

FORMS PACKET

NCCTG N0177: A Pilot and Phase II Study of OSI-774 and Temozolomide in Combination with Radiation Therapy in Glioblastoma Multiforme

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 - Generic forms completion instructions (November 14, 2002)
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 - ✓ Evaluation/treatment form for Cycle 1 (Weeks 1 through 7) (5/27/2009)
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✓ designates revised/new forms

NORTH CENTRAL CANCER TREATMENT GROUP

Eligibility Checklist

(Study 2)

06/05/2009

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N0177: **A Pilot and Phase II Study of OSI-774 and Temozolomide in Combination with Radiation Therapy in Glioblastoma Multiforme**

Study 2 (Mayo Rochester, Jacksonville, Scottsdale, University of Alabama at Birmingham, and University of Virginia only): ***Prior to discussing protocol entry with the patient, call the Randomization Center (507/284-4130) for dose level and to insure that a place on the protocol is open to the patient.***

Registration date (date on) (mm/dd/yyyy) ___/___/___

Patient study ID number (provided at time of Reg/Random) _____

NCCTG member (participant sponsor) _____

NCCTG treating location (chemo) _____
(RT) _____

NCCTG treating physician (chemo) _____
(RT) _____

Institution patient number (local subject number) _____

IRB approval date (chemo) (mm/dd/yyyy) ___/___/___ IRB approval date (RT) (mm/dd/yyyy) ___/___/___

Patient initials (last, first, middle) _____	Race (check all that apply)
Gender (check one) ___ Male ___ Female ___ Unknown	___ White
Date of birth (mm/dd/yyyy) ___/___/___	___ Black or African American
ZIP code _____	___ Native Hawaiian or Other Pacific Islander
Country of Residence _____	___ Asian
Method of payment (check one)	___ American Indian or Alaska Native
___ PI (Private Insurance)	___ Not reported: Patient refused or not available
___ MR (Medicare)	___ Unknown: Patient unsure
___ MRP (Medicare and Private Insurance)	Ethnicity (check one)
___ MD (Medicaid)	___ Not Hispanic or Latino
___ MM (Medicaid and Medicare)	___ Hispanic or Latino
___ MVA (Military or Veterans Sponsored, Not Otherwise Specified (NOS))	___ Not reported: Refused or data not available
___ MS (Military Sponsored [including CHAMPUS & TRCARE])	___ Unknown: Unsure of their ethnicity
___ MV (Veterans Sponsored)	
___ SP (Self pay [no insurance])	
___ NP (No means of payment [no insurance])	
___ OTH (Other)	
___ UNK (Unknown)	

Addendum 15 dated June 5, 2009 IRB approved?

___ Yes. If Yes, Addendum 15 approval date (mm/dd/yyyy) ___/___/___

___ No. If No, End form, Addendum 15 IRB approval required.

NCCTG Eligibility Checklist N0177
(Study 2)

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Patient study ID number _____

Eligibility Check - Answer questions below (yes/no). All requirements must be confirmed. All dates are to be M/D/Y.

Yes No

Currently on EIACs.

Histologically confirmed glioblastoma multiforme (grade 4 of 4 astrocytoma). Gliosarcomas and other grade 4 astrocytoma variants (e.g., giant cell) may be included. Central pathology review is mandatory prior to study entry to confirm eligibility. It should be initiated as soon after surgery as possible.

Patients must be enrolled ≥ 1 week after, but ≤ 4 weeks after biopsy or surgery.

≥ 18 years. Age = _____. Because no dosing or adverse event data are currently available on the use of OSI-774 in patients < 18 years of age, children are excluded from this study but will be eligible for future pediatric single-agent trials, if applicable.

ECOG performance status ≤ 2 (Karnofsky $\geq 60\%$, see Appendix II).

Which was done?

ECOG PS \rightarrow PS = _____.

Karnofsky \rightarrow Karnofsky = _____.

Life expectancy of ≥ 6 months.

The following laboratory values obtained ≤ 14 days prior to registration. Earliest laboratory test date ____-____-____; latest laboratory test date ____-____-____. NOTE: These dates pertain to the following labs only.

• ANC $\geq 1500/\mu\text{L}$. ANC = _____.

• Hemoglobin ≥ 9 . Hemoglobin = _____.

• PLT $\geq 100,000/\mu\text{L}$. PLT = _____.

• Total bilirubin \leq institutional upper limit of normal (ULN)

Total bilirubin = _____; ULN = _____.

• AST (SGOT) ≤ 2.5 x institutional (ULN). AST (SGOT) = _____; ULN = _____.

• Creatinine ≤ 1.5 x institutional (ULN). Creatinine = _____; ULN = _____.

Is this patient a woman of childbearing potential? (This question may be answered yes or no.)

Yes \rightarrow Complete; Negative serum pregnancy test ... question

No \rightarrow Skip; Negative serum pregnancy test ... question..

Negative serum pregnancy test done ≤ 7 days prior to registration, for women of childbearing potential only.

Negative serum pregnancy test date ____-____-____.

Ability to understand, and the willingness to sign a written informed consent.

All responses in above section must be "Yes."

Any of the following because OSI-774 is an epidermal growth factor inhibitor with the potential for teratogenic or abortifacient effects based on the data suggesting that EGFR expression is important for normal organ development:

- Pregnant women
- Nursing women
- Men or women of childbearing potential who are unwilling to employ adequate contraception (condoms, diaphragm, birth control pills, injections, intrauterine device [IUD], surgical sterilization, abstinence, etc.)

Other active cancers requiring therapy to control disease.

Prior chemotherapy or radiation therapy for any brain tumor. No prior temozolomide.

Receiving any other investigational agents.

NCCTG Eligibility Checklist N0177
(Study 2)

06/05/2009
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Patient study ID number _____

Eligibility Check - (Contraindications - continued)

Yes No

- ____ ____ Major surgery (excluding neurosurgical biopsy or resection of brain tumor) or significant traumatic injury occurring ≤ 21 days prior to treatment.
Major surgery (excluding neurosurgical biopsy or resection of brain tumor) date ____ - ____ - ____ vs. not applicable ____.
Significant traumatic injury date ____ - ____ - ____ vs. not applicable ____.
Treatment start date ____ - ____ - ____.
- ____ ____ Abnormalities of the cornea based on history (e.g., dry eye syndrome, Sjogren's syndrome), congenital abnormality (e.g., Fuch's dystrophy), abnormal slit-lamp examination using a vital dye (e.g., fluorescein, Bengal-Rose), and/or an abnormal corneal sensitivity test (Schirmer test or similar tear production test).
- ____ ____ Gastrointestinal tract disease resulting in an inability to take oral medication or a requirement for IV alimentation, prior surgical procedures affecting absorption, or active uncontrolled peptic ulcer disease.
- ____ ____ Uncontrolled intercurrent illness including, but not limited to, ongoing or active infection, symptomatic congestive heart failure, unstable angina pectoris, cardiac arrhythmia, or psychiatric illness/social situations that would limit compliance with study requirements.
- ____ ____ HIV-positive patients receiving combination anti-retroviral therapy are excluded from the study because of possible pharmacokinetic interactions with OSI-774. Appropriate studies will be undertaken in patients receiving combination anti-retroviral therapy when indicated.
- ____ ____ Receiving warfarin (Coumadin) therapy.
- ____ ____ Any history of allergy or intolerance to Dacarbazine (DTIC).

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 M/D/Y.

