

February 5, 2010

## FORMS PACKET

N027D: A Phase I Study of CCI-779 and Temozolomide in Combination with Radiation Therapy in Glioblastoma Multiforme

Contents:

- Pre-registration eligibility checklist (9/5/08)
- Registration eligibility checklist (3/28/08)
- \* Forms completion instructions (11/14/02)
- Preregistration screening failure form (3/7/06)
- Concurrent treatment log – baseline (12/14/05)
- Concurrent treatment log – active monitoring phase (12/14/05)
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√designates revised/new forms

\*Generic forms completion instructions are available on the NCCTG web site under “the CRA link in the Remote Registration and Data Entry section and are titled “Remote Data Entry Screen Instructions (Forms Completion).”

The specific forms instructions take precedence over the generic forms instructions, so it is very important to review them in addition to the generic forms instructions.

Pre-Registration Eligibility Checklist  
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**Prior to checking eligibility and pre-registering a patient, contact the Registration Office (507/284-4130) for study status and dose level for Arm A or to ensure a place on the protocol for patients on Arm B.**

**To register a patient, call (507/284-4130) or fax (507/284-0885) a completed eligibility checklist to the Registration Office between 8 a.m. and 4:30 p.m. central time Monday through Friday.**

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

If yes: Prior study number \_\_\_\_\_; prior patient study ID number \_\_\_\_\_

Registration date (date on) (mm/dd/yyyy) ___/___/_____
Patient study ID number (provided at time of Pre-Reg) _____
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) _____ (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
Date of birth (mm/dd/yyyy) ___/___/_____	<input type="checkbox"/> Black or African American
Zip code _____	<input type="checkbox"/> Native Hawaiian or Other Pacific Islander
Country of Residence _____	<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 not available
<input type="checkbox"/> MR (Medicare)	<input type="checkbox"/> Unknown: Patient unsure
<input type="checkbox"/> MRP (Medicare and Private Insurance)	Ethnicity (check one)
<input type="checkbox"/> MD (Medicaid)	<input type="checkbox"/> Not Hispanic or Latino
<input type="checkbox"/> MM (Medicaid and Medicare)	<input type="checkbox"/> Hispanic or Latino
<input type="checkbox"/> MVA (Military or Veterans Sponsored, Not Otherwise Specified (NOS))	<input type="checkbox"/> Not reported: Refused or data not available
<input type="checkbox"/> MS (Military Sponsored [including CHAMPUS & TRCARE])	<input type="checkbox"/> Unknown: Unsure of their ethnicity
<input type="checkbox"/> MV (Veterans Sponsored)	
<input type="checkbox"/> SP (Self pay [no insurance])	
<input type="checkbox"/> NP (No means of payment [no insurance])	
<input type="checkbox"/> OTH (Other)	
<input type="checkbox"/> UNK (Unknown)	

Addendum 4 dated September 5, 2008 IRB approved?  
 Yes. If Yes, Addendum 4 approval date (mm/dd/yyyy) \_\_\_/\_\_\_/\_\_\_\_\_  No. If No, End form, Addendum 4 IRB approval required.

NCCTG Pre-Registration Eligibility Checklist N027D  
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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 *mm/dd/yyyy*.

**Required Characteristics**

Yes No NA

Central pathology review submission. This review is mandatory prior to registration to confirm eligibility. It should be initiated as soon after surgery as possible.	____
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**All responses in above section must be “Yes.”**

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.	____
<b>Non-USA institution only</b> ( <i>check NA</i> ) vs. Date of authorization __ __ / __ __ / __ __ __ __.	____
The site has reviewed and understands the process listed in Section 17.0 and must account for sufficient time to complete pre-registration and registration steps.	____

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

Assigned Treatment

\_\_\_\_\_ Pre-Registration

Person registering \_\_\_\_\_ Signature      Registration Office specialist \_\_\_\_\_ initials

Physician \_\_\_\_\_ Signature      M    D    Y

NORTH CENTRAL CANCER TREATMENT GROUP

Registration Eligibility Checklist

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**N027D: A Phase I Study of CCI-779 and Temozolomide in Combination with Radiation Therapy in Glioblastoma Multiforme**

***To register a patient, call (507/284-4130) or fax (507/284-0885) a completed eligibility checklist to the Registration Office between 8 a.m. and 4:30 p.m. Central time Monday through Friday.***

Has the patient ever been on a prior study entered through this Registration Office?  Yes

If yes: Prior study number N027D pre-registration; prior patient study ID number \_\_\_\_\_

Registration date (date on) (mm/dd/yyyy) ___/___/_____
Patient study ID number (provided at time of Pre-Reg) _____
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) _____ (For Mayo Rochester patients, include first four letters of last name.)	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)	
___ MD (Medicaid)	Ethnicity (check one)
___ MM (Medicaid and Medicare)	___ Not Hispanic or Latino
___ MVA (Military or Veterans Sponsored, Not Otherwise Specified (NOS))	___ Hispanic or Latino
___ MS (Military Sponsored [including CHAMPUS & TRCARE])	___ Not reported: Refused or data not available
___ MV (Veterans Sponsored)	___ Unknown: Unsure of their ethnicity
___ SP (Self pay [no insurance])	
___ NP (No means of payment [no insurance])	
___ OTH (Other)	
___ UNK (Unknown)	

NCCTG Registration Eligibility Checklist N027D  
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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 *mm/dd/yyyy*.

**Required Characteristics**

Yes No NA

Histologically confirmed GBM (grade 4 astrocytoma) by central pathology review. Gliosarcomas and other grade 4 astrocytoma variants (e.g., giant cell) may be included.	____	____	____
Currently not on enzyme inducing anti-convulsants (EIACs). Note: For the purpose of this study, EIAC will be defined as carbamazepine, phenytoin, or phenobarbital/primidone.	____	____	____
≥1 week and ≤6 weeks following surgical resection or biopsy. Surgical resection or biopsy date ____/____/____.	____	____	____
≥18 years. Because no dosing or adverse event data are currently available on the use of CCI-779 in patients <18 years of age, children are excluded from this study. Age = ____	____	____	____
ECOG Performance Status (PS) 0, 1, or 2.	____	____	____
The following laboratory values obtained ≤21 days prior to registration. Earliest laboratory test date ____/____/____; latest laboratory test date ____/____/____. NOTE: These dates pertain to the following labs only.	____	____	____
• ANC ≥1500/μL. ANC = _____	____	____	____
• Hemoglobin ≥9.0 g/dL. Hemoglobin = _____	____	____	____
• PLT ≥100,000/μL. PLT = _____.	____	____	____
• Total bilirubin ≤2.5 x institutional upper limit of normal (ULN). Total bilirubin = _____; ULN = _____.	____	____	____
• Serum total cholesterol <350 mg/dL. Serum total cholesterol = _____.	____	____	____
• Serum total triglycerides <400 mg/dL. Serum total triglycerides = _____.	____	____	____
• AST (SGOT) ≤2.5 x ULN. AST (SGOT) = _____; ULN = _____.	____	____	____
• Creatinine ≤1.5 x ULN. Creatinine = _____; ULN = _____.	____	____	____
Negative serum pregnancy test done ≤7 days prior to registration, for women of childbearing potential only. Women not of childbearing potential or male ( <i>check NA</i> ) vs. Negative serum pregnancy test date ____/____/____.	____	____	____
Ability to understand, and willingness to sign, a written informed consent.	____	____	____
Willingness and ability to comply with antibiotic prophylaxis with either trimethoprim/sulfamethoxazole (daily or 3 x per week) or monthly IV pentamidine combined with daily levofloxacin.	____	____	____
Mayo Clinic Rochester (MCR) Patients ONLY: Willingness to undergo mandatory blood tests for immune monitoring (Sections 6.34, 14.1 and 14.2). Not an MCR patient ( <i>check NA</i> )	____	____	____

