REB approval date (<i>mm/dd/yyyy</i>) ___/___/_____	Person Completing Form:
Date of Pre-Registration (<i>mm/dd/yyyy</i>) ___/___/_____	Last Name: _____
	First Name: _____
	Phone: _____
	Fax: _____
	Email: _____

Patient initials (<i>last, first, middle</i>) _____ (<i>For Mayo Rochester patients, include first four letters of last name.</i>)	Race (<i>check all that apply</i>)
Gender (<i>check one</i>) <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Unknown	<input type="checkbox"/> White
Patient's Date of Birth (<i>mm/dd/yyyy</i>) ___/___/_____	<input type="checkbox"/> Black or African American
Patient's Zip code (<i>USA</i>) _____	<input type="checkbox"/> Native Hawaiian or Other Pacific Islander
Country of Residence (<i>if not USA</i>) _____	<input type="checkbox"/> Asian
Method of payment (<i>check one</i>)	<input type="checkbox"/> American Indian or Alaska Native
<input type="checkbox"/> PI (<i>Private Insurance</i>)	<input type="checkbox"/> Not reported: <i>Patient refused or data not available</i>
<input type="checkbox"/> MR (<i>Medicare</i>)	<input type="checkbox"/> Unknown: <i>Patient is unsure of race</i>
<input type="checkbox"/> MRP (<i>Medicare and Private Insurance</i>)	Ethnicity (<i>check one</i>)
<input type="checkbox"/> MD (<i>Medicaid</i>)	<input type="checkbox"/> Not Hispanic or Latino
<input type="checkbox"/> MM (<i>Medicaid and Medicare</i>)	<input type="checkbox"/> Hispanic or Latino
<input type="checkbox"/> MVA (<i>Military or Veterans Sponsored, Not Otherwise Specified (NOS)</i>)	<input type="checkbox"/> Not reported: <i>Patient refused or data not available</i>
<input type="checkbox"/> MS (<i>Military Sponsored [including CHAMPUS & TRCARE]</i>)	<input type="checkbox"/> Unknown: <i>Patient is unsure of their ethnicity</i>
<input type="checkbox"/> MV (<i>Veterans Sponsored</i>)	Weight (kg) _____ . _____
<input type="checkbox"/> SP (<i>Self pay [no insurance]</i>)	Performance Status _____
<input type="checkbox"/> NP (<i>No means of payment [no insurance]</i>)	0=fully active (Karnofsky 90-100)
<input type="checkbox"/> OTH (<i>Other</i>)	1=ambulatory, capable of light work (K 70-80)
<input type="checkbox"/> UNK (<i>Unknown</i>)	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 <i>Magnetic Resonance Imaging (MRI) Guidelines</i> 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: <ul style="list-style-type: none"> • 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 (<i>check NA</i>) 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 (<i>check NA</i>) 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 Signature initials

Physician _____ M - D - Y
Signature

NCI COOPERATIVE GROUP RANDOMIZATION CHECKLIST

04/17/2009

Page 1 of 2

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

If yes: Prior protocol number N0574; prior study patient ID number _____

NCCTG Patient ID (provided at time of Preregistration) _____	
Patient Medical Record Number _____	
Participating Group Code (Cooperative Group where credit will be applied) _____	
Randomization 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) ___/___/_____	Person Completing Form:
Date of Randomization (mm/dd/yyyy) ___/___/_____	Last Name: _____
	First Name: _____
	Phone: _____
	Fax: _____
	Email: _____