Yes No

- ____ ____ Consent form signed and dated. Date informed consent signed ____ - ____ - ____.
- ____ ____ Authorization for use and disclosure of protected health information signed and dated.
Date of authorization ____ - ____ - ____ vs. not applicable (Non-U.S.A. institution only) ____.
- ____ ____ Treatment must commence and continue at an NCCTG institution under the supervision of a NCCTG member physician.
- ____ ____ Registration must be done ≥ 1 week but ≤ 4 weeks after biopsy or surgery.
Date of surgery ____ - ____ - ____.
- ____ ____ Treatment cannot begin prior to registration and must begin ≤ 7 days after registration.
- ____ ____ Radiation oncology consult; Medical oncology consult; History; Toxicity assessment; Exam, wt, PS; Height; Neuro History and Exam; MMSE (Appendix V); Hematology group; Chemistry group; Serum free EIAC Level-(For patients taking EIAC [enzyme-inducing anticonvulsants] only); Anticonvulsant and steroid treatment log; sEGFR assay; and MGMT assay in blood must be completed ≤ 14 days prior to registration (see Section 4.0). Earliest pretreatment test date ____ - ____ - ____; latest pretreatment test date ____ - ____ - _____. NOTE: The earliest pretreatment test date must be less than or equal to the earliest laboratory test date **and** the latest pretreatment test date must be greater than or equal to the latest laboratory test date.
- Exceptions to the above dates:**
- MRI or CT scan (MRI preferred but CT scans are accepted) up to 21 days before treatment (see Section 4.0).
Date of MRI or CT scan ____ - ____ - ____.
- ____ ____ All required baseline symptoms must be documented and graded on the on-study form.
- ____ ____ Study drug availability checked.
- ____ ____ A radiation oncologist and medical oncologist have seen the patient and confirmed the patient is a suitable candidate for this study.

All responses in above section must be "Yes."

NCCTG Eligibility Checklist N0177
(Study 2)

06/05/2009
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Patient study ID number _____

Registration Check – (continued)

Yes No

- ____ ____ Patients should be registered on NCCTG 94-72-52. Will this patient be registered on NCCTG 94-72-52? Randomization Center will register patients separately to the translational research component of this study (see Section 14.0). (This is optional.)
 - Patient has given permission to allow tissue samples to be used for the translational goals of this study
 - Patient has given permission to allow blood to be drawn and used for the translational goals of this study
- ____ ____ Patient has given permission to store blood sample(s) for future research of genetics.
- ____ ____ Patient has given permission to store tissue sample(s) for future research of genetics.
- ____ ____ Patient has given permission to store blood sample(s) for future research to learn, prevent, or treat other health problems.
- ____ ____ Patient has given permission to store tissue sample(s) for future research to learn, prevent, or treat other health problems.
- ____ ____ Patient has given NCCTG permission to give their blood sample(s) to outside researchers.
- ____ ____ Patient has given NCCTG permission to give their tissue sample(s) to outside researchers.

Responses in above section may be “Yes” or “No.”

Grouping Factor

Study
2
N/A 3

Descriptive Factors

- Family history of brain tumor
- ____ Yes (check all that apply)
- ____ Father
 - ____ Mother
 - ____ Brother or sister
 - ____ Child
 - ____ Other (list: _____)
- ____ No

- Contrast enhancement on preoperative scans
- ____ Yes
 - ____ No
 - ____ Uncertain

Maximum diameter in cm on a preoperative scan of:

Contrast Enhancement . (cm) vs. not applicable: ____

T2 abnormality on MRI or Low attenuation on CT . (cm)

- Corticosteroid therapy at study entry
- ____ Yes
 - ____ No

Assigned Treatment

Study 2:

- ____ E) RT + OSI-774* + TMZ

*OSI-774: Dose = _____ (mg); Level = _____
RT: Dose is fixed at 6000 cGy

Person registering Signature _____ Registration Office specialist initials _____

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

Generic Instructions for Forms Completion	
<i>General Information</i>	<ul style="list-style-type: none"> • All forms are protocol specific and contain only the data that is pertinent to the protocol's analysis. • Forms will be returned to the site if any of the fields have not been completed. • 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. <ul style="list-style-type: none"> ✓ Shaded areas or blank items do not need to be filled in.
<i>On-Study Form</i>	<ul style="list-style-type: none"> • Refer to Section 18.0 for submission of the On-Study Form. • For the majority of protocols, the On-Study Form must be submitted within 14 days of registration.
<i>Evaluation Treatment Form</i>	<ul style="list-style-type: none"> • NCCTG defines a cycle as the time treatment starts until the patient returns for reevaluation by the physician. • An Evaluation/Treatment Form must be submitted for each cycle of treatment and/or observation. <ul style="list-style-type: none"> ✓ The first cycle is number 1. ✓ The cycle number, treatment arm, performance score (PS), body surface area (BSA), treatment delay, and dose level refer to the agent's start date. ✓ The agent(s) and primary reason(s) for treatment delay(s) and dose adjustment(s) are prefilled on the form.
<i>Nadir/Adverse Event Log</i>	<ul style="list-style-type: none"> • All hematologic and non-hematologic adverse events (AEs) are collected on the Nadir/AE Log. • The evaluation date is the date the patient was evaluated by a physician before starting the next cycle of treatment or observation. Thus, the evaluation date may not be the same as the required laboratory tests/imaging studies. <i>Example:</i> If the CT scan was obtained on March 12, the laboratory tests were obtained on March 13, and the physician's evaluation of the patient occurred on March 14, the evaluation date is March 14.

***Nadir Adverse
Event Log
(continued)***

***Nadir values on
the
Nadir/Adverse
Event Log***

- Nadir value is the lowest value of a blood test occurring between two treatment cycles. The values obtained prior to the next treatment cycle are to be included in determining the nadir value. Therefore, the nadir could also be day 1 values used for retreatment.

Example 1. Nadirs occurring mid cycle:

Patient received his/her first cycle of treatment on October 12 and is returning for evaluation on November 9. The date of the WBC, ANC, and PLT nadirs is the same day, November 2.

<u>Date</u>	<u>10/12</u>	<u>10/19</u>	<u>10/26</u>	<u>11/02</u>	<u>11/09</u>
PLT K/uL or 10 ⁹ /L	140	100	90	80	100
WBC K/uL or 10 ⁹ /L	5.8	6.4	6.0	3.2	6.0
ANC K/uL or 10 ⁹ /L	4.5	3.4	3.3	1.0	4.1

Example 2. Nadir occurring on date of evaluation :

Patient received his/her first cycle of treatment on February 12 and is returning for evaluation on March 12. The date of the WBC and ANC nadir is March 12, and the PLT nadir is February 26.

<u>Date</u>	<u>02/12</u>	<u>02/19</u>	<u>02/26</u>	<u>03/05</u>	<u>03/12</u>
PLT K/uL or 10 ⁹ /L	120	100	70	80	100
WBC K/uL or 10 ⁹ /L	10.8	8.4	6.2	6.0	3.2
ANC K/uL or 10 ⁹ /L	7.5	4.4	3.3	1.1	1.0

Example 3. Delay treatment/nadir occurring after eval. date:

Patient received his/her second cycle of treatment on March 12 and is returning for evaluation on March 31. The date of the WBC nadir is March 31, ANC nadir is April 5, and PLT nadir is March 19. (The nadir for the ANC, WBC, and/or PLT can occur after the evaluation date.)

<u>Date</u>	<u>03/12</u>	<u>03/19</u>	<u>03/26</u>	<u>03/31</u>	<u>04/05</u>	<u>04/09</u>
PLT K/uL or 10 ⁹ /L	140	60	70	80	100	120
WBC K/uL or 10 ⁹ /L	9.8	7.4	4.2	2.2	2.3	3.5
ANC K/uL or 10 ⁹ /L	7.5	5.4	3.3	1.0	0.9	1.6

Example 4. Interval counts not done/not required:

Patient was last treated on 5/1 and is now returning for evaluation on 7/8 having no interval counts drawn. Nadirs will be the blood counts drawn on 7/8 as long as they are drawn prior to subsequent treatment. Since nadirs are not required on observation cycles, record the values obtained at the subsequent evaluation, i.e., 07/08.

