

FORMS PACKET

N0779: Phase II Study of Vorinostat (SAHA) in Combination with Bortezomib (PS-341) in Patients with Recurrent Glioblastoma Multiforme

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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).”

NORTH CENTRAL CANCER TREATMENT GROUP
Pre-Registration (Step 1) Eligibility Checklist

08/28/2009
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N0779: Phase II Study of Vorinostat (SAHA) in Combination with Bortezomib (PS-341) in Patients with Recurrent Glioblastoma Multiforme

To pre-register a patient, access the NCCTG web page at <https://ncctg.mayo.edu/training> and enter the remote registration/randomization application.

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 _____

Pre-Registration date (date on) (mm/dd/yyyy) __/__/____

Patient study ID number (provided at time of Pre-Registration) _____

NCCTG member (participant sponsor) _____

NCCTG treating location _____

NCCTG treating physician _____

Institution patient number (local subject number) _____

IRB approval date (mm/dd/yyyy) __/__/____

Person Completing Form:

Last Name: (print) _____ First Name: (print) _____

Phone: _____ Fax: _____ Email: _____

Patient initials (last, first, middle) _____	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
	<input type="checkbox"/> American Indian or Alaska Native
	<input type="checkbox"/> Not reported: Patient refused or not available
	<input type="checkbox"/> Unknown: Patient unsure
Method of payment (check one)	Ethnicity (check one)
<input type="checkbox"/> PI (Private Insurance)	<input type="checkbox"/> Not Hispanic or Latino
<input type="checkbox"/> MR (Medicare)	<input type="checkbox"/> Hispanic or Latino
<input type="checkbox"/> MRP (Medicare and Private Insurance)	<input type="checkbox"/> Not reported: Refused or data not available
<input type="checkbox"/> MD (Medicaid)	<input type="checkbox"/> Unknown: Unsure of their ethnicity
<input type="checkbox"/> MM (Medicaid and Medicare)	
<input type="checkbox"/> MVA (Military or Veterans Sponsored, Not Otherwise Specified (NOS))	
<input type="checkbox"/> MS (Military Sponsored [including CHAMPUS & TRCARE])	
<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)	

NCCTG Pre-Registration (Step 1) Eligibility Checklist N0779

08/28/2009
Page 2 of 2

Patient study ID number _____

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

Inclusion Criteria

Yes No NA

Central pathology review submission. This review is mandatory prior to registration to confirm eligibility (see Section 17.2). It should be initiated as soon as possible after pre-registration.	_____	_____	_____
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Response in above section must be “Yes.”

Pre-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. If not a USA institution (<i>check NA</i>); If a USA institution - Date of authorization ____/____/_____	_____	_____	_____
The site has reviewed and understands the process listed in Section 17.2 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
_____ mm dd yyyy

NORTH CENTRAL CANCER TREATMENT GROUP
Registration (Step 2) Eligibility Checklist

10/23/2009
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N0779: **Phase II Study of Vorinostat (SAHA) in Combination with Bortezomib (PS-341) in Patients with Recurrent Glioblastoma Multiforme**

To register a patient, access the NCCTG web page at <https://ncctg.mayo.edu/training> and enter the remote registration/randomization application.

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 Reg/Random) _____

NCCTG member (participant sponsor) _____

NCCTG treating location _____

NCCTG treating physician _____

Institution patient number (local subject number) _____

IRB approval date (mm/dd/yyyy) ___/___/_____

Person Completing Form:

Last Name: **(print)** _____ First Name: **(print)** _____

Phone: _____ Fax: _____ Email: _____

Patient initials (last, first, middle) _____

Gender (check one) Male Female Unknown

Date of birth (mm/dd/yyyy) ___/___/_____

Zip code _____

Country of Residence _____

Race (check all that apply)

- White
 Black or African American
 Native Hawaiian or Other Pacific Islander
 Asian
 American Indian or Alaska Native
 Not reported: Patient refused or not available
 Unknown: Patient unsure

Method of payment (check one)

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

Ethnicity (check one)

- Not Hispanic or Latino
 Hispanic or Latino
 Not reported: Refused or data not available
 Unknown: Unsure of their ethnicity