Patient initials (last, first, middle) _____ (For Mayo Rochester patients, include first four letters of last name.)	Race (check all that apply)
Gender (check one) <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Unknown	<input type="checkbox"/> White
Patient's Date of Birth (mm/dd/yyyy) ___/___/_____	<input type="checkbox"/> Black or African American
Patient's Zip code (USA) _____	<input type="checkbox"/> Native Hawaiian or Other Pacific Islander
Country of Residence (if not USA) _____	<input type="checkbox"/> Asian
Method of payment (check one)	<input type="checkbox"/> American Indian or Alaska Native
<input type="checkbox"/> PI (Private Insurance)	<input type="checkbox"/> Not reported: Patient refused or data not available
<input type="checkbox"/> MR (Medicare)	<input type="checkbox"/> Unknown: Patient is unsure of race
<input type="checkbox"/> MRP (Medicare and Private Insurance)	
<input type="checkbox"/> MD (Medicaid)	Ethnicity (check one)
<input type="checkbox"/> MM (Medicaid and Medicare)	<input type="checkbox"/> Not Hispanic or Latino
<input type="checkbox"/> MVA (Military or Veterans Sponsored, Not Otherwise Specified (NOS))	<input type="checkbox"/> Hispanic or Latino
<input type="checkbox"/> MS (Military Sponsored [including CHAMPUS & TRCARE])	<input type="checkbox"/> Not reported: Patient refused or data not available
<input type="checkbox"/> MV (Veterans Sponsored)	<input type="checkbox"/> Unknown: Patient is unsure of their ethnicity
<input type="checkbox"/> SP (Self pay [no insurance])	Weight (kg) _____ . _____
<input type="checkbox"/> NP (No means of payment [no insurance])	Performance Status _____
<input type="checkbox"/> OTH (Other)	0=fully active (Karnofsky 90-100)
<input type="checkbox"/> UNK (Unknown)	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)

NCI Cooperative Group Randomization Eligibility Checklist N0574

04/17/2009
Page 2 of 2

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

Planning MRI confirmed one to three lesions. Each lesion must measure <3.0 cm in maximal extent on the contrasted planning MRI brain scan. NOTE: The pre-registration MRI scan may be used for the planning scan if obtained ≤14 days prior to randomization.	_____ _____
Negative urine or serum pregnancy test done ≤7 days prior to randomization, for women of childbearing potential only. If not a woman of childbearing potential or male (<i>check NA</i>) If a woman of childbearing potential - Negative urine or serum pregnancy test date ____ - ____ - ____	_____ _____

All responses in above section must be “Yes” 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

Treatment on this protocol must commence at the accruing membership under the supervision of an NCCTG or CTSU member physician.	_____
Treatment cannot begin prior to randomization and must begin ≤7 days after randomization.	_____
Tests/procedures must be completed ≤14 days prior to randomization (see Section 4.0 for further details). Note: Quality of Life; Functional independence; and Neurocognitive tests completed after informed consent and prior to randomization. Date of consent (from pre-registration checklist) ____ - ____ - ____. NOTE: These dates are for the Quality of Life; Functional independence; and Neurocognitive test only. The negative serum or urine pregnancy test date is collected in the Required Characteristics above. Earliest test/procedure date ____ - ____ - ____; latest test procedure date ____ - ____ - ____	_____

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

Stratification Factors

Age (years)	Extracranial disease controlled (months)	Number of Brain Metastases
____ 18 to 59	____ ≤3	____ 1
____ ≥60	____ >3	____ 2
		____ 3

Assigned Treatment

____ A) SRS
 ____ B) SRS + WBRT

Person registering Signature _____ Registration Office specialist initials _____

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

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

NCCTG Protocol Number: N0574

NCCTG Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

**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)

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

NCCTG Protocol Number: N0574

ON-STUDY FORM

NCCTG Patient ID: _____ Patient Initials: _____

L F M

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)

DESCRIPTION OF PRIMARY DISEASE

MedDRA Code: 10059282 [Metastases to brain parenchyma, NOS]

DISEASE/HISTORY

Primary Site: (check one)

- 1 Breast
- 2 Colorectal
- 3 Lung
- 4 Skin/Melanoma
- 5 Prostate
- 6 Bladder
- 7 Kidney
- 8 Sarcoma
- 9 Gynecologic
- 10 Other, specify _____

NEUROLOGIC EXAMINATION

Cranial Nerves: (check one) 1 Normal 2 Abnormal

Sensation: (check one) 1 Normal 2 Abnormal

Motor (check one) 1 Normal 2 Abnormal (e.g., mild to marked hemiparesis)

Cerebellar: (check one) 1 Normal 2 Abnormal

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

NCCTG Protocol Number: N0574

**BASELINE
ADVERSE EVENTS FORM**

NCCTG Patient ID: _____ Patient Initials: _____

L F M

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)