<p>Nadir Adverse Event Log (continued)</p>	<table border="1"> <thead> <tr> <th>Date</th> <th>05/01</th> <th>05/08</th> <th>06/26</th> <th>07/01</th> <th>07/08</th> </tr> </thead> <tbody> <tr> <td>PLT K/uL or 10⁹/L</td> <td>215</td> <td>ND</td> <td>ND</td> <td>ND</td> <td>195</td> </tr> <tr> <td>WBC K/uL or 10⁹/L</td> <td>4.1</td> <td>ND</td> <td>ND</td> <td>ND</td> <td>4.6</td> </tr> <tr> <td>ANC K/uL or 10⁹/L</td> <td>5.2</td> <td>ND</td> <td>ND</td> <td>ND</td> <td>6.3</td> </tr> </tbody> </table>	Date	05/01	05/08	06/26	07/01	07/08	PLT K/uL or 10 ⁹ /L	215	ND	ND	ND	195	WBC K/uL or 10 ⁹ /L	4.1	ND	ND	ND	4.6	ANC K/uL or 10 ⁹ /L	5.2	ND	ND	ND	6.3
Date	05/01	05/08	06/26	07/01	07/08																				
PLT K/uL or 10 ⁹ /L	215	ND	ND	ND	195																				
WBC K/uL or 10 ⁹ /L	4.1	ND	ND	ND	4.6																				
ANC K/uL or 10 ⁹ /L	5.2	ND	ND	ND	6.3																				
<p>Selecting "Yes" for grading of adverse events</p>	<ul style="list-style-type: none"> • If the patient had even one adverse event, all required adverse events (prefilled on the form) and any other adverse events must be graded. • To indicate a serious AE has been reported, check the last column on the Nadir/Adverse Event Log. This information is required for NCI reporting. All events that have been included as serious events must be included on the expedited SAE. <i>Note: The last column does not need to be checked when only the NCCTG Grade 4 or 5 Notification Form was submitted.</i> • The "highest grade observed this cycle" (including grade 0) and the "relationship to study medication" (if the grade is >0) must be completed when grading required AEs (i.e. prefilled on the form and assessed at every evaluation) for a cycle of treatment/observation. <ul style="list-style-type: none"> ✓ Section 10 of the protocol must be reviewed prior to grading AEs. ✓ All grades, regardless of attribution, must be entered for required AEs. ✓ Adverse events beyond those specified in Section 10 of the protocol must have IMT/MedDRA codes, CTC description and grades, and relationships entered. 																								
<p>Selecting "No" for grading of adverse events</p>	<ul style="list-style-type: none"> • If the patient did not experience any adverse events for a cycle, check "No Adverse Events." Nothing further is required. <ul style="list-style-type: none"> ✓ If "No Adverse Events" is selected, submit only page one of the Nadir/Adverse Event Log. 																								
<p>Measurement Form</p>	<ul style="list-style-type: none"> • Before completing the Measurement Form, refer to Section 11 of the protocol to review the response and reporting criteria. • A Measurement Form must be submitted for each cycle of treatment/observation. • Date of tumor assessment is determined as follows: <ul style="list-style-type: none"> ✓ <i>Tumor assessment is not required:</i> Tumor assessment date is the date the patient was evaluated for further treatment, and the objective status is "N/A." ✓ <i>Tumor assessment is completed:</i> Tumor assessment date is 																								

<p>Measurement Form (continued)</p>	<p>the date the imaging study was completed (not the date the imaging study was interpreted).</p> <ul style="list-style-type: none"> ✓ <i>No progression/no response</i>: Tumor assessment date is the latest assessment date. ✓ <i>Progression/response</i>: Tumor assessment date is the date of the assessment that indicates the progression/response. <ul style="list-style-type: none"> • Both the target (measurable) and non-target (non-measurable) sections of the Measurement Form must be completed. • Always record the lesions in the same order. • At each required tumor assessment date: <ul style="list-style-type: none"> ✓ Record the sum of the target lesions. ✓ Record the change (status) of non-target lesions. • Record the overall objective status by combining the status of target lesions, non-target lesions and new lesions (refer to Section 11 of the protocol). • If overall objective status is response: <ul style="list-style-type: none"> ✓ Submit documentation to verify response. • If overall objective status is progression: <ul style="list-style-type: none"> ✓ Indicate if there were new lesions. ✓ If applicable, indicate if progression was due only to clinical deterioration. ✓ Submit documentation to verify progression.
<p>End of Active Treatment Form</p>	<ul style="list-style-type: none"> • The End of Active Treatment Form is submitted once per patient following the discontinuation of all protocol therapy. <i>Note</i>: Observation is not considered active treatment. • The “date of last treatment dose on this study” refers to the last date that the protocol treatment is administered. If there is a five-day treatment regimen (treatment begins on March 10 and ends on March 14) the “date of the last treatment dose on this study” is day 5—March 14. • The “date decision was made to end active treatment” corresponds to the date primary reason to discontinue active treatment was made. If the primary reason to discontinue treatment was progressive disease, the “date decision was made to end active treatment” is the date the physician evaluated the patient and confirmed progression.

<p><i>End of Active Treatment Form</i> <i>(continued)</i></p>	<ul style="list-style-type: none"> • Refer to the following when determining the primary reason for discontinuing the protocol: <ul style="list-style-type: none"> ✓ Completed Treatment Per Protocol: Patient completed all of the treatment required per protocol. ✓ Refused Further Treatment: Patient and/or patient’s family refused further protocol treatment. ✓ Adverse Event: Complications, most likely related to protocol, or AEs making it medically necessary to stop protocol treatment. ✓ Disease Progression Before Active Treatment Started: Disease progression before any treatment on the protocol schema is given (e.g. surgery, chemotherapy, radiation, etc.). ✓ Disease Progression: Progressive disease or relapse during the active protocol treatment has been documented. ✓ Alternative Therapy: Patient was taken off protocol treatment to receive alternative non-protocol therapy. ✓ Other Medical Problems: Patient was removed from protocol treatment due to other medical problems not related to the protocol treatment. ✓ Died On Study: Patient died during the protocol’s active treatment phase. ✓ Cytogenetic resistance: Resistance to the treatment by the tissue or tumor due to a genetic trait in the patient. ✓ New Primary/Secondary Malignancy: Patient was removed from protocol treatment due to new primary/secondary malignancy diagnosis. ✓ Other: Patient was removed from protocol treatment for other reasons (i.e., physician discretion, insurance/financial, family problems).
<p><i>Event Monitoring Form</i></p>	<ul style="list-style-type: none"> • The Event Monitoring Form is used to report progression, follow-up, new primary cancer, late adverse event, and/or death. • The “date of last attempt to contact the patient” is ONLY used when there is no new information to report since the submission of the last Event Monitoring Form. • Late Adverse Event section should be checked ‘yes’ under the following circumstances: <ul style="list-style-type: none"> ✓ Adverse event not previously reported post completion of the active monitoring phase. ✓ Adverse event not previously reported at least possibly attributed to treatment on the study.

<i>Event Monitoring Form (continued)</i>	<ul style="list-style-type: none"> ✓ Death within 30 days of treatment not due to disease progression. ✓ Death any time at least possibly treatment related.
<i>Event Monitoring Continuation Form (Late Adverse Event Reporting)</i>	<ul style="list-style-type: none"> • If 'yes' is checked for Late Adverse Event on the Event Monitoring Form, submit the continuation page of the Event Monitoring Form. • Adverse Events entered on this form must include the following: <ul style="list-style-type: none"> ✓ MedDRA codes ✓ CTC description and grading ✓ Late adverse event start date