Patient study ID number _____

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

Inclusion Criteria

Yes No NA

Histologically confirmed glioblastoma multiforme as determined by pre-registration central pathology review. NOTE: Gliosarcomas and other grade 4 astrocytoma variants (e.g., giant cell) are eligible.	_____	_____	_____
Evidence of tumor progression by MRI or CT scan following RT or following the most recent anti-tumor therapy. NOTE: Radiographic progression soon after RT may represent altered blood-brain barrier function rather than tumor progression.	_____	_____	_____
Bidimensionally measurable or evaluable disease by MRI or CT scan.	_____	_____	_____
≥ 8 weeks since the completion of RT prior to registration. If no prior RT (<i>check NA</i>); If prior RT - Last day of RT ____/____/____	_____	_____	_____
≥ 18 years of age. Age = _____	_____	_____	_____
Fixed dose of corticosteroids (or no corticosteroids) ≥ 1 week prior to baseline scan.	_____	_____	_____
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.	_____	_____	_____
• WBC ≥3000/mm ³ WBC = _____	_____	_____	_____
• ANC ≥1500/mm ³ ANC = _____	_____	_____	_____
• PLT ≥100,000/mm ³ PLT = _____	_____	_____	_____
• Hgb ≥9 g/dL Hgb = _____	_____	_____	_____
• Total bilirubin ≤ 1.5 x upper normal limit (UNL) Total bilirubin = _____; UNL = _____	_____	_____	_____
• SGOT (AST) ≤ 3 x UNL SGOT (AST) = _____; UNL = _____	_____	_____	_____
• Creatinine ≤ UNL Creatinine = _____; UNL = _____	_____	_____	_____
ECOG Performance Status (PS) 0, 1, or 2. PS = _____	_____	_____	_____
Willingness to discontinue taking during this study any of the following Category I medications that are generally accepted to have a risk of causing Torsades de Pointes: <ul style="list-style-type: none"> • Quinidine, procainamide, disopyramide • Amiodarone, sotalol, ibutilide, dofetilide • Erythromycin, clarithromycin • Chlorpromazine, haloperidol, mesoridazine, thioridazine, pimozide • Cisapride, bepridil, droperidol, methadone, arsenic, chloroquine, domperidone, halofantrine, levomethadyl, pentamidine, sparfloxacin, lidoflazine 	_____	_____	_____
Willingness to provide mandatory correlative laboratory tissue samples, as described in Section 17.3.	_____	_____	_____
Arm A (Patients NOT undergoing surgery): ≤1 chemotherapy regimen for progressive/recurrent disease. Arm B (Patients undergoing surgery at time of recurrence): Any number of chemotherapy regimens for progressive/recurrent disease. NOTE: Adjuvant chemotherapy for all groups is allowed and does not count toward the number of regimens for progressive/recurrent disease.	_____	_____	_____
Negative pregnancy test done ≤7 days prior to registration, for women of childbearing potential only. If not a woman of childbearing potential or male (<i>check NA</i>) If a woman of childbearing potential - Negative pregnancy test date ____/____/____	_____	_____	_____
Willingness to return to an NCCTG institution for follow-up.	_____	_____	_____