BASELINE ADVERSE EVENTS

Required Baseline Adverse Events from Section 10.0 of Protocol		
CTC Adverse Event Term (CTCAE v3.0)	MedDRA Code (v. 9.0)	CTC Adverse Event Grade
Hair loss/alopecia (scalp or body)	1 0 0 0 1 7 6 0	0 1 2
Rash: dermatitis associated with radiation - Radiation	1 0 0 6 1 1 0 3	0 1 2 3 4
Nausea	1 0 0 2 8 8 1 3	0 1 2 3 4
Vomiting	1 0 0 4 7 7 0 0	0 1 2 3 4
Cognitive disturbance	1 0 0 0 9 8 4 5	0 1 2 3 4
Neuropathy: motor	1 0 0 3 4 5 8 0	0 1 2 3 4
CNS necrosis/cystic progression	1 0 0 6 5 7 8 4	0 1 2 3 4
Retinopathy	1 0 0 3 8 9 2 3	0 1 2 3 4
Hearing: patients without baseline audiogram and not enrolled in a monitoring program	1 0 0 1 9 2 4 6	0 2 3 4
Otitis, external ear (non-infectious)	1 0 0 6 5 8 3 7	0 1 2 3 4

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

NCCTG Protocol Number: N0574

EVALUATION/TREATMENT FORM

NCCTG Patient ID: _____ Patient Initials: _____

L F M

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)

Use one form per cycle, one column per agent.

Current Cycle Number: 1

Was this cycle of treatment held?

3 Yes, unplanned 2 No

↓
Primary Reason Treatment Held:

99 Other (*not per protocol*) _____

Agent	Radiosurgery (SRS)
Date first lesion(s) treated (mm/dd/yyyy)	___/___/___

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

NCCTG Protocol Number: N0574

EVALUATION/OBSERVATION FORM

NCCTG Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

ALL ITEMS MUST BE COMPLETED

Page 2 of 2

Institution: _____

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

Treatment of Any Recurrence

Has the patient been treated for any recurrence of the Central Nervous System (CNS) disease?

2 No 1 Yes *If yes, Therapy administered: (check all that apply)*

- Stereotactic Radiosurgery
- Whole Brain Radiation Therapy
- Palliative Surgery (open resection)
- Other, specify _____

Notice of New Primary

Has a new primary cancer or MDS been diagnosed **that has not been previously reported?**

2 No 1 Yes → *If yes, New Primary Cancer Date:* ___/___/___
(mm/dd/yyyy)

Site of New Primary: _____

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

NCCTG Protocol Number: N0574

END OF ACTIVE TREATMENT/CANCEL NOTIFICATION FORM

Submit Once Per Patient

NCCTG Patient ID: _____ Patient Initials: _____

L F M

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)

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)

- 1 Observation (Follow test schedule and enter cycle data.)
- 2 Event monitoring (Follow Event Monitoring schedule)

Reason Treatment Ended (check one)	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 (cancel)	
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

NCCTG Protocol Number: N0574

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

Institution Number: _____

Institution: _____

**PRETREATMENT
MEASUREMENT FORM**
(obtained from the Planning MRI Scan)
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 measurable lesions (refer to protocol).
2. There can NOT be more than 3 lesions, if this is the case the patient is ineligible.
NOTE: No tumor measurement can be greater than 2.9 cm, if this is the case the patient is ineligible.
3. Measure measurable tumor areas in cm. using longest perpendicular diameters. State both diameters.
4. Record measurements at on study.
5. Maintain same type of assessment throughout study.

Assessment Date (mm/dd/yyyy)	____/____/____
--	----------------

Target Lesion Site(s)	Method of Evaluation	Dimension 1 (cm)	Dimension 2
	MRI		
1	3 <input type="checkbox"/>	____.____ X ____.	
2	3 <input type="checkbox"/>	____.____ X ____.	
3	3 <input type="checkbox"/>	____.____ X ____.	

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

NCCTG Protocol Number: N0574

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

Institution Number: _____

Institution: _____

**ACTIVE MONITORING
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 measurable lesions (refer to protocol).
2. Record no more than three lesions.
3. Measure measurable tumor areas in cm. using longest perpendicular diameters. State both diameters.
4. Record measurements at scheduled evaluations and progression (refer to protocol Section 4).
5. Maintain same type of assessment throughout study.
6. Record lesions in the same order as previous form.