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

**Exclusion Criteria**

Yes No NA

Prior chemotherapy for any brain tumor. Prior TMZ or mTOR inhibitor therapies. Any prior cranial radiotherapy.	____	____	____
Receiving any other investigational agents.	____	____	____
Any of the following because CCI-779 has potential teratogenic or abortifacient effects based on the potential that mTOR expression is important for normal organ development: • Pregnant women • Nursing women • Men or women of childbearing potential who are unwilling to employ adequate contraception	____	____	____
Other active cancers requiring therapy to control disease.	____	____	____
Major surgery (excluding neurosurgical biopsy or resection of brain tumor) or significant traumatic injury occurring ≤21 days prior to registration.	____	____	____
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.	____	____	____

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**Exclusion Criteria – (continued)**

Yes No NA

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. (Note: Patients receiving combination anti-retroviral therapy are excluded from the study because of possible pharmacokinetic interactions with CCI-779.)	____	____	
Any history of allergy or intolerance to Dacarbazine (DTIC).	____	____	
Patients who require warfarin (see Section 9.4).	____	____	
Severe allergy to sulfa medications and inability to tolerate either intravenous pentamidine or levofloxacin.	____	____	

**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

MCR PATIENTS ONLY: A mandatory translational research component is part of this study, the patient will be automatically registered onto this component (Sections 3.29b, 14.1, 14.2). Not an MCR patient ( <i>check NA</i> )	____	____	
Treatment on this protocol must commence at the accruing membership under the supervision of a NCCTG member physician.	____	____	
Treatment cannot begin prior to registration and must begin $\leq 7$ days after registration. Treatment may not start $\leq 6$ days following a stereotactic biopsy or $\leq 13$ days following an open craniotomy. Treatment start date ____/____/____.	____	____	
Pretreatment tests/procedures must be completed $\leq 21$ days prior to registration (see Section 4.0). Earliest pretreatment test date ____/____/____; latest pretreatment test date ____/____/____. NOTE: The earliest pretreatment test/procedure date must be less than or equal to the earliest laboratory test date <b>and</b> the latest pretreatment test/procedure date must be greater than or equal to the latest laboratory test date.	____	____	
All required baseline symptoms must be documented and graded.	____	____	
Study drug availability checked.	____	____	
A radiation oncologist has seen the patient and confirms the patient is a suitable candidate for this study.	____	____	

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

Yes No NA

An optional translational research component is part of this study. There will be an option to select if the patient is to be registered onto this component (Section 14.3).	____	____	
<ul style="list-style-type: none"> <li>• Patient has given permission to give tissue sample(s) for research testing.</li> </ul>	____	____	
At the time of registration, the following will also be recorded:	____	____	
<ul style="list-style-type: none"> <li>• Patient has given permission to keep sample(s) for use in future research to learn about, prevent, or treat cancer.</li> </ul>	____	____	
<ul style="list-style-type: none"> <li>• Patient has given permission to keep sample(s) for use in future research to learn about, prevent, or treat other health problems (for example: diabetes, Alzheimer’s disease, or heart disease).</li> </ul>	____	____	
<ul style="list-style-type: none"> <li>• Patient has given NCCTG permission to give sample(s) to outside researchers.</li> </ul>	____	____	
Patients should be registered on NCCTG 94-72-52.	____	____	
<ul style="list-style-type: none"> <li>• Patient will be registered on NCCTG 94-72-52</li> </ul>	____	____	

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

NCCTG Registration Eligibility Checklist N027D  
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Patient study ID number \_\_\_\_\_

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

Corticosteroid therapy at study entry  
\_\_\_\_ Yes  
\_\_\_\_ No

Paraffin-embedded specimen collected  
\_\_\_\_ Yes  
\_\_\_\_ No

ECOG PS  
\_\_\_\_ 0  
\_\_\_\_ 1  
\_\_\_\_ 2

Age (years)  
\_\_\_\_ ≤40  
\_\_\_\_ 41-60  
\_\_\_\_ >60

Subgroup code (for Full CDUS reporting):

\_\_\_\_ SG1 - Patients who are not taking enzyme inducing anti-convulsants (non EIAC patients)

Assigned Treatment

\_\_\_\_ A) CCI-779\* + RT + TMZ\*\* → TMZ  
\_\_\_\_ B) RT + TMZ → TMZ

\*CCI-779: Dose = \_\_\_\_\_; Level = \_\_\_\_\_  
\*\*TMZ: Dose = \_\_\_\_\_; Level = \_\_\_\_\_

Person registering \_\_\_\_\_ Random. specialist \_\_\_\_\_  
Signature Signature initials

Physician \_\_\_\_\_ M - D - Y  
Signature

## Generic Instructions for Forms Completion

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

**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.

Date	10/12	10/19	10/26	11/02	11/09
PLT K/uL or 10 <sup>9</sup> /L	140	100	90	80	100
WBC K/uL or 10 <sup>9</sup> /L	5.8	6.4	6.0	3.2	6.0
ANC K/uL or 10 <sup>9</sup> /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.

Date	02/12	02/19	02/26	03/05	03/12
PLT K/uL or 10 <sup>9</sup> /L	120	100	70	80	100
WBC K/uL or 10 <sup>9</sup> /L	10.8	8.4	6.2	6.0	3.2
ANC K/uL or 10 <sup>9</sup> /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.)