N0177 Forms Completion Instructions	
On-Study	<ul style="list-style-type: none"> • If the day is unknown for “Date Onset” First Symptoms use “15”. • Height must be documented in cm not inches.
Evaluation Treatment Form	<ul style="list-style-type: none"> • Please note for the first 7 weeks of treatment, a cycle is one week and this form needs to be completed and submitted as such. • Please note the need to fax immediately any necessary forms (as defined in the statement at the bottom of the Evaluation/Treatment Form for weeks 1 through 7) in the event your patient has experienced a Dose-Limiting Toxicity (DLT) during the first 7 weeks of treatment. • After 7 weeks, please use the form marked as the period following week 7 (completing of RT). At this time a cycle is defined in protocol section 4.0. These cycles are defined as every 2 months post RT completion for 1 year, every 3 months for the following year, etc. • Please document weight in kg not pounds.
Nadir/Adverse Event Log	<ul style="list-style-type: none"> • If the patient does <u>not</u> experience an adverse event listed in the protocol section 10.0, the grade 0 box must be X’d. • MedDra codes must be assigned by the membership for any adverse event beyond those required in protocol section 10.0 which meet the criteria defined on this form. • The Relationship to Study Medication (attribution) question must be answered for all adverse events experienced by the patient.
Anticonvulsant and Steroid Treatment Log	<ul style="list-style-type: none"> • We are collecting <u>only</u> anticonvulsant and steroid use. • All “no” boxes must be X’d if the patient is not receiving the drug in question. • Please document TOTAL daily dose. If drug is given as 100 mg TID document 300 mg <u>NOT</u> 100 mg TID.
Measurement Form	<ul style="list-style-type: none"> • All questions must be answered with an X in the appropriate box. • If the scan was not done check that box but also check the type of scan the patient has been having done even though a scan was not done that evaluation. On the cycles where the scan was not done the Objective Status is “UNKN.” Otherwise use the boxes to determine the Objective Status. • Once a patient has a response (CR, PR for measurable disease or REGR for evaluable disease) the Objective Status stays as that response until the patient has progressive disease.

Notification Form	<ul style="list-style-type: none">• Report all grade 4 myelosuppression or hospitalization (grade 3, 4, or 5 events precipitating hospitalization or prolonging existing hospitalization) regardless of expected or unexpected and attribution.• Answer all questions.• If an ADEERS report has been electronically submitted for this event do not submit this form.
End of Active Treatment Form	<ul style="list-style-type: none">• Check only ONE primary reason for ending active treatment.

Protocol # N0177

**NORTH CENTRAL CANCER TREATMENT GROUP
PRIMARY ASTROCYTOMA
ON-STUDY FORM**

Patient ID # _____ Initials: _____
L F M

Local ID # _____ Institution _____

DISEASE/HISTORY

/ /
m m d d y y y y

Date Onset First Symptoms

/ /
m m d d y y y y

Date of Operative Procedure

EXTENT OF RESECTION (check one)

- 1 Biopsy only
- 2 Subtotal resection
- 3 Gross total resection

LOCATION OF PRIMARY NEOPLASM (check all that apply)

- | | | |
|--------------------------|--------------------------|------------|
| L | R | |
| <input type="checkbox"/> | <input type="checkbox"/> | Frontal |
| <input type="checkbox"/> | <input type="checkbox"/> | Parietal |
| <input type="checkbox"/> | <input type="checkbox"/> | Temporal |
| <input type="checkbox"/> | <input type="checkbox"/> | Occipital |
| <input type="checkbox"/> | <input type="checkbox"/> | Cerebellum |

- | | | |
|--------------------------|--------------------------|---------------|
| L | R | |
| <input type="checkbox"/> | <input type="checkbox"/> | Thalamus |
| <input type="checkbox"/> | <input type="checkbox"/> | Basal ganglia |
| <input type="checkbox"/> | <input type="checkbox"/> | Hypothalamus |
| <input type="checkbox"/> | <input type="checkbox"/> | 3rd ventricle |

- | | | |
|--------------------------|--------------------------|----------------------|
| L | R | |
| <input type="checkbox"/> | <input type="checkbox"/> | Optic Chiasm |
| <input type="checkbox"/> | <input type="checkbox"/> | Brain Stem |
| <input type="checkbox"/> | <input type="checkbox"/> | 4th ventricle |
| <input type="checkbox"/> | <input type="checkbox"/> | Other specify: _____ |

SIDE OF PRIMARY TUMOR

- 1 RIGHT 2 LEFT 3 MIDLINE 4 BILATERAL

MULTIFOCAL TUMORS

- 1 YES 2 NO

ANY PREVIOUS CANCER

- 1 YES 2 NO

Site: _____ Date Dx:

Treatment: _____

HEIGHT (cm):

BASELINE TOXICITY/SYMPTOMS

Baseline # of stools per day

Protocol # N0177

Patient ID # _____ Initials: _____

Local ID # _____ Institution _____ L F M

NORTH CENTRAL CANCER TREATMENT GROUP

EVALUATION/TREATMENT FORM

ALL ITEMS MUST BE COMPLETED

Amended Data: if yes, check box and highlight amended areas

Use this form for Cycle 1 (Weeks 1 through 7)

Cycle:

Actual Weight (kg): .
(used for this cycle, round to the nearest tenth)

ECOG Perf. Status (used for this cycle) (check one):

BSA (m²): .
(used for this cycle)

Agent Start Date this cycle (mm/dd/yyyy)	<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"/>	<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"/>
Agent	OSI-774	TMZ
Dose Level day one this cycle (i.e. mg/m ²)		
Total Dose (mg) this cycle		
Did this patient have Dose-Limiting Toxicity?	<p>1 <input type="checkbox"/> Yes* ↓ (check all that apply)</p> <p><input type="checkbox"/> Diarrhea ≥ grade 3</p> <p><input type="checkbox"/> Skin rash/desquamation ≥ grade 3</p> <p><input type="checkbox"/> Neutropenia ≥ grade 4</p> <p><input type="checkbox"/> Thrombocytopenia ≥ grade 3</p> <p><input type="checkbox"/> Non-hematologic toxicity ≥ grade 3</p> <p><input type="checkbox"/> Radiation dermatitis ≥ grade 4</p> <p><input type="checkbox"/> Neuro toxicity ≥ grade 3</p> <p><input type="checkbox"/> Pulmonary ≥ grade 2</p> <p>2 <input type="checkbox"/> No</p>	<p>1 <input type="checkbox"/> Yes* ↓ (check all that apply)</p> <p><input type="checkbox"/> Diarrhea ≥ grade 3</p> <p><input type="checkbox"/> Skin rash/desquamation ≥ grade 3</p> <p><input type="checkbox"/> Neutropenia ≥ grade 4</p> <p><input type="checkbox"/> Thrombocytopenia ≥ grade 3</p> <p><input type="checkbox"/> Non-hematologic toxicity ≥ grade 3</p> <p><input type="checkbox"/> Radiation dermatitis ≥ grade 4</p> <p><input type="checkbox"/> Neuro toxicity ≥ grade 3</p> <p><input type="checkbox"/> Pulmonary ≥ grade 2</p> <p>2 <input type="checkbox"/> No</p>
Was DOSE LEVEL adjusted? (i.e. mg)	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No ↓	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No ↓
PRIMARY REASON for Dose Adjustment per section 8.0. Not BSA changes. (check one)	<p>42 <input type="checkbox"/> Diarrhea</p> <p>45 <input type="checkbox"/> Rash/desquamation</p> <p>154 <input type="checkbox"/> Metabolic/Laboratory</p> <p>181 <input type="checkbox"/> Pain - eye</p> <p>99 <input type="checkbox"/> Other, (not per protocol), Specify _____</p>	<p>46 <input type="checkbox"/> Nausea</p> <p>50 <input type="checkbox"/> Hepatic</p> <p>35 <input type="checkbox"/> Hematologic</p> <p>99 <input type="checkbox"/> Other, (not per protocol), Specify _____</p>

*Immediately fax the Evaluation Treatment Form, AE Log, Measurement Form and any other forms required in protocol Section 10.2 to Butch Kvittem (507-266-7240).