Current Cycle Number	_____
Assessment Date (mm/dd/yyyy) (Assessment date is the date reflecting type of assessment, not the physicians interpretation date.)	____/____/____
Overall Response Status* (check one)	1 <input type="checkbox"/> CR** 2 <input type="checkbox"/> PR** 5 <input type="checkbox"/> SD 6 <input type="checkbox"/> PD** ↓ • Was the appearance of any new lesions documented? 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No • Symptomatic Deterioration? 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No

Target Lesion Site(s)	Dimension 1 (cm)	Dimension 2
1.	____.____ X ____.	
2.	____.____ X ____.	
3.	____.____ X ____.	

* Refer to Section 11.0 of protocol.
** Submit documentation to verify CR, PR, PD.

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

NCCTG Protocol Number: N0574

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

Institution Number: _____

Institution: _____

ADVERSE EVENT 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)

Current Cycle Number
(adverse events associated with treatment cycle) : _____

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

CTC Adverse Event Term (CTCAE v3.0)	MedDRA Code (v. 9.0) <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?* <i>(Enter 1 for Yes or 2 for No)</i>
-------------------------------------	--	--	--	--

Required Adverse Events from Section 10.0 of Protocol

Hair loss/alopecia (scalp or body)	1 0 0 0 1 7 6 0	0 1 2	1 2 3 4 5	—
Rash: dermatitis associated with radiation - Radiation	1 0 0 6 1 1 0 3	0 1 2 3 4 5 (death)	1 2 3 4 5	—
Nausea	1 0 0 2 8 8 1 3	0 1 2 3 4 5 (death)	1 2 3 4 5	—
Vomiting	1 0 0 4 7 7 0 0	0 1 2 3 4 5 (death)	1 2 3 4 5	—
Cognitive disturbance	1 0 0 0 9 8 4 5	0 1 2 3 4 5 (death)	1 2 3 4 5	—
Neuropathy: motor	1 0 0 3 4 5 8 0	0 1 2 3 4 5 (death)	1 2 3 4 5	—
CNS necrosis/cystic progression	1 0 0 6 5 7 8 4	0 1 2 3 4 5 (death)	1 2 3 4 5	—
Retinopathy	1 0 0 3 8 9 2 3	0 1 2 3 4	1 2 3 4 5	—
Hearing: patients without baseline audiogram and not enrolled in a monitoring program	1 0 0 1 9 2 4 6	0 2 3 4	1 2 3 4 5	—
Otitis, external ear (non-infectious)	1 0 0 6 5 8 3 7	0 1 2 3 4 5	1 2 3 4 5	—

* See Section 10.0 of the protocol.

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

NCCTG Protocol Number: N0574

ADVERSE EVENT FORM

NCCTG Patient ID: _____ Patient Initials: _____

ALL ITEMS MUST BE COMPLETED

Institution Number: _____ L F M

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 treatment cycle): _____

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

- 1 Yes, and reportable adverse events occurred
 - 2 No (*Stop here*)
 - 3 Yes, but no reportable adverse events occurred (*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 Term not listed (CTCAE v3.0)	MedDRA Code (v. 9.0) <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	_____

** See Section 10.0 of the protocol.

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

NCCTG Protocol Number: N0574

**FUNCTIONAL INDEPENDENCE (FI)
Physician/Allied Health Professional Evaluation**

NCCTG Patient ID: _____ Patient Initials: _____

L F M

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)

Time point: Baseline or Current Cycle Number: _____

Date Completed: (mm/dd/yyyy) ____ / ____ / ____

Barthel Functional Index

Mark an "X" in the box that best represents the patient's level of function for each item. If you are unsure, please discuss with patient and/or family. Please mark one box for each item listed.