Date	03/12	03/19	03/26	03/31	04/05	04/09
PLT K/uL or 10 <sup>9</sup> /L	140	60	70	80	100	120
WBC K/uL or 10 <sup>9</sup> /L	9.8	7.4	4.2	2.2	2.3	3.5
ANC K/uL or 10 <sup>9</sup> /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><b>Nadir Adverse Event Log</b> (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 10<sup>9</sup>/L</td> <td>215</td> <td>ND</td> <td>ND</td> <td>ND</td> <td>195</td> </tr> <tr> <td>WBC K/uL or 10<sup>9</sup>/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 10<sup>9</sup>/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 <sup>9</sup> /L	215	ND	ND	ND	195	WBC K/uL or 10 <sup>9</sup> /L	4.1	ND	ND	ND	4.6	ANC K/uL or 10 <sup>9</sup> /L	5.2	ND	ND	ND	6.3
Date	05/01	05/08	06/26	07/01	07/08																				
PLT K/uL or 10 <sup>9</sup> /L	215	ND	ND	ND	195																				
WBC K/uL or 10 <sup>9</sup> /L	4.1	ND	ND	ND	4.6																				
ANC K/uL or 10 <sup>9</sup> /L	5.2	ND	ND	ND	6.3																				
<p><b>Selecting "Yes" for grading of adverse events</b></p>	<ul style="list-style-type: none"> <li>• If the patient had even one adverse event, all required adverse events (prefilled on the form) and any other adverse events must be graded.</li> <li>• 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 <b>not</b> need to be checked when <b>only</b> the NCCTG Grade 4 or 5 Notification Form was submitted.</i></li> <li>• The "highest grade observed this cycle" (including grade 0) and the "relationship to study medication" (if the grade is &gt;0) must be completed when grading <b>required</b> AEs (i.e. prefilled on the form and assessed at every evaluation) for a cycle of treatment/observation. <ul style="list-style-type: none"> <li>✓ Section 10 of the protocol must be reviewed prior to grading AEs.</li> <li>✓ All grades, regardless of attribution, must be entered for required AEs.</li> <li>✓ Adverse events beyond those specified in Section 10 of the protocol must have IMT/MedDRA codes, CTC description and grades, and relationships entered.</li> </ul> </li> </ul>																								
<p><b>Selecting "No" for grading of adverse events</b></p>	<ul style="list-style-type: none"> <li>• 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"> <li>✓ If "No Adverse Events" is selected, submit only page one of the Nadir/Adverse Event Log.</li> </ul> </li> </ul>																								
<p><b>Measurement Form</b></p>	<ul style="list-style-type: none"> <li>• Before completing the Measurement Form, refer to Section 11 of the protocol to review the response and reporting criteria.</li> <li>• A Measurement Form must be submitted for each cycle of treatment/observation.</li> <li>• Date of tumor assessment is determined as follows: <ul style="list-style-type: none"> <li>✓ <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."</li> <li>✓ <i>Tumor assessment is completed:</i> Tumor assessment date is</li> </ul> </li> </ul>																								

<p><b>Measurement Form</b> (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"> <li>✓ <i>No progression/no response</i>: Tumor assessment date is the latest assessment date.</li> <li>✓ <i>Progression/response</i>: Tumor assessment date is the date of the assessment that indicates the progression/response.</li> </ul> <ul style="list-style-type: none"> <li>• Both the target (measurable) and non-target (non-measurable) sections of the Measurement Form must be completed.</li> <li>• Always record the lesions in the same order.</li> <li>• At each required tumor assessment date: <ul style="list-style-type: none"> <li>✓ Record the sum of the target lesions.</li> <li>✓ Record the change (status) of non-target lesions.</li> </ul> </li> <li>• 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).</li> <li>• If overall objective status is <b>response</b>: <ul style="list-style-type: none"> <li>✓ Submit documentation to verify response.</li> </ul> </li> <li>• If overall objective status is <b>progression</b>: <ul style="list-style-type: none"> <li>✓ Indicate if there were new lesions.</li> <li>✓ If applicable, indicate if progression was due only to clinical deterioration.</li> <li>✓ Submit documentation to verify progression.</li> </ul> </li> </ul>
<p><b>End of Active Treatment Form</b></p>	<ul style="list-style-type: none"> <li>• 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.</li> <li>• 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.</li> <li>• 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.</li> </ul>

***End of Active Treatment Form (continued)***

- Refer to the following when determining the primary reason for discontinuing the protocol:
  - ✓ 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).

***Event Monitoring Form***

- 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:
  - ✓ 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.

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

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP**

Protocol # N027D

**PREREGISTRATION  
SCREENING FAILURE FORM  
ALL ITEMS MUST BE COMPLETED**

Patient ID # \_\_\_\_\_ Initials:     L    F    M    

Local ID # \_\_\_\_\_ Institution \_\_\_\_\_

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

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, specify \_\_\_\_\_

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP**

**CONCURRENT TREATMENT LOG  
(BASELINE)**

**ALL ITEMS MUST BE COMPLETED**

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

Protocol # N027D

Patient ID # \_\_\_\_\_ Initials: \_\_\_\_\_

L F M

Local ID # \_\_\_\_\_ Institution \_\_\_\_\_

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

Concomitant medications? (check one)

1  Yes    2  No (Stop here)



Enter all medications (including prescription, over-the-counter, and alternative medications).

Concomitant Treatment

PLACE LABEL HERE

N027D

Protocol # \_\_\_\_\_

Patient ID # \_\_\_\_\_ Initials: \_\_\_\_\_

L F M

Local ID # \_\_\_\_\_ Institution \_\_\_\_\_

**NORTH CENTRAL CANCER TREATMENT GROUP**

**CONCURRENT TREATMENT LOG  
(ACTIVE MONITORING PHASE)**

**ALL ITEMS MUST BE COMPLETED**

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

Cycle: \_\_\_\_\_

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

Has there been any change in medications since the previous visit?

1  Yes    2  No (*Stop here*)



Enter all medications (*including prescription, over-the-counter, and alternative medications*).

Concomitant Treatment

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP  
CONCURRENT STERIOD AND ANTICONVULSANT  
TREATMENT LOG  
(ACTIVE MONITORING PHASE)  
ALL ITEMS MUST BE COMPLETED**

Protocol # N027D

Patient ID # \_\_\_\_\_ Initials: \_\_\_\_\_

L F M

Local ID # \_\_\_\_\_ Institution \_\_\_\_\_

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

Cycle: \_\_\_\_\_

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

Concomitant Treatment	Total Daily Dose
Corticosteroids 2 <input type="checkbox"/> No    1 <input type="checkbox"/> Yes ↓	
Decadron/Dexamethasone 2 <input type="checkbox"/> No    1 <input type="checkbox"/> Yes →	
Other corticosteroid 2 <input type="checkbox"/> No    1 <input type="checkbox"/> Yes → (specify) _____	
Anticonvulsants 2 <input type="checkbox"/> No    1 <input type="checkbox"/> Yes ↓	
Neurontin 2 <input type="checkbox"/> No    1 <input type="checkbox"/> Yes →	
Phenytoin/Dilantin 2 <input type="checkbox"/> No    1 <input type="checkbox"/> Yes →	
Carbamazepine/Tegretol 2 <input type="checkbox"/> No    1 <input type="checkbox"/> Yes →	
Valproic acid/Depakene 2 <input type="checkbox"/> No    1 <input type="checkbox"/> Yes →	
Phenobarbital 2 <input type="checkbox"/> No    1 <input type="checkbox"/> Yes →	

Concomitant Treatment	Total Daily Dose
Keppra 2 <input type="checkbox"/> No    1 <input type="checkbox"/> Yes →	
Other anticonvulsant 2 <input type="checkbox"/> No    1 <input type="checkbox"/> Yes → (specify) _____	
Antiemetics 2 <input type="checkbox"/> No    1 <input type="checkbox"/> Yes ↓	
Compazine 2 <input type="checkbox"/> No    1 <input type="checkbox"/> Yes →	
Granisetron 2 <input type="checkbox"/> No    1 <input type="checkbox"/> Yes →	
Ondansetron 2 <input type="checkbox"/> No    1 <input type="checkbox"/> Yes →	
Ativan 2 <input type="checkbox"/> No    1 <input type="checkbox"/> Yes →	
Other antiemetic 2 <input type="checkbox"/> No    1 <input type="checkbox"/> Yes → (specify) _____	