PLACE LABEL HERE

Protocol Number: N0177

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: Dr. Bernd Scheithauer, Mayo Clinic Rochester - Rochester, MN

Number of slides sent: ___

Accession numbers on the slides sent:

_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

Number of blocks sent: ___

Accession numbers on the blocks sent:

_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

Comments:

Institution Contact Information: (Please Print)
CRA/Nurse Contact: _____
Institution Name: _____
Street Address: _____
City: _____
State: _____ Zip: _____
Phone Number: _____
Fax Number: _____
E-mail Address: _____

NORTH CENTRAL CANCER TREATMENT GROUP

NADIR/ADVERSE EVENT LOG

ALL ITEMS MUST BE COMPLETED

page 1 of 2

Amended Data: if yes, check box and **highlight** amended areas

Protocol # N0177

Patient ID # _____ Initials: _____

L F M

Local ID # _____ Institution _____

Nadirs/Adverse Events associated with treatment cycle :

Evaluation Date : / /
 m m d d y y y y

Test	Date of Nadir	Nadir Value ¹	Is this nadir below the LLN? Check if Yes	Relationship to Study Medication 1 = Not related 2 = Unlikely 3 = Possible 4 = Probable 5 = Definite	AER* Check if submitted
PLT K/uL or 10 ⁹ /L	<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"/> <input type="checkbox"/> <input type="checkbox"/> .	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	1 <input type="checkbox"/>
WBC K/uL or 10 ⁹ /L	<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"/> <input type="checkbox"/> . <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	1 <input type="checkbox"/>
ANC K/uL or 10 ⁹ /L	<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"/> <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"/>	1 <input type="checkbox"/>

1. Note: 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.

Adverse Event 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No Adverse Events (stop here) GRADE ALL ADVERSE EVENTS BELOW	MedDRA Code (must be completed)	Grade (highest grade this cycle) INCLUDE GRADE 0's	Relationship to Study Medication If Grade > 0 1 = Not related 2 = Unlikely 3 = Possible 4 = Probable 5 = Definite	AER* Check if submitted
------------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------	--------------------------------------------------------------	-----------------------------------------------------------------------------------------------------------------------------------	----------------------------

Required Adverse Events from Section 10.0 of Protocol

Cough	<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"/> <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"/> (death)	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	1 <input type="checkbox"/>
Dyspnea	<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"/> <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"/> (death)	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	1 <input type="checkbox"/>
Rash/desquamation	<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"/> <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"/> (death)	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	1 <input type="checkbox"/>
Keratitis	<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"/> <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"/> (death)	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	1 <input type="checkbox"/>

* See Section 10.0 of the protocol.
 CONTINUED ON PAGE 2

NORTH CENTRAL CANCER TREATMENT GROUP

NADIR/ADVERSE EVENT LOG (continuation)

Protocol # N0177

Patient ID # _____ Initials: _____

Local ID # _____ Institution _____ L F M

ALL ITEMS MUST BE COMPLETED

page 2 of 2

Amended Data: if yes, check box and **highlight** amended areas

Nadirs/Adverse Events associated with treatment cycle :

Evaluation Date : / /
m m d d y y y y

Adverse Event	MedDRA Code (must be completed)	Grade (highest grade this cycle) INCLUDE GRADE 0's	Relationship to Study Medication If Grade > 0 1 = Not related 2 = Unlikely 3 = Possible 4 = Probable 5 = Definite	AER* Check if submitted
Diarrhea - without colostomy	<input type="checkbox"/> 1 <input type="checkbox"/> 0 <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 7 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<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	1 <input type="checkbox"/>
Diarrhea - with colostomy	<input type="checkbox"/> 9 <input type="checkbox"/> 0 <input type="checkbox"/> 0 <input type="checkbox"/> 0 <input type="checkbox"/> 4 <input type="checkbox"/> 0 <input type="checkbox"/> 4 <input type="checkbox"/> 8	<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	1 <input type="checkbox"/>
Nausea	<input type="checkbox"/> 1 <input type="checkbox"/> 0 <input type="checkbox"/> 0 <input type="checkbox"/> 2 <input type="checkbox"/> 8 <input type="checkbox"/> 8 <input type="checkbox"/> 1 <input type="checkbox"/> 3	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <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	1 <input type="checkbox"/>
Brain - Late RT	<input type="checkbox"/> 9 <input type="checkbox"/> 0 <input type="checkbox"/> 0 <input type="checkbox"/> 0 <input type="checkbox"/> 4 <input type="checkbox"/> 1 <input type="checkbox"/> 3 <input type="checkbox"/> 0	<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	1 <input type="checkbox"/>

Adverse Events beyond those required in Section 10.0 of the protocol.
Record grade 1 & 2 with attribution of possible, probable or definite and all grade 3, 4 and 5 regardless of attribution.**

Other:	<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"/> 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	1 <input type="checkbox"/>
Other:	<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"/> 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	1 <input type="checkbox"/>
Other:	<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"/> 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	1 <input type="checkbox"/>
Other:	<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"/> 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	1 <input type="checkbox"/>
Other:	<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"/> 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	1 <input type="checkbox"/>
Other:	<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"/> 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	1 <input type="checkbox"/>
Other:	<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"/> 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	1 <input type="checkbox"/>

* 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.

Protocol # N0177

Patient ID # _____ Initials: _____

Local ID # _____ Institution _____ L F M

NORTH CENTRAL CANCER TREATMENT GROUP

EVALUATION/TREATMENT FORM

ALL ITEMS MUST BE COMPLETED

Amended Data: if yes, check box and **highlight** amended areas

Use one form per cycle after cycle 1 (completion of RT), one column per agent.

Cycle:

Actual Weight (kg): .
(used for this cycle, round to the nearest tenth)

ECOG Perf. Status (used for this cycle) (check one): 0 1 2 3 4

BSA (m²): .
(used for this cycle)

Agent Start Date this cycle (mm/dd/yyyy)	<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"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Agent	OSI-774	TMZ*
Dose Level day one this cycle (i.e. mg/m ²)		
Total Dose (mg) this cycle		
Was DOSE LEVEL adjusted? (i.e. mg)	1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no ↓	1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no ↓
PRIMARY REASON for Dose Adjustment per section 8.0. Not BSA changes. (check one)	42 <input type="checkbox"/> Diarrhea 45 <input type="checkbox"/> Rash/desquamation 154 <input type="checkbox"/> Metabolic/Laboratory 181 <input type="checkbox"/> Pain - eye 99 <input type="checkbox"/> Other, (not per protocol), Specify _____	46 <input type="checkbox"/> Nausea 50 <input type="checkbox"/> Hepatic 35 <input type="checkbox"/> Hematologic 99 <input type="checkbox"/> Other, (not per protocol), Specify _____

*TMZ does not apply during cycle 2, cycles >8, or for patients registered prior to Addendum 6, Addendum 7, and update 2.

Protocol # N0177

Patient ID # _____ Initials: _____

L F M

Local ID # _____ Institution _____

NORTH CENTRAL CANCER TREATMENT GROUP
ANTICONVULSANT and STEROID TREATMENT LOG

ALL ITEMS MUST BE COMPLETED

Amended Data: if yes, check box and **highlight** amended areas

Baseline: or Cycle:

Evaluation Date: / /
 m m d d y y y y

Is this patient receiving steroids or anticonvulsants?

1 Yes 2 No (Stop here)

↓
(if one or more of these medications are being received, complete the entire form)

Anticonvulsants	Check one for each medication	Total Daily Dose
Neurontin	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
Phenytoin/Dilantin	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
Carbamazepine/Tegretol	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
Valproic acid/Depakene	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
Phenobarbital	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
Keppra/Levetiracetam	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
Other anticonvulsant (specify) _____	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	

Steroids	Check one for each medication	Total Daily Dose
Decadron	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
Other (specify) _____	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
Other (specify) _____	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
Other (specify) _____	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP
EVENT MONITORING FORM
(Progression/Recurrence, Follow-up, New Primary, Death)

Protocol # N0177

Patient ID # _____ Initials: _____

Local ID # _____ Institution _____ L F M

Amended Data: if yes, check box and **highlight** amended areas

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: / / → Return form to Operations Office
m m d d y y y y

VITAL STATUS

1 Alive } Date last known alive or death: / /
2 Dead } m m d d y y y y

Cause of death → 1 This cancer 4 Adverse Event (Late Adverse Event section below must be completed) 2 Other, specify _____

DISEASE FOLLOW-UP STATUS

Has the patient been assessed by a physician for this cancer since **submission of the last event monitoring form**?*

2 No → Go to Notice of New Primary.

1 Yes. If Yes, Date of Assessment: / /
m m d d y y y y

NOTICE OF FIRST RELAPSE/PROGRESSION

Has the patient had a first relapse/progression of this cancer **that has not been previously reported**?