Function	Score	Description
1. Feeding	10 <input type="checkbox"/>	Independent. Able to put on any assistance device. Eats in reasonable time.
	5 <input type="checkbox"/>	Needs Help, e.g., for cutting food.
	0 <input type="checkbox"/>	Dependent
2. Chair/bed transfers	15 <input type="checkbox"/>	Independent. Can lock a wheelchair, lift footrests, and get out.
	10 <input type="checkbox"/>	Minimum assistance or supervision.
	5 <input type="checkbox"/>	Able to sit, but needs maximum assistance to transfer.
	0 <input type="checkbox"/>	Dependent
3. Grooming	5 <input type="checkbox"/>	Independent. Can wash face, comb hair, brush teeth, shave (can manage plug in electric razor).
	0 <input type="checkbox"/>	Needs help with grooming.
4. Toilet Transfers	10 <input type="checkbox"/>	Independent. Can get on and off, handle clothes, or toilet paper.
	5 <input type="checkbox"/>	Needs help for balance, handling clothes, or toilet paper.
	0 <input type="checkbox"/>	Dependent
5. Bathing	5 <input type="checkbox"/>	Independent. Able to use bath tub, shower, or take complete sponge bath without supervision.
	0 <input type="checkbox"/>	Dependent.
6. Walking	15 <input type="checkbox"/>	Independent to 50 yards. May use assistive devices.
	10 <input type="checkbox"/>	Can walk with help for 50 yards.
	5 <input type="checkbox"/>	Unable to walk, but independent in wheelchair for 50 yards.
	0 <input type="checkbox"/>	Dependent
7. Stairs	10 <input type="checkbox"/>	Independent up and down. May use assistive devices.
	5 <input type="checkbox"/>	Needs help or supervision.
	0 <input type="checkbox"/>	Unable
8. Dressing	10 <input type="checkbox"/>	Independent. Can tie shoes, fasten fasteners, undress.
	5 <input type="checkbox"/>	Needs help but does at least half of task within reasonable time.
	0 <input type="checkbox"/>	Dependent.
9. Bowel Control	10 <input type="checkbox"/>	No accidents. Able to use enema or suppository, if needed.
	5 <input type="checkbox"/>	Occasional accidents (<1/week) or needs help with enema or suppository.
	0 <input type="checkbox"/>	Incontinent.
10. Bladder Control	10 <input type="checkbox"/>	No accidents. Able to care for collecting device, if used.
	5 <input type="checkbox"/>	Occasional accidents (<1/day) or needs help with external device.
	0 <input type="checkbox"/>	Incontinent.

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

NCCTG Protocol Number: N0574

PATIENT FACT-Br BOOKLET COMPLIANCE FORM

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

ALL ITEMS MUST BE COMPLETED

Institution Number: _____

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

Institution: _____

Complete this form if the Patient FACT-Br booklet was not completed for a required cycle (per test schedule).

Current Cycle Number: _____

Form Completion Date: / /
(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
- 5 Other reason, specify _____

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

EVENT MONITORING FORM

NCCTG Protocol Number: N0574

NCCTG Patient ID: 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)

Were you able to obtain any information about the patient since the last report?*

1 Yes 2 No -> Date of last attempt to contact patient: (mm/dd/yyyy) -> Return form to Operations Office

VITAL STATUS

1 Alive 2 Dead } Date of last contact or death: (mm/dd/yyyy)

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 -> Go to Notice of New Primary. 1 Yes. If Yes, Cancer Follow-up Status Date: (mm/dd/yyyy)

NOTICE OF RELAPSE/PROGRESSION

Has the patient developed a relapse or progression that has not been previously reported?

2 No 1 Yes. If yes, Date of Relapse or Progression: (mm/dd/yyyy)

Site(s) of Relapse/Progression: Local brain failure** Distant brain failure Systemic disease 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

Submit page 2 of the Event Monitoring Form for Late Adverse Event Reporting

* If this is the first event monitoring form check yes, enter assessment date and complete the rest of the form.