PLACE LABEL HERE

N027D

Protocol # \_\_\_\_\_

Patient ID # \_\_\_\_\_ Initials: \_\_\_\_\_

Local ID # \_\_\_\_\_ Institution \_\_\_\_\_ L F M

**NORTH CENTRAL CANCER TREATMENT GROUP  
CONCURRENT STEROID AND ANTICONVULSANT  
TREATMENT LOG  
(BASELINE)**

**ALL ITEMS MUST BE COMPLETED**

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

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

Concomitant Treatment	Total Daily Dose
Corticosteroids 2 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes ↓	
Decadron/Dexamethasone 2 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes →	
Other corticosteroid 2 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes → (specify) _____	
Anticonvulsants 2 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes ↓	
Neurontin 2 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes →	
Phenytoin/Dilantin 2 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes →	
Carbamazepine/Tegretol 2 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes →	
Valproic acid/Depakene 2 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes →	
Phenobarbital 2 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes →	

Concomitant Treatment	Total Daily Dose
Keppra 2 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes →	
Other anticonvulsant 2 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes → (specify) _____	
Antiemetics 2 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes ↓	
Compazine 2 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes →	
Granisetron 2 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes →	
Ondansetron 2 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes →	
Ativan 2 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes →	
Other antiemetic 2 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes → (specify) _____	

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP**

Protocol # N027D

**ON-STUDY FORM  
ALL ITEMS MUST BE COMPLETED**

Patient ID # \_\_\_\_\_ Initials: \_\_\_\_\_

L F M

Local ID # \_\_\_\_\_ Institution \_\_\_\_\_

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

**DISEASE/HISTORY**

\_\_\_/\_\_\_/\_\_\_ Date Onset First Symptoms  
(mm/dd/yyyy)

\_\_\_/\_\_\_/\_\_\_ Date of Operative Procedure  
(mm/dd/yyyy)

**MAXIMUM DIAMETER OF TUMOR ON PRE-OPERATIVE SCAN (cm)**

\_\_\_ . \_\_\_ cm Contrast Enhancement

\_\_\_ . \_\_\_ cm T2 Abnormality on MRI or Low Attenuation on CT

**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                        |            | L                        | R                        |               | L                        | R                        |                      |
| <input type="checkbox"/> | <input type="checkbox"/> | Frontal    | <input type="checkbox"/> | <input type="checkbox"/> | Thalamus      | <input type="checkbox"/> | <input type="checkbox"/> | Optic chiasm         |
| <input type="checkbox"/> | <input type="checkbox"/> | Parietal   | <input type="checkbox"/> | <input type="checkbox"/> | Basal ganglia | <input type="checkbox"/> | <input type="checkbox"/> | Brainstem            |
| <input type="checkbox"/> | <input type="checkbox"/> | Temporal   | <input type="checkbox"/> | <input type="checkbox"/> | Hypothalamus  | <input type="checkbox"/> | <input type="checkbox"/> | 4th ventricle        |
| <input type="checkbox"/> | <input type="checkbox"/> | Occipital  | <input type="checkbox"/> | <input type="checkbox"/> | 3rd ventricle | <input type="checkbox"/> | <input type="checkbox"/> | Other specify: _____ |
| <input type="checkbox"/> | <input type="checkbox"/> | Cerebellum |                          |                          |               |                          |                          |                      |

**SIDE OF PRIMARY TUMOR (check one)**

- 1  Right
- 2  Left
- 3  Midline
- 4  Bilateral

**MULTIFOCAL TUMORS**

- 1  Yes
- 2  No

**ANY PREVIOUS CANCER**

- 1  Yes
- 2  No

Site: \_\_\_\_\_ Date Dx: \_\_\_/\_\_\_/\_\_\_  
(mm/dd/yyyy)

Treatment: \_\_\_\_\_

**HEIGHT** (cm): \_\_\_\_\_

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP**

Protocol # N027D

Patient ID # \_\_\_\_\_ Initials: \_\_\_\_\_

L F M

Local ID # \_\_\_\_\_ Institution \_\_\_\_\_

**BASELINE  
ADVERSE EVENTS/SYMPTOMS FORM  
ALL ITEMS MUST BE COMPLETED**

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

**BASELINE ADVERSE EVENTS/SYMPTOMS**

Baseline # of Stools Per Day: \_\_\_\_\_

<b>Required Baseline Adverse Events from Section 10.0 of Protocol</b>		
<b>Adverse Event/Symptom</b>	<b>MedDRA Code v. 6.0</b>	<b>Grade (CTCAE v. 3.0)</b>
<b>Nausea</b>	1 0 0 2 8 8 1 3	0 1 2 3 4
<b>Triglyceride, serum-high (hypertriglyceridemia)</b>	1 0 0 2 0 8 6 9	0 1 2 3 4
<b>Cholesterol, serum-high (hypercholesteremia)</b>	1 0 0 2 0 6 0 3	0 1 2 3 4
<b>Cough</b>	1 0 0 1 1 2 2 4	0 1 2 3
<b>Dyspnea (shortness of breath)</b>	1 0 0 1 3 9 6 8	0 1 2 3 4

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP**

**ARM A - CYCLE 1 ONLY**

**EVALUATION/TREATMENT FORM**

**ALL ITEMS MUST BE COMPLETED**

Protocol # N027D

Patient ID # \_\_\_\_\_ Initials: \_\_\_\_\_

Local ID # \_\_\_\_\_ Institution \_\_\_\_\_ L F M

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

Cycle: 1

Actual Weight (kg): \_\_\_\_\_ . \_\_\_\_\_

(used for this cycle, round to the nearest tenth)

ECOG Perf. Status (check one):  0  1  2  3  4

(used for this cycle)

BSA(m<sup>2</sup>): \_\_\_\_\_ . \_\_\_\_\_

(used for this cycle)

Was this cycle of treatment held? 1  Yes 2  No

Primary Reason: (check one)