2 No 1 Yes. If Yes, Date of Relapse:** / /
m m d d y y y y

Site(s) of Relapse/Progression: (check all that apply) Primary site Other, specify _____
 Other brain site
 Spine
 Distant metastasis

Method(s) of Diagnosis: (check all that apply) Pathological (biopsy) Other, specify _____
 Radiographic
 Clinical

NOTICE OF NEW PRIMARY

Has a new malignant neoplasm or myelodysplastic syndrome (MDS) been diagnosed **that has not been previously reported**?

2 No 3 Unknown 1 Yes. If Yes, Date of New Primary: / /
m m d d y y y y

Specify New Primary Site: _____

LATE ADVERSE EVENT (post completion of active monitoring)

Has the patient developed any of the following **not previously reported**:

- Adverse events at least possibly attributed to treatment on this study.
- Death within 30 days of treatment not due to disease progression.
- Death any time at least **possibly** treatment related.

2 No 3 Unknown/ Not evaluated 1 Yes

↓
Submit Event Monitoring Continuation 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 PROG.

Protocol # N0177

Patient ID # _____ Initials: _____

L F M

Local ID # _____ Institution _____

NORTH CENTRAL CANCER TREATMENT GROUP

EVENT MONITORING CONTINUATION FORM

(LATE ADVERSE EVENT REPORTING)

ALL ITEMS MUST BE COMPLETED

Amended Data: if yes, check box and **highlight** amended areas

LATE ADVERSE EVENTS

The CTC Version 2.0 will be used to evaluate the following signs/symptoms:

Adverse Event	MedDRA Code (must be completed)	Highest Grade	Late Adverse Event Start Date (mm/dd/yyyy)
Other:	<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"/>	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Other:	<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"/>	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Other:	<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"/>	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Other:	<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"/>	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Other:	<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"/>	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Other:	<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"/>	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Other:	<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"/>	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Other:	<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"/>	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Other:	<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"/>	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Other:	<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"/>	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Other:	<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"/>	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

CTEP REPORT VARIABLES

PRIOR THERAPY

Protocol # N0177

Patient ID # _____ Initials: _____

L F M

Local ID # _____ Institution _____

Please indicate all prior cancer treatment the patient has received. More than one therapy may be included. Multi-modality treatment should be listed separately (e.g. mastectomy followed by tamoxifen-code as surgery and hormonal therapy).

Check all that apply.

- No prior therapy [10052052]
- Chemotherapy single agent systemic [10008456]
- Chemotherapy multi-agent systemic [10008452]
- Chemotherapy Not Otherwise Specified (NOS) [10050693]
- Chemotherapy non-cytotoxic [90003014]
- Immunotherapy (e.g. interleukin-2, interferon) [90003006]
- Hormonal Therapy (e.g. tamoxifen, androgen deprivation) [10042027]
- Surgery [10030858]
- Radiotherapy (NOS) [10037794]
- Bone Marrow Transplant [10005990]
- Prior therapy (NOS) [90003010]
- Gene transfer [90003004]
- Anti-retroviral Therapy [90003000]
- Antisense [90003002]
- Oncolytic Virotherapy [90003008]
- Vaccine [10036903]
- Therapy NOS [90003012]

of prior chemotherapy regimens

I. Data Manager	PLACE LABEL HERE	NORTH CENTRAL CANCER TREATMENT GROUP PATHOLOGY REPORTING FORM BRAIN TUMOR
	Protocol # <u>N0177</u> Patient ID # _____ Initials: _____ <div style="text-align: right; margin-right: 100px;">L F M</div> Local ID # _____ Institution _____	Primary Pathologist: _____ No. of slides sent: _____ Clinic/Hospital: _____ Date sent: _____ Reviewer: _____ Slide No. _____ Sequence No. _____

1. DATE OF OPERATIVE PROCEDURE (MO-DAY-YEAR) _____ to _____

II. Information obtained from pathology report	<p>2. RADIATION EFFECTS (if prior radiation) <input type="checkbox"/> 1. Yes <input type="checkbox"/> 2. No</p> <p>3. MICROSCOPIC FEATURE OF PRIMARY NEOPLASM (0-Absent, 1-Present, 9-Uncertain)</p> <div style="display: flex; justify-content: space-between;"> <div><input type="checkbox"/> Nuclear abnormalities (atypia, pleomorphism)</div> <div><input type="checkbox"/> Mitoses</div> <div><input type="checkbox"/> Endothelial proliferation</div> <div><input type="checkbox"/> Necrosis</div> </div> <p>4. HISTOLOGIC SUBTYPE (number all that apply; for mixed tumors, specify by prevalence):</p> <div style="display: flex; flex-wrap: wrap;"> <div style="width: 33%;"><input type="checkbox"/> Oligodendroglioma</div> <div style="width: 33%;"><input type="checkbox"/> Astrocytoma, fibrillary</div> <div style="width: 33%;"><input type="checkbox"/> Astrocytoma, NOS (describe in comments)</div> <div style="width: 33%;"><input type="checkbox"/> Astrocytoma, pilocytic</div> <div style="width: 33%;"><input type="checkbox"/> Astrocytoma, gemistocytic</div> <div style="width: 33%;"><input type="checkbox"/> Gliosarcoma</div> <div style="width: 33%;"><input type="checkbox"/> Astrocytoma, microcystic (cerebellar type)</div> <div style="width: 33%;"><input type="checkbox"/> Astrocytoma, giant cell</div> <div style="width: 33%;"><input type="checkbox"/> Astrocytoma, small cell (undifferentiated)</div> <div style="width: 33%;"><input type="checkbox"/> Astrocytoma, protoplasmic</div> </div> <p>5. HISTOLOGIC GRADE OF PRIMARY NEOPLASM (degree of differentiation, check one)</p> <div style="display: flex; justify-content: space-around;"> <div>1 <input type="checkbox"/> Grade I</div> <div>2 <input type="checkbox"/> Grade II</div> <div>3 <input type="checkbox"/> Grade III</div> <div>4 <input type="checkbox"/> Grade IV</div> </div> <p>COMMENTS: _____ _____ _____</p> <p style="text-align: center;">FOR PATIENTS WITH REBIOPSY AFTER RADIATION</p> <div style="border: 1px solid black; padding: 10px; text-align: center; margin: 10px auto; width: 80%;"> PLEASE COMPLETE ALL THESE ITEMS FOLLOWING REBIOPSY </div> <p>6. MICROSCOPIC FEATURES OF RADIATION EFFECT (0-Absent, 1-Present, 9-Uncertain)</p> <div style="display: flex; justify-content: space-between;"> <div>Vascular Changes:</div> <div>Tissue Changes:</div> </div> <div style="display: flex; justify-content: space-between;"> <div><input type="checkbox"/> Proliferation</div> <div><input type="checkbox"/> Atrophy/Gliosis</div> <div><input type="checkbox"/> Other (specify): _____</div> </div> <div style="display: flex; justify-content: space-between;"> <div><input type="checkbox"/> Necrosis, thrombosis, sclerosis</div> <div><input type="checkbox"/> Necrosis</div> </div> <p>COMMENTS: _____</p>
-------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

III. Signatures	_____ Reviewer _____ Date <input type="checkbox"/> 1. Agree with diagnosis <input type="checkbox"/> 2. Minor disagreement <input type="checkbox"/> 3. Substantial disagreement Comments: _____ _____ _____	_____ Research Base Advisor _____ Date <input type="checkbox"/> 1. Agree with diagnosis <input type="checkbox"/> 2. Minor disagreement <input type="checkbox"/> 3. Substantial disagreement Comments: _____ _____ _____	_____ Committee Chairman _____ Date <input type="checkbox"/> 1. Agree with diagnosis <input type="checkbox"/> 2. Minor disagreement <input type="checkbox"/> 3. Substantial disagreement Comments: _____ _____ _____
	Block/Slide number(s) to be used for research/banking: _____		

NORTH CENTRAL CANCER TREATMENT GROUP

RADIATION THERAPY REPORTING FORM

Protocol # N0177

Patient ID # _____ Initials: _____

L F M

Local ID # _____ Institution _____

Amended Data: if yes, check box and highlight amended areas

BRAIN

Please Enclose a Copy of:

1. Preoperative and postoperative scans.
2. Prescription, dosimetry calculations, and daily treatment record.
3. Isodose plots.
4. Simulator port films.
5. Port films.