** Submit documentation to verify PD.

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

NCCTG Protocol Number: N0574

**EVENT MONITORING FORM
(LATE ADVERSE EVENT REPORTING)**

NCCTG Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

ALL ITEMS MUST BE COMPLETED

Page 2 of 2

Institution: _____

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

LATE ADVERSE EVENTS

The CTC AE Version 3.0 will be used to evaluate the following signs/symptoms:

CTC Adverse Event Term	MedDRA Code (v. 9.0) <i>(must be completed)</i>	CTC Adverse Event Grade <i>(Highest Grade)</i>	CTC AE Attribution Code 1 = Unrelated 2 = Unlikely 3 = Possible 4 = Probable 5 = Definite	Late Adverse Event Onset Date <i>(mm/dd/yyyy)</i>
	<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

NCCTG Protocol Number: N0574

ARM B
RADIATION THERAPY REPORTING FORM

NCCTG Patient ID: _____ Patient Initials: _____

Institution Number: _____ L F M

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)

BRAIN

Date Start Whole Brain Radiotherapy: / /
(mm/dd/yyyy)

See Section 18.0 of the protocol for submission guidelines

Date End Whole Brain Radiotherapy: / /
(mm/dd/yyyy)

TECHNIQUE

Modality	Field	Field Size	Treatment Distance	Target (1=SSD, 2=SAD)
Primary: (check one)	_____	<input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	cm	<input type="text"/> <input type="text"/> cm
1 <input type="checkbox"/> Cobalt	_____	<input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	cm	<input type="text"/> <input type="text"/> cm
2 <input type="checkbox"/> Linear Accelerator	_____	<input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	cm	<input type="text"/> <input type="text"/> cm
_____ MV Dose	_____	<input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	cm	<input type="text"/> <input type="text"/> cm
3 <input type="checkbox"/> Other	_____	<input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	cm	<input type="text"/> <input type="text"/> cm
_____ MV Dose	_____	<input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	cm	<input type="text"/> <input type="text"/> cm
	_____	<input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	cm	<input type="text"/> <input type="text"/> cm
	_____	<input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	cm	<input type="text"/> <input type="text"/> cm

Treatment Areas, Dose and Time

RT Site	RT Total Dose (cGy)	Total Number of Fractions	Elapsed Days
Initial Volume	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>

Were there any unscheduled interruptions in radiation therapy? 1=Yes, 2=No. (If yes, enter number of days and reasons below)

Days Treatment Was Interrupted

Reasons

1 = Social

4 = Machine down

2 = Local reaction

5 = Other, specify: _____

3 = Systemic reaction

6 = Unknown

(Radiation Oncologist's) Comments:

Radiation Oncologist's Signature

Date (mm/dd/yyyy)

Radiation Oncologist's Name (PLEASE PRINT)

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

RADIOSURGERY (SRS) REPORTING FORM

Complete One Form Per Each Lesion

ALL ITEMS MUST BE COMPLETED

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

NCCTG Protocol Number: N0574

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

Institution Number: _____

Institution: _____

Radiosurgery Treating Institution: _____

Target Lesion Site (as entered on the Pretreatment Measurement Form): (check one) 1 Site (1)
2 Site (2)
3 Site (3)

Date of Radiosurgery Procedure: __ __ / __ __ / __ __ __ __
(mm/dd/yyyy)

Treatment Unit (check one)

1 Linear Accelerator:
Manufacturer Name _____ Model Number _____ Energy _____ MV

2 Gamma Knife

Technique

Number of isocenters or beam-center positions _____

Number of stationary beams _____ arcs _____

If applicable, sum of degrees per arc for all arcs _____ Collimator diameter(s): isocenter#1 _____ mm
#2 _____ mm

Target Volume

Largest measure in any direction _____ mm Anterior-posterior measure _____ mm

Left-right measure _____ mm Cephalad-caudad measure _____ mm

Target volume _____ cm³

Prescription Dose

_____ Gy to _____ % isodose contour Maximum within target volume _____ Gy

Minimum within target volume _____ Gy Volume inside prescription isodose surface _____ cm³

Ratio of Prescription Isodose Volume/Target Volume _____

Radiation Oncologist's Signature

Date (mm/dd/yyyy)

Radiation Oncologist's Name (PLEASE PRINT)

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

NCCTG Protocol Number: N0574

NOTIFICATION FORM
Grade 4 or 5 Non-AER Reportable Events/Hospitalization

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

ALL ITEMS MUST BE COMPLETED

Institution Number: _____

NCCTG MEMBERS ONLY

Institution: _____

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.
- 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):

Person Completing Form:

____/____/_____
(mm/dd/yyyy)

Name: _____

Phone #: () _____ - _____

Cycle Number: ____ Assigned Treatment Arm: ____

Event ≥ Grade 4

2 No 1 Yes

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? ¹
____/____/____		<input type="checkbox"/> 4 <input type="checkbox"/> 5	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 3 <input type="checkbox"/> Unknown
____/____/____		<input type="checkbox"/> 4 <input type="checkbox"/> 5	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 3 <input type="checkbox"/> Unknown
____/____/____		<input type="checkbox"/> 4 <input type="checkbox"/> 5	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 3 <input type="checkbox"/> Unknown
____/____/____		<input type="checkbox"/> 4 <input type="checkbox"/> 5	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 3 <input type="checkbox"/> Unknown
____/____/____		<input type="checkbox"/> 4 <input type="checkbox"/> 5	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 3 <input type="checkbox"/> Unknown

1. Answer YES if attribution is unlikely, possible, probable or definite.
Answer NO if unrelated, answer UNKNOWN if you are not sure.

Hospitalization

2 No 1 Yes → Hospital Admission Date: ____/____/_____
(mm/dd/yyyy)

Reason(s) for Hospitalization:

1 Adverse Event, specify type and grade _____

2 Prophylactic, specify _____

3 Other, specify _____

PLACE LABEL HERE

NCCTG Protocol Number: N0574

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

Institution Number: _____

Institution: _____

NORTH CENTRAL CANCER TREATMENT GROUP

**NEUROCOGNITIVE TESTING
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)

Current Cycle Number: _____

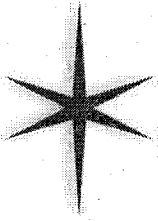
Form Completion Date: ____/____/____
(mm/dd/yyyy)

Was the Neurocognitive Testing Booklet completed (this cycle)?

2 No 1 Yes → End form

↓
Reason Neurocognitive Testing 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
- 5 Other reason, specify _____



NCCTG

NORTH CENTRAL CANCER TREATMENT GROUP

Attention OSU Clerk:

Booklets Order Form

Title: 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

Booklets needed:	Amount requested:
Fact BR Questionnaire	
Neurocognitive Examiners Booklet	
Neurocognitive Patient Completed Booklet	
Total number of booklets needed:	

Note to OSU clerk:

There are 3 different booklets for this study! Be sure to send the same amount of each booklet as requested by the site above.

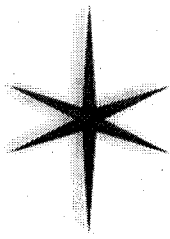
Fax form to: 507-284-1902
Attention: NCCTG Operational Support Clerk

Requestor: _____ Phone: _____

Affiliate/Membership: _____/_____

Shipping address: _____

Date: _____



NCCTG

NORTH CENTRAL CANCER TREATMENT GROUP

N0574 Neurocognitive Testing Verification Form

FAX completed form to Dr. Elana Farace at 717-531-0748

Institution name: _____

NCI Institution code: _____

Name of Physician Group Leader: _____

CTEP ID # of Physician Group Leader: _____

Person Completing Training: _____

Email: _____

Phone: _____

Fax: _____

Are you an NCCTG member?

Yes No

If yes, under which membership? _____

The protocol *N0574, A Phase III Randomized Trial of the Role of Whole Brain Radiation Therapy in Addition to Radiosurgery in the Management of Patients with One to Three Metastases*, requires careful and accurate documentation of the neurocognitive testing. In order to ensure reliability, this form **MUST** be completed upon completion of the online training.

1. I have read the entire N0574 protocol and understand it.
 Yes No Please initial here: _____
2. I have watched the N0574 Neurocognitive online training, fully understand it, and agree to administer the neurocognitive tests as specified.
 Yes No Please initial here: _____
3. I have performed one set of practice tests on an individual who is not a patient and submitted them to Dr. Farace.
 Yes No Please initial here: _____
4. I agree to contact Dr. Farace with any questions about the administration of the assessments.
 Yes No Please initial here: _____
5. Please check all that apply:
I am a:
 Licensed clinical psychologist Neuro Psych technician
 Study coordinator Other: _____

Approval Signature: _____ Date: _____

Elana Farace, Ph.D.

(Version date: 11/8/2006)