35  Hematologic

154  Metabolic/Laboratory

60  GI

38  Nonhematologic adverse event

140  Pulmonary

99  Other (not per protocol) \_\_\_\_\_

Agent	CCI-779 (CCI779)	Temozolomide (TMZ)
Agent Start Date this cycle (mm/dd/yyyy)	____/____/____	____/____/____
Dose Level day one this cycle	mg	mg/m <sup>2</sup>
Total Dose (mg) this cycle	mg	mg
Was <b>DOSE LEVEL</b> adjusted from previous cycle? (mg - mg/m <sup>2</sup> )	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No ↓	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No ↓
<b>PRIMARY REASON</b> for Dose Adjustment per Section 8.0. Not BSA changes. (If Yes, check one Primary Reason.)	35 <input type="checkbox"/> Hematologic 60 <input type="checkbox"/> GI 154 <input type="checkbox"/> Metabolic/Laboratory 140 <input type="checkbox"/> Pulmonary 38 <input type="checkbox"/> Other nonhematologic adverse event 99 <input type="checkbox"/> Other (not per protocol) _____	35 <input type="checkbox"/> Hematologic 60 <input type="checkbox"/> GI 38 <input type="checkbox"/> Other nonhematologic adverse event 99 <input type="checkbox"/> Other (not per protocol) _____
Did this patient have dose limiting toxicity this cycle? (If Yes, check all that apply.)	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No ↓ <input type="checkbox"/> ≥ grade 3 diarrhea <input type="checkbox"/> ≥ grade 3 skin rash/desquamation <input type="checkbox"/> ≥ grade 4 neutropenia or leukopenia <input type="checkbox"/> ≥ grade 4 thrombocytopenia <input type="checkbox"/> ≥ grade 4 triglyceridemia or hypercholesterolemia <input type="checkbox"/> ≥ grade 3 (other) nonhematologic adverse event, except hyperlipidemia <input type="checkbox"/> ≥ grade 4 radiation dermatitis <input type="checkbox"/> Failure to administer >75% or interruption of radiation for more than 5 days due to toxicity <input type="checkbox"/> Severe acute CNS deterioration which cannot be controlled with corticosteroid administration	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No ↓ <input type="checkbox"/> ≥ grade 3 diarrhea <input type="checkbox"/> ≥ grade 3 skin rash/desquamation <input type="checkbox"/> ≥ grade 4 neutropenia or leukopenia <input type="checkbox"/> ≥ grade 4 thrombocytopenia <input type="checkbox"/> ≥ grade 4 triglyceridemia or hypercholesterolemia <input type="checkbox"/> ≥ grade 3 (other) nonhematologic adverse event, except hyperlipidemia <input type="checkbox"/> ≥ grade 4 radiation dermatitis <input type="checkbox"/> Failure to administer >75% or interruption of radiation for more than 5 days due to toxicity <input type="checkbox"/> Severe acute CNS deterioration which cannot be controlled with corticosteroid administration

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP  
ARMS A and B**

Protocol # N027D

Patient ID # \_\_\_\_\_ Initials: \_\_\_\_\_

Local ID # \_\_\_\_\_ Institution \_\_\_\_\_ L F M

**EVALUATION FORM FOR END OF 4-6 WEEK REST PERIOD**

**ALL ITEMS MUST BE COMPLETED**

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

Cycle: 2

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

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

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

PLACE LABEL HERE

Protocol # N027D

Patient ID # \_\_\_\_\_ Initials: \_\_\_\_\_

L F M

Local ID # \_\_\_\_\_ Institution \_\_\_\_\_

**NORTH CENTRAL CANCER TREATMENT GROUP**

**ARM A - CYCLES 3 through 8**  
**ARM B - CYCLES 1 and 3 through 8**  
**EVALUATION/TREATMENT FORM**  
**ALL ITEMS MUST BE COMPLETED**

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

**Use one form per cycle, one column per agent.**

Cycle: \_\_\_\_\_

Actual Weight (kg): \_\_\_\_\_ . \_\_\_\_\_

(used for this cycle, round to the nearest tenth)

ECOG Perf. Status (check one):  0  1  2  3  4

(used for this cycle)

BSA(m<sup>2</sup>): \_\_\_\_\_ . \_\_\_\_\_

(used for this cycle)

Was this cycle of treatment held? 1  Yes 2  No

↓  
Primary Reason: (check one)

35  Hematologic

38  Other nonhematologic adverse event

99  Other (not per protocol) \_\_\_\_\_

Agent	Temozolomide (TMZ)
Agent Start Date this cycle (mm/dd/yyyy)	___/___/___
Dose Level day one this cycle	_____ mg/m <sup>2</sup>
Total Dose this cycle	_____ mg
Was <b>DOSE LEVEL</b> adjusted from previous cycle? (mg/m <sup>2</sup> )	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No ↓
<b>PRIMARY REASON</b> for Dose Adjustment per Section 8.0. Not BSA changes. (If Yes, check one Primary Reason.)	35 <input type="checkbox"/> Hematologic 60 <input type="checkbox"/> GI 38 <input type="checkbox"/> Other nonhematologic adverse event 99 <input type="checkbox"/> Other (not per protocol) _____

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

EVALUATION/OBSERVATION FORM

ALL ITEMS MUST BE COMPLETED

Protocol # N027D

Patient ID # \_\_\_\_\_ Initials: \_\_\_\_\_  
L F M

Local ID # \_\_\_\_\_ Institution \_\_\_\_\_

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

**Use one form per cycle.**

Cycle: \_\_\_\_\_

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

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

Observation\* → Day 1 of this observation cycle     /    /      
*(mm/dd/yyyy)*  
↓  
1  End of observation? (*check if yes*)  
↓  
Stop here

\*When observation ends amend the last existing Evaluation/Observation Form by checking the End of observation box above.

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

NADIR/ADVERSE EVENT LOG

Protocol # N027D

Patient ID # \_\_\_\_\_ Initials: \_\_\_\_\_

L F M

Local ID # \_\_\_\_\_ Institution \_\_\_\_\_

ALL ITEMS MUST BE COMPLETED

page 1 of 2

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

Nadirs/Adverse Events associated with treatment cycle : \_\_\_\_\_

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

Test	Date of Nadir (Date of lab test) (mm/dd/yyyy)	Nadir Value <sup>1</sup> <i>(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.)</i>	Is this nadir below the LLN?  (check one)	Relationship to Study Medication  1 = Not related 4 = Probable 2 = Unlikely 5 = Definite 3 = Possible	AER*  Check if submitted
PLT K/uL or 10 <sup>9</sup> /L	____/____/____	_____	1 <input type="checkbox"/> Yes → 2 <input type="checkbox"/> No → (Go to ANC)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	1 <input type="checkbox"/>
ANC K/uL or 10 <sup>9</sup> /L	____/____/____	_____	1 <input type="checkbox"/> Yes → 2 <input type="checkbox"/> No → (Go to Adverse Event)	<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 Event CTCAE v. 3.0	MedDRA Code v. 6.0 (must be completed)	Grade (highest grade this cycle)	Relationship to Study Medication If Grade > 0	AER*  Check if submitted
1 <input type="checkbox"/> Yes GRADE ALL ADVERSE EVENTS BELOW 2 <input type="checkbox"/> No Adverse Events (stop here)		INCLUDE GRADE 0's	1 = Not related 2 = Unlikely 3 = Possible 4 = Probable 5 = Definite	

**Required Adverse Events from Section 10.0 of Protocol**

<b>Rash/desquamation</b>	<input type="checkbox"/> 1 <input type="checkbox"/> 0 <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 7	<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"/>
<b>Diarrhea</b>	<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"/>
<b>Nausea</b>	<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"/> 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"/>
<b>Triglyceride, serum-high (hypertriglyceridemia)</b>	<input type="checkbox"/> 1 <input type="checkbox"/> 0 <input type="checkbox"/> 0 <input type="checkbox"/> 2 <input type="checkbox"/> 0 <input type="checkbox"/> 8 <input type="checkbox"/> 6 <input type="checkbox"/> 9	<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"/>

\* See Section 10.0 of the protocol.