Date Start Radiotherapy

M	D	Y

Date End Radiotherapy

--	--	--

TECHNIQUE

	Modality		Field		Field Size		Treatment Distance										
Primary:	<input type="checkbox"/>		_____		<table style="display: inline-table; border-collapse: collapse;"><tr><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td></tr></table> cm X <table style="display: inline-table; border-collapse: collapse;"><tr><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td></tr></table> cm							<table style="display: inline-table; border-collapse: collapse;"><tr><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td></tr></table> cm				<input type="checkbox"/>	1=SSD
1-Cobalt	1-Cobalt		_____		<table style="display: inline-table; border-collapse: collapse;"><tr><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td></tr></table> cm X <table style="display: inline-table; border-collapse: collapse;"><tr><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td></tr></table> cm							<table style="display: inline-table; border-collapse: collapse;"><tr><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td></tr></table> cm				<input type="checkbox"/>	2=SAD
	2-Linear Accel.	___ MV	_____		<table style="display: inline-table; border-collapse: collapse;"><tr><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td></tr></table> cm X <table style="display: inline-table; border-collapse: collapse;"><tr><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td></tr></table> cm							<table style="display: inline-table; border-collapse: collapse;"><tr><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td></tr></table> cm				<input type="checkbox"/>	
	3-Other	___ MV	_____		<table style="display: inline-table; border-collapse: collapse;"><tr><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td></tr></table> cm X <table style="display: inline-table; border-collapse: collapse;"><tr><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td></tr></table> cm							<table style="display: inline-table; border-collapse: collapse;"><tr><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td></tr></table> cm				<input type="checkbox"/>	
Boost:	<input type="checkbox"/>		_____		<table style="display: inline-table; border-collapse: collapse;"><tr><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td></tr></table> cm X <table style="display: inline-table; border-collapse: collapse;"><tr><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td></tr></table> cm							<table style="display: inline-table; border-collapse: collapse;"><tr><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td></tr></table> cm				<input type="checkbox"/>	1=SSD
1-Cobalt	1-Cobalt	___ MV	_____		<table style="display: inline-table; border-collapse: collapse;"><tr><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td></tr></table> cm X <table style="display: inline-table; border-collapse: collapse;"><tr><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td></tr></table> cm							<table style="display: inline-table; border-collapse: collapse;"><tr><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td></tr></table> cm				<input type="checkbox"/>	2=SAD
	2-Linear Accel.	___ MV	_____		<table style="display: inline-table; border-collapse: collapse;"><tr><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td></tr></table> cm X <table style="display: inline-table; border-collapse: collapse;"><tr><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td></tr></table> cm							<table style="display: inline-table; border-collapse: collapse;"><tr><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td></tr></table> cm				<input type="checkbox"/>	
	3-Other	_____	_____		<table style="display: inline-table; border-collapse: collapse;"><tr><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td></tr></table> cm X <table style="display: inline-table; border-collapse: collapse;"><tr><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td></tr></table> cm							<table style="display: inline-table; border-collapse: collapse;"><tr><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td></tr></table> cm				<input type="checkbox"/>	

Treatment Areas, Dose and Time

Site	Tumor Dose (cGy)	# of Fractions	Elapsed Days							
Initial Volume	<table style="display: inline-table; border-collapse: collapse;"><tr><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td></tr></table>				<table style="display: inline-table; border-collapse: collapse;"><tr><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td></tr></table>			<table style="display: inline-table; border-collapse: collapse;"><tr><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td></tr></table>		
Boost Volume	<table style="display: inline-table; border-collapse: collapse;"><tr><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td></tr></table>				<table style="display: inline-table; border-collapse: collapse;"><tr><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td></tr></table>			<table style="display: inline-table; border-collapse: collapse;"><tr><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td></tr></table>		

Unscheduled Interruptions? 1 = yes, 2 = No. If yes, # of days and reasons:

Days	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

OPERATIONS OFFICE

3/25/02

NORTH CENTRAL CANCER TREATMENT GROUP

NEURO MEASUREMENT FORM

Protocol # N0177

Patient ID # _____ Initials: _____

L F M

Local ID # _____ Institution _____

Amended Data: if yes, check box and **highlight** amended areas

	Pretreatment	Cycle <input type="checkbox"/> <input type="checkbox"/>	Cycle <input type="checkbox"/> <input type="checkbox"/>	Cycle <input type="checkbox"/> <input type="checkbox"/>	
Date (mm/dd/yyyy)	<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"/> <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"/> / <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"/> <input type="checkbox"/> / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
Primary Indicator Lesion Site	Type of Assessment	Type of Assessment	Type of Assessment	Type of Assessment	
	CT 2 <input type="checkbox"/>	MRI 4 <input type="checkbox"/>	CT 2 <input type="checkbox"/>	MRI 4 <input type="checkbox"/>	CT 2 <input type="checkbox"/>
CT/MRI Scan Score ①	NED on baseline scan? 1 <input type="checkbox"/> yes 2 <input type="checkbox"/> no	0 <input type="checkbox"/> NED 1 <input type="checkbox"/> CR 2 <input type="checkbox"/> PR 3 <input type="checkbox"/> REGR	5 <input type="checkbox"/> STAB 6 <input type="checkbox"/> PROG 7 <input type="checkbox"/> NOT DONE	0 <input type="checkbox"/> NED 1 <input type="checkbox"/> CR 2 <input type="checkbox"/> PR 3 <input type="checkbox"/> REGR	5 <input type="checkbox"/> STAB 6 <input type="checkbox"/> PROG 7 <input type="checkbox"/> NOT DONE 8 <input type="checkbox"/> UNKN
Neuro Exam Score ②		1 <input type="checkbox"/> B 2 <input type="checkbox"/> S 3 <input type="checkbox"/> W	7 <input type="checkbox"/> NOT DONE	1 <input type="checkbox"/> B 2 <input type="checkbox"/> S 3 <input type="checkbox"/> W	7 <input type="checkbox"/> NOT DONE
Objective Status ③		0 <input type="checkbox"/> NED 1 <input type="checkbox"/> CR 2 <input type="checkbox"/> PR 3 <input type="checkbox"/> REGR	5 <input type="checkbox"/> STAB 6 <input type="checkbox"/> PROG 8 <input type="checkbox"/> UNKN	0 <input type="checkbox"/> NED 1 <input type="checkbox"/> CR 2 <input type="checkbox"/> PR 3 <input type="checkbox"/> REGR	5 <input type="checkbox"/> STAB 6 <input type="checkbox"/> PROG 8 <input type="checkbox"/> UNKN

① CT/MRI SCAN SCORE (compared to pre-Rx exam)

NED	= no evidence of disease
CR	= complete disappearance of all tumor
PR	= ≥50% reduction of L x W of 1 ^o lesions; no new lesion
REGR	= Unequivocal decrease in size of contrast enhancement or in mass effect and no new lesions
STAB	= failure to qualify for CR, PR, Regr or Prog
PROG	= ≥25% increase in L x W of any lesions or appearance of new lesion

② NEURO EXAM SCORE (compared to pre-Rx exam)

B = Better:	must be stable or decreasing dose of steroids
S = Same:	failure to qualify for B or W
W = Worse:	includes patients requiring increasing steroid doses to remain stable