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

Patient study ID number _____

Exclusion Criteria

Yes No NA

Exclusion Criteria	Yes	No	NA
Any of the following:			
<ul style="list-style-type: none"> • ≤6 weeks since last day of nitrosourea-based chemotherapy and/or If no prior nitrosourea-based chemotherapy (<i>check NA</i>); If prior nitrosourea-based chemotherapy - Last day of prior nitrosourea-based chemo@therapy ___/___/_____ 	___	___	___
<ul style="list-style-type: none"> • ≤4 weeks since last day of other chemotherapy prior to registration If no other prior chemotherapy (<i>check NA</i>) If other prior chemotherapy - Last day of other chemotherapy ___/___/_____ 	___	___	___
<ul style="list-style-type: none"> • ≤2 weeks since last day of small molecule cell cycle inhibitors prior to registration If no prior small molecule cell cycle inhibitors (<i>check NA</i>); If prior small molecule cell cycle inhibitors - Last date of prior small molecule cell cycle inhibitors ___/___/_____ 	___	___	___
<ul style="list-style-type: none"> • ≤4 weeks since last day of Avastin® prior to registration If no prior Avastin® (<i>check NA</i>); If prior Avastin® - Last day of Avastin® ___/___/_____ 	___	___	___
≤ 6 weeks since prior stereotactic radiosurgery or interstitial brachytherapy prior to registration. EXCEPTION: Separate lesion on MRI which is not part of the previous treatment field.	___	___	
Any of the following: <ul style="list-style-type: none"> • Pregnant women • Nursing women • Men or women of childbearing potential who are unwilling to employ adequate contraception during the study and for 6 months following the last dose of vorinostat <p>NOTE: Vorinostat and bortezomib are investigational agents whose genotoxic effects on the developing fetus and newborn are unknown.</p>	___	___	
Known hypersensitivity to any of the components of vorinostat or bortezomib.	___	___	
History of myocardial infarction or unstable angina ≤6 months prior to registration or congestive heart failure (CHF) requiring use of ongoing maintenance therapy, or history of life-threatening ventricular arrhythmias.	___	___	
Uncontrolled intercurrent illness including, but not limited to, ongoing or active infection, or psychiatric illness/social situations that would limit compliance with study requirements.	___	___	
Other active malignancy ≤3 years prior to registration. EXCEPTIONS: Non-melanotic skin cancer or carcinoma-in-situ of the cervix. NOTE: If there is a history of prior malignancy, they must not be receiving other specific treatment (other than hormonal therapy) for their cancer.	___	___	
Co-morbid systemic illnesses or other severe concurrent disease which, in the judgment of the investigator, would make the patient inappropriate for entry into this study or interfere significantly with the proper assessment of safety and adverse events of the prescribed regimens.	___	___	
Immunocompromised patients. NOTE: Patients known to be HIV positive, but without clinical evidence of an immunocompromised state, are eligible for this trial.	___	___	
Use of valproic acid, another histone deacetylase inhibitor, for ≤ 7 days prior to registration.	___	___	
Receiving enzyme-inducing antiepileptic drugs (EIAcs; e.g., phenytoin, fosphenytoin, carbamazepine, phenobarbital, or primidone) or any other potent CYP3A4 inducer such as rifampin or St. John's wort. Note: See Appendix V for a complete list.	___	___	
≥grade 2 peripheral neuropathy due to any cause or ≥grade 1 peripheral neuropathy with pain.	___	___	
Receiving any other investigational agent which would be considered as a treatment for the primary neoplasm.	___	___	
Prior treatment with vorinostat or bortezomib.	___	___	
Inability to take oral medications.	___	___	
Congenital long QT syndrome.	___	___	
Prolonged QTc interval (>450 msec).	___	___	

Patient study ID number _____

Exclusion Criteria (continued)

Yes No NA

Any of the following Category I drugs that are generally accepted to have a risk of causing Torsades de Pointes ≤ 7 days prior to registration: <ul style="list-style-type: none"> • Quinidine, procainamide, disopyramide • Amiodarone, sotalol, ibutilide, dofetilide • Erythromycin, clarithromycin • Chlorpromazine, haloperidol, mesoridazine, thioridazine, pimozide • Cisapride, bepridil, droperidol, methadone, arsenic, chloroquine, domperidone, halofantrine, levomethadyl, pentamidine, sparfloxacin, lidoflazine 	____	____	____
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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

A mandatory translational research component for tissue is part of this study; the patient will be automatically registered onto this component (Sections 3.29b and 17.0).	____	____	____
Treatment on this protocol must commence at the accruing membership under the supervision of an NCCTG member physician.	____	____	____
Treatment cannot begin prior to registration and must begin ≤ 14 days after registration.	____	____	____
Pretreatment tests/procedures must be completed ≤ 21 days prior to registration (see Section 4.0). NOTE: MRI date collected under “Exceptions to the above dates.” Earliest pretreatment test date ___/___/____; latest pretreatment test date ___/___/____	____	____	____
<u>Exceptions to the above dates:</u> <ul style="list-style-type: none"> • Hematology: WBC, ANC, PLT, Hgb and Chemistry: SGOT [AST], alkaline phosphatase, total bilirubin, sodium, potassium, glucose, calcium, creatinine obtained ≤ 14 days prior to registration (see Section 4.0, footnote 1). NOTE: The earliest hematology/chemistry test date must be less than or equal to the earliest laboratory test date and the latest hematology/chemistry test date must be greater than or equal to the latest laboratory test date. Earliest hematology/chemistry test date ___/___/____; Latest hematology/chemistry test date ___/___/____ • If patient was on prior Avastin®, baseline MRI needs to be ≤ 7 days prior to registration. Patient received prior Avastin®? (this question may be answered yes or no) ____ Yes. If Yes, MRI date (≤ 7