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol # N027D

NADIR/ADVERSE EVENT LOG

Patient ID # \_\_\_\_\_ Initials: \_\_\_\_\_

ALL ITEMS MUST BE COMPLETED

page 2 of 2

Local ID # \_\_\_\_\_ Institution \_\_\_\_\_

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

Nadirs/Adverse Events associated with treatment cycle : \_\_\_\_\_

Adverse Event CTCAE v. 3.0	MedDRA Code v. 6.0 (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 sub- mitted
Cholesterol, serum-high (hypercholesteremia)	1 0 0 2 0 6 0 3	0 1 2 3 4 5 (death)	1 2 3 4 5	1 <input type="checkbox"/>
Cough	1 0 0 1 1 2 2 4	0 1 2 3	1 2 3 4 5	1 <input type="checkbox"/>
Dyspnea (shortness of breath)	1 0 0 1 3 9 6 8	0 1 2 3 4 5 (death)	1 2 3 4 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"/>	1 2 3 4 5 (death)	1 2 3 4 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"/>	1 2 3 4 5 (death)	1 2 3 4 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"/>	1 2 3 4 5 (death)	1 2 3 4 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"/>	1 2 3 4 5 (death)	1 2 3 4 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"/>	1 2 3 4 5 (death)	1 2 3 4 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"/>	1 2 3 4 5 (death)	1 2 3 4 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"/>	1 2 3 4 5 (death)	1 2 3 4 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"/>	1 2 3 4 5 (death)	1 2 3 4 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.

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol # N027D

LATE EFFECTS OF RADIATION THERAPY

Patient ID # \_\_\_\_\_ Initials: \_\_\_\_\_

ALL ITEMS MUST BE COMPLETED

Local ID # \_\_\_\_\_ Institution     L    F    M    

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

Adverse Events associated with treatment cycle : \_\_\_\_\_

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

Adverse Event CTCAE v. 3.0  1 <input type="checkbox"/> Yes      2 <input type="checkbox"/> No Adverse GRADE      Events ALL      (stop here) ADVERSE EVENTS BELOW ↓	MedDRA Code v. 6.0 (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 sub- mitted
--	---	--	--	--

**Required Adverse Events from Section 10.0 of Protocol**

Ataxia (incoordination)	1 0 0 0 3 5 9 1	0 1 2 3 4 5 (death)	1 2 3 4 5	1 <input type="checkbox"/>
CNS necrosis/cystic progression	9 0 0 3 0 5 6 0	0 1 2 3 4 5 (death)	1 2 3 4 5	1 <input type="checkbox"/>
Cognitive disturbance	1 0 0 5 7 6 6 8	0 1 2 3 4 5 (death)	1 2 3 4 5	1 <input type="checkbox"/>
Memory impairment	1 0 0 2 7 1 7 5	0 1 2 3 4	1 2 3 4 5	1 <input type="checkbox"/>
Speech impairment (e.g., dysphasia or aphasia)	1 0 0 4 1 4 6 6	0 2 3 4	1 2 3 4 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:	□ □ □ □ □ □ □ □	1 2 3 4 5 (death)	1 2 3 4 5	1 <input type="checkbox"/>
Other:	□ □ □ □ □ □ □ □	1 2 3 4 5 (death)	1 2 3 4 5	1 <input type="checkbox"/>
Other:	□ □ □ □ □ □ □ □	1 2 3 4 5 (death)	1 2 3 4 5	1 <input type="checkbox"/>
Other:	□ □ □ □ □ □ □ □	1 2 3 4 5 (death)	1 2 3 4 5	1 <input type="checkbox"/>
Other:	□ □ □ □ □ □ □ □	1 2 3 4 5 (death)	1 2 3 4 5	1 <input type="checkbox"/>

\* See Section 10.0 of the protocol.

\*\* Both hematologic and nonhematologic Adverse Events must be graded on this form as applicable.

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol # N027D

CTEP REPORT VARIABLES

PRIOR THERAPY

ALL ITEMS MUST BE COMPLETED

Patient ID # \_\_\_\_\_ Initials: \_\_\_\_\_

L F M

Local ID # \_\_\_\_\_ Institution \_\_\_\_\_

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

***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 \_\_\_\_

MedDRA code for primary tumor site: Glioblastoma multiforme [ 10018337 ]

Treatment Assignment Code:  A-2     A3  
 A-1     A4  
 A0     A5  
 A1     B  
 A2

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

RADIATION THERAPY REPORTING FORM

ALL ITEMS MUST BE COMPLETED

Protocol # N027D

Patient ID # \_\_\_\_\_ Initials: \_\_\_\_\_

L F M

Local ID # \_\_\_\_\_ Institution \_\_\_\_\_

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

BRAIN

Date Start Radiotherapy: \_\_\_/\_\_\_/\_\_\_ (mm/dd/yyyy)

Date End Radiotherapy: \_\_\_/\_\_\_/\_\_\_ (mm/dd/yyyy)

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.

TECHNIQUE

Modality	Field	Field Size	Treatment Distance
Primary: <input type="checkbox"/>	_____	_____ cm X _____ cm	_____ cm 1=SSD
1-Cobalt	_____	_____ cm X _____ cm	_____ cm 2=SAD
2-Linear Accel. _____ MV	_____	_____ cm X _____ cm	_____ cm
3-Other _____ MV	_____	_____ cm X _____ cm	_____ cm
Modality	Field	Field Size	Treatment Distance
Boost: <input type="checkbox"/>	_____	_____ cm X _____ cm	_____ cm 1=SSD
1-Cobalt _____ MV	_____	_____ cm X _____ cm	_____ cm 2=SAD
2-Linear Accel. _____ MV	_____	_____ cm X _____ cm	_____ cm
3-Other	_____	_____ cm X _____ cm	_____ cm

Treatment Areas, Dose and Time

Site	Tumor Dose (cGy)	# of Fractions	Elapsed Days
Initial Volume	_____	_____	_____
Boost Volume	_____	_____	_____

Unscheduled Interruptions?  1 = Yes, 2 = No. If yes, enter number of days and reasons below:

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

NORTH CENTRAL CANCER TREATMENT GROUP

PLACE LABEL HERE

Protocol # N027D

Patient ID # \_\_\_\_\_ Initials: \_\_\_\_\_

L F M

Local ID # \_\_\_\_\_ Institution \_\_\_\_\_

**PRETREATMENT  
NEURO MEASUREMENT FORM  
ALL ITEMS MUST BE COMPLETED**

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

Date:     /    /      
(mm/dd/yyyy)

Primary Indicator Lesion Site Type of Assessment: (check one)

2  CT

4  MRI

NORTH CENTRAL CANCER TREATMENT GROUP

ACTIVE MONITORING  
NEURO MEASUREMENT FORM  
ALL ITEMS MUST BE COMPLETED

PLACE LABEL HERE

Protocol # N027D

Patient ID # \_\_\_\_\_ Initials: \_\_\_\_\_  
L F M

Local ID # \_\_\_\_\_ Institution \_\_\_\_\_

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

Cycle: \_\_\_\_\_

Date (mm/dd/yyyy)	___/___/_____	
Primary Indicator Lesion Site	Type of Assessment (check one)	
	CT 2 <input type="checkbox"/>	MRI 4 <input type="checkbox"/>
CT/MRI Scan Score ① (check one)	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 (check one)	1 <input type="checkbox"/> B 2 <input type="checkbox"/> S 3 <input type="checkbox"/> W	7 <input type="checkbox"/> NOT DONE
Objective Status ③ (check one)	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 pretreatment exam)