③ OBJECTIVE STATUS CODE

(objective status has value shown in table below)

NEURO STATUS	SCAN STATUS					
	NED	CR	PR	REGR	STAB	PROG
Better						UNKN*
Same	NED	CR	PR	REGR	STAB	
Worse	UNKN*					PROG

* Set the Objective Status equal to unknown. Treat one more cycle and at the next visit evaluate according to the table below:

NEURO STATUS	SCAN STATUS					
	NED	CR	PR	REGR	STAB	PROG
Better						
Same	NED	CR	PR	REGR	STAB	
Worse						PROG

NORTH CENTRAL CANCER TREATMENT GROUP

NEURO MEASUREMENT FORM (continuation)

Protocol # N0177

Patient ID # _____ Initials: _____

L F M

Local ID # _____ Institution _____

Amended Data: if yes, check box and **highlight** amended areas

	Cycle <input type="text"/> <input type="text"/>	Cycle <input type="text"/> <input type="text"/>	Cycle <input type="text"/> <input type="text"/>	Cycle <input type="text"/> <input type="text"/>				
Date (mm/dd/yyyy)	<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"/> <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"/> / <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"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>				
Primary Indicator Lesion Site	Type of Assessment		Type of Assessment		Type of Assessment		Type of Assessment	
	CT 2 <input type="checkbox"/>	MRI 4 <input type="checkbox"/>	CT 2 <input type="checkbox"/>	MRI 4 <input type="checkbox"/>	CT 2 <input type="checkbox"/>	MRI 4 <input type="checkbox"/>	CT 2 <input type="checkbox"/>	MRI 4 <input type="checkbox"/>
CT/MRI Scan Score ①	0 <input type="checkbox"/> NED 1 <input type="checkbox"/> CR 2 <input type="checkbox"/> PR 3 <input type="checkbox"/> REGR	5 <input type="checkbox"/> STAB 6 <input type="checkbox"/> PROG 7 <input type="checkbox"/> NOT DONE	0 <input type="checkbox"/> NED 1 <input type="checkbox"/> CR 2 <input type="checkbox"/> PR 3 <input type="checkbox"/> REGR	5 <input type="checkbox"/> STAB 6 <input type="checkbox"/> PROG 7 <input type="checkbox"/> NOT DONE	0 <input type="checkbox"/> NED 1 <input type="checkbox"/> CR 2 <input type="checkbox"/> PR 3 <input type="checkbox"/> REGR	5 <input type="checkbox"/> STAB 6 <input type="checkbox"/> PROG 7 <input type="checkbox"/> NOT DONE	0 <input type="checkbox"/> NED 1 <input type="checkbox"/> CR 2 <input type="checkbox"/> PR 3 <input type="checkbox"/> REGR	5 <input type="checkbox"/> STAB 6 <input type="checkbox"/> PROG 7 <input type="checkbox"/> NOT DONE
Neuro Exam Score ②	1 <input type="checkbox"/> B 2 <input type="checkbox"/> S 3 <input type="checkbox"/> W	7 <input type="checkbox"/> NOT DONE	1 <input type="checkbox"/> B 2 <input type="checkbox"/> S 3 <input type="checkbox"/> W	7 <input type="checkbox"/> NOT DONE	1 <input type="checkbox"/> B 2 <input type="checkbox"/> S 3 <input type="checkbox"/> W	7 <input type="checkbox"/> NOT DONE	1 <input type="checkbox"/> B 2 <input type="checkbox"/> S 3 <input type="checkbox"/> W	7 <input type="checkbox"/> NOT DONE
Objective Status ③	0 <input type="checkbox"/> NED 1 <input type="checkbox"/> CR 2 <input type="checkbox"/> PR 3 <input type="checkbox"/> REGR	5 <input type="checkbox"/> STAB 6 <input type="checkbox"/> PROG 8 <input type="checkbox"/> UNKN	0 <input type="checkbox"/> NED 1 <input type="checkbox"/> CR 2 <input type="checkbox"/> PR 3 <input type="checkbox"/> REGR	5 <input type="checkbox"/> STAB 6 <input type="checkbox"/> PROG 8 <input type="checkbox"/> UNKN	0 <input type="checkbox"/> NED 1 <input type="checkbox"/> CR 2 <input type="checkbox"/> PR 3 <input type="checkbox"/> REGR	5 <input type="checkbox"/> STAB 6 <input type="checkbox"/> PROG 8 <input type="checkbox"/> UNKN	0 <input type="checkbox"/> NED 1 <input type="checkbox"/> CR 2 <input type="checkbox"/> PR 3 <input type="checkbox"/> REGR	5 <input type="checkbox"/> STAB 6 <input type="checkbox"/> PROG 8 <input type="checkbox"/> UNKN

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② NEURO EXAM SCORE (compared to pre-Rx exam)

B = Better:	must be stable or decreasing dose of steroids
S = Same:	failure to qualify for B or W
W = Worse:	includes patients requiring increasing steroid doses to remain stable

③ OBJECTIVE STATUS CODE

(objective status has value shown in table below)

NEURO STATUS	SCAN STATUS					
	NED	CR	PR	REGR	STAB	PROG
Better						UNKN*
Same	NED	CR	PR	REGR	STAB	
Worse	UNKN*					PROG

* Set the Objective Status equal to unknown. Treat one more cycle and at the next visit evaluate according to the table below:

NEURO STATUS	SCAN STATUS					
	NED	CR	PR	REGR	STAB	PROG
Better						
Same	NED	CR	PR	REGR	STAB	
Worse						PROG

NORTH CENTRAL CANCER TREATMENT GROUP

END OF ACTIVE TREATMENT FORM

Submit Once Per Patient

Protocol # N0177

Patient ID # _____ Initials: _____

L F M

Local ID # _____ Institution _____

Amended Data: if yes, check box and **highlight** amended areas

Date of last treatment dose on this study : / /
m m d d y y y y

Date decision was made to end active treatment : / /
m m d d y y y y

This patient will now go to : 2 Event monitoring

PRIMARY REASON (check one)	COMMENTS
1 <input type="checkbox"/> Completed Treatment Per Protocol	
2 <input type="checkbox"/> Refused Further Treatment	Complete Event Monitoring Form**
3 <input type="checkbox"/> Adverse Event	Complete Event Monitoring Form**
4 <input type="checkbox"/> Disease Progression*	Complete Event Monitoring Form
5 <input type="checkbox"/> Alternative Treatment	Complete Event Monitoring Form** Specify:
6 <input type="checkbox"/> Other Medical Problems	Complete Event Monitoring Form**
7 <input type="checkbox"/> Died On Study	Complete Event Monitoring Form
8 <input type="checkbox"/> Other	Complete Event Monitoring Form** Specify:
9 <input type="checkbox"/> New Primary Cancer	Complete Event Monitoring Form

* Submit documentation to verify PROG. See Section 11.0 of protocol.

** If patient goes to Event Monitoring Phase complete Event Monitoring Form for any reason.

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

MINI MENTAL STATE EXAMINATION

Appendix V

Protocol # N0177

Patient ID # _____ Initials: _____

L F M

Local ID # _____ Institution _____

Date: / /
m m d d y y y y

Age _____

Sex _____

___/5 What is the: (year) (season) (date) (day) (month)?

___/5 Where are we: (state) (county) (town) (building) (floor) ?

___/3 Learn: "apple, table, penny." ___ # of trials.

___/5 Subtract serial 7's: (100, 93, 86, 79, 72); or, spell "WORLD" backwards.

___/3 Recall: "apple, table penny."

___/2 Name: "pencil" and "watch."

___/1 Repeat: "no ifs, ands or buts."

___/3 "Take this paper in your right hand, fold it in half, and put it on the floor."

___/1 Read and obey: "Close your eyes."

___/1 Write a sentence on the back of this card.

___/1 Copy the design on the back of this card.

___/30 Total (abnormal if <24; if <8th grade, then <21 is considered abnormal.)

Close your eyes.