NED = no evidence of disease  
CR = complete disappearance of all tumor  
PR = ≥50% reduction of L x W of 1<sup>o</sup> lesions; no new lesion  
REGR = Unequivocal decrease in size of contrast enhancement or in mass effect and no new lesion  
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 pretreatment 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	PROG
Worse	UNKN*					

\* 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						PROG
Same	NED	CR	PR	REGR	STAB	
Worse						

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP**

Protocol Number: N027D

**END OF ACTIVE TREATMENT/CANCEL NOTIFICATION FORM**

Patient ID: \_\_\_\_\_ Patient Initials: \_\_\_\_\_

**Submit Once Per Patient**

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 or date decision made not to initiate protocol treatment)*

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 of the protocol)*

- 1  Observation (Arm A only)(follow test schedule and enter cycle data)
- 2  Event Monitoring (follow Event Monitoring schedule)
- 9  Off Study

Reason Treatment Ended <i>(check one)</i>	COMMENTS
1 <input type="checkbox"/> Treatment Completed Per Protocol Criteria	
2 <input type="checkbox"/> Patient Withdrawal/Refusal <b>After</b> Beginning Protocol Therapy	Specify:
24 <input type="checkbox"/> Patient Withdrawal/Refusal <b>Prior To</b> Beginning Protocol Therapy <i>(cancel)</i>	Specify:
3 <input type="checkbox"/> Adverse Event/Side Effects/Complications	Specify:
4 <input type="checkbox"/> Disease Progression, Relapse During Active Treatment*	Complete Event Monitoring Form
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

EVENT MONITORING FORM  
(Progression/Recurrence, Follow-up, New Primary, Death)  
ALL ITEMS MUST BE COMPLETED

page 1 of 2

Protocol # N027D

Patient ID # \_\_\_\_\_ Initials: \_\_\_\_\_

L F M

Local ID # \_\_\_\_\_ Institution \_\_\_\_\_

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  
(mm/dd/yyyy)

VITAL STATUS

1  Alive } Date last known alive or death: \_\_\_/\_\_\_/\_\_\_  
2  Dead } (mm/dd/yyyy)

Cause of death → 1  This cancer 4  Adverse Event 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: \_\_\_/\_\_\_/\_\_\_  
(mm/dd/yyyy)

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:\*\* \_\_\_/\_\_\_/\_\_\_  
(mm/dd/yyyy)

Site(s) of Relapse/Progression:  Local  
(check all that apply)  Distant  
 Other, specify \_\_\_\_\_

Method(s) of Diagnosis:  Clinical exam  Other, specify \_\_\_\_\_  
(check all that apply)  Radiographic  
 Pathologic

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: \_\_\_/\_\_\_/\_\_\_  
(mm/dd/yyyy)

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.
- Death any time at least **possibly** treatment related.

2  No 3  Unknown/ 1  Yes  
Not evaluated

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 PROG.

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP**

**EVENT MONITORING FORM**

**(LATE ADVERSE EVENT REPORTING)**

**ALL ITEMS MUST BE COMPLETED**

Protocol # N027D

Patient ID # \_\_\_\_\_ Initials: \_\_\_\_\_

L F M

Local ID # \_\_\_\_\_ Institution \_\_\_\_\_

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

**LATE ADVERSE EVENTS**

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

Adverse Event CTCAE v. 3.0	MedDRA Code v. 6.0 <i>(must be completed)</i>	Highest Grade	Relationship to Study Medication 1 = Not related 2 = Unlikely 3 = Possible 4 = Probable 5 = Definite	Late Adverse Event Start Date <i>(mm/dd/yyyy)</i>
<b>Other:</b>	<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 2 3 4 5 (death)	1 2 3 4 5	_ / _ / _ _ _
<b>Other:</b>	<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 2 3 4 5 (death)	1 2 3 4 5	_ / _ / _ _ _
<b>Other:</b>	<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 2 3 4 5 (death)	1 2 3 4 5	_ / _ / _ _ _
<b>Other:</b>	<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 2 3 4 5 (death)	1 2 3 4 5	_ / _ / _ _ _
<b>Other:</b>	<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 2 3 4 5 (death)	1 2 3 4 5	_ / _ / _ _ _
<b>Other:</b>	<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 2 3 4 5 (death)	1 2 3 4 5	_ / _ / _ _ _
<b>Other:</b>	<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 2 3 4 5 (death)	1 2 3 4 5	_ / _ / _ _ _
<b>Other:</b>	<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 2 3 4 5 (death)	1 2 3 4 5	_ / _ / _ _ _
<b>Other:</b>	<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 2 3 4 5 (death)	1 2 3 4 5	_ / _ / _ _ _
<b>Other:</b>	<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 2 3 4 5 (death)	1 2 3 4 5	_ / _ / _ _ _
<b>Other:</b>	<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 2 3 4 5 (death)	1 2 3 4 5	_ / _ / _ _ _
<b>Other:</b>	<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 2 3 4 5 (death)	1 2 3 4 5	_ / _ / _ _ _
<b>Other:</b>	<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 2 3 4 5 (death)	1 2 3 4 5	_ / _ / _ _ _

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP  
PATHOLOGY REPORTING FORM  
BRAIN TUMOR**

Protocol # N027D

Patient ID # \_\_\_\_\_ Initials: \_\_\_\_\_

L F M

Local ID # \_\_\_\_\_ Institution \_\_\_\_\_

Primary Pathologist: \_\_\_\_\_ No. of slides sent: \_\_\_\_\_

Clinic/Hospital: \_\_\_\_\_ Date sent: \_\_\_\_\_

Reviewer: \_\_\_\_\_ Slide No. \_\_\_\_\_ Sequence No. \_\_\_\_\_

**I. DATE OF OPERATIVE PROCEDURE**

/   /      
m m d d y y y y

\_\_\_\_\_ to \_\_\_\_\_  
\_\_\_\_\_ to \_\_\_\_\_

**II. RADIATION EFFECTS (if prior radiation)**

1. Yes  2. No

**3. MICROSCOPIC FEATURE OF PRIMARY NEOPLASM (0-Absent, 1-Present, 9-Uncertain)**

Nuclear abnormalities (atypia, pleomorphism)  Mitoses  Endothelial proliferation  Necrosis

**4. HISTOLOGIC SUBTYPE (number all that apply; for mixed tumors, specify by prevalence):**

Oligodendroglioma  Astrocytoma, fibrillary  Astrocytoma, NOS (describe in comments)  
 Astrocytoma, pilocytic  Astrocytoma, gemistocytic  Gliosarcoma  
 Astrocytoma, microcystic (cerebellar type)  Astrocytoma, giant cell  
 Astrocytoma, protoplasmic  Astrocytoma, small cell (undifferentiated)

**5. HISTOLOGIC GRADE OF PRIMARY NEOPLASM (degree of differentiation, check one)**

1  Grade I 2  Grade II 3  Grade III 4  Grade IV

COMMENTS: \_\_\_\_\_

**FOR PATIENTS WITH REBIOPSY AFTER RADIATION**

**PLEASE COMPLETE ALL THESE  
ITEMS FOLLOWING REBIOPSY**

**6. MICROSCOPIC FEATURES OF RADIATION EFFECT (0-Absent, 1-Present, 9-Uncertain)**

Vascular Changes:

Proliferation  
 Necrosis, thrombosis, sclerosis

Tissue Changes:

Atrophy/Gliosis  Other (specify): \_\_\_\_\_  
 Necrosis

COMMENTS: \_\_\_\_\_

I. CRA/RN

II. Completed by the NCCTG Central Pathology reviewer

III. Signatures

\_\_\_\_\_  
NCCTG Pathology Reviewer

\_\_\_\_\_  
Date

1. Agree with original local diagnosis  
2. Minor disagreement with original local diagnosis  
3. Substantial disagreement with original local diagnosis

Comments: \_\_\_\_\_

\_\_\_\_\_  
Research Base Advisor

\_\_\_\_\_  
Date

1. Agree with original local diagnosis  
2. Minor disagreement with original local diagnosis  
3. Substantial disagreement with original local diagnosis

Comments: \_\_\_\_\_

\_\_\_\_\_  
Committee Chairperson

\_\_\_\_\_  
Date

1. Agree with original local diagnosis  
2. Minor disagreement with original local diagnosis  
3. Substantial disagreement with original local diagnosis

Comments: \_\_\_\_\_

**Block/Slide number(s) to be used for research/banking:** \_\_\_\_\_



PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP**

**BASELINE**

**TISSUE SPECIMEN SUBMISSION FORM**

**ALL ITEMS MUST BE COMPLETED**

Protocol # N027D

Patient ID # \_\_\_\_\_ Initials: \_\_\_\_\_

L F M

Local ID # \_\_\_\_\_ Institution \_\_\_\_\_

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

**INSTRUCTIONS**

*Complete this form for all patients and enter into the remote data entry system within 60 days of study entry. See Section 14 of the protocol for specimen requirements and shipment.*

Did this patient consent to provide paraffin block for research?

1  Yes → Complete rest of form.

2  No → End form.

Was a research paraffin block obtained?

1  Yes Date of biopsy: (mm/dd/yyyy) \_\_\_/\_\_\_/\_\_\_\_\_

Date sent: (mm/dd/yyyy) \_\_\_/\_\_\_/\_\_\_\_\_

2  No Reason: \_\_\_\_\_

PLACE LABEL HERE

**NORTH CENTRAL CANCER TREATMENT GROUP**

**MAYO CLINIC ROCHESTER ONLY**

**ACTIVE MONITORING  
BLOOD SPECIMEN SUBMISSION 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)*

Protocol Number: N027D

Patient ID: \_\_\_\_\_ Patient Initials: \_\_\_\_\_  
L F M

Institution Number: \_\_\_\_\_

Institution: \_\_\_\_\_

Current Cycle Number: \_\_\_\_\_

**INSTRUCTIONS:**

Complete this form **for all patients** and enter into the remote data entry system within 7 days of specimen collection.  
See Section 14 of the protocol for specimen requirements and shipment.

Time point: (check one)

- 1  In the last week of RT
- 2  Prior to Cycle 3
- 3  Prior to Cycle 5

Was a research blood specimen collected? (check one)

1  Yes. If Yes: Date of collection: (mm/dd/yyyy) \_\_\_/\_\_\_/\_\_\_\_\_

Date Specimen Shipped: (mm/dd/yyyy) \_\_\_/\_\_\_/\_\_\_\_\_

2  No. If No, reason: \_\_\_\_\_

PLACE LABEL HERE

Protocol # N027D

Patient ID # \_\_\_\_\_ Initials: \_\_\_\_\_  
L F M

Local ID # \_\_\_\_\_ Institution \_\_\_\_\_

**NORTH CENTRAL CANCER TREATMENT GROUP**  
**NOTIFICATION FORM**  
**Grade 4 or 5 Non-AER Reportable Events/Hospitalization**  
**ALL ITEMS MUST BE COMPLETED**

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

**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): (mm/dd/yyyy) \_\_\_/\_\_\_/\_\_\_

Name of Person Completing Form: \_\_\_\_\_ Phone Number (\_\_\_\_) \_\_\_\_\_ - \_\_\_\_\_

Cycle Number: \_\_\_\_\_ Assigned Treatment Arm: \_\_\_\_\_

Event ≥ Grade 4    1  Yes    2  No



Date of First Occurrence of Adverse Event (mm/dd/yyyy)	Common Toxicity Criteria Adverse Event Term Type (only one event per line)	CTC Adverse Event Grade	Relationship to study medication. In your opinion, is this related to the study medication? <sup>1</sup>
___/___/___		<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:**    1  Yes    2  No



Hospital Admission Date: (mm/dd/yyyy) \_\_\_/\_\_\_/\_\_\_

Reason(s) for Hospitalization:

1  Adverse Event, specify type and grade: \_\_\_\_\_

2  Prophylactic, specify: \_\_\_\_\_

3  Other reason, specify \_\_\_\_\_

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

MINI MENTAL STATE EXAMINATION

Appendix IV

Protocol # N027D

Patient ID # \_\_\_\_\_ Initials: \_\_\_\_\_

L F M

Local ID # \_\_\_\_\_ Institution \_\_\_\_\_

Date: \_\_\_/\_\_\_/\_\_\_  
(mm/dd/yyyy)

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."

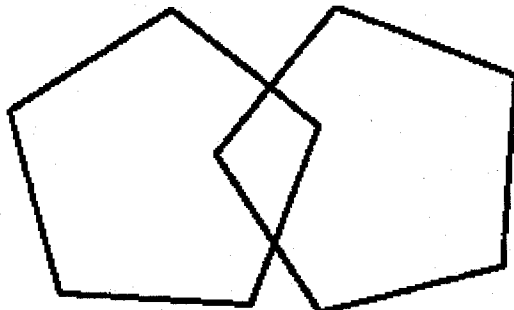
\_\_\_/1 Read and obey: "Close your eyes."

\_\_\_/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.



# Fax Supply Order Form

No Cover Sheet Necessary

**Fax to Ann Tuma: 1-507-266-5193**

**SPONSOR COMPANY: North Central Cancer Treatment Group (NCCTG)**

**PROTOCOL: N027D**

Investigator: \_\_\_\_\_

Order placed by \_\_\_\_\_

Phone #: ( ) \_\_\_\_\_

Fax #: ( ) \_\_\_\_\_

**Name of Main Member investigator: \_\_\_\_\_ (required)**

**Name and address kits should be sent to:**

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Today's Date:** \_\_\_\_\_

**YOU WILL RECEIVE YOUR SUPPLIES WITHIN 2 WEEKS OF TODAY'S DATE.**

Please call 1-507-284-0803 or e-mail [tuma.ann@mayo.edu](mailto:tuma.ann@mayo.edu) if you have questions about this order.

Lab Supplies:

Quantity:

<u>Kit 1:</u> Order for ALL Patients	_____ each
<u>Kit 2:</u> Order Only for Patients at MTD (Kit 1 must also be ordered, if Kit 1 has not been previously ordered)	_____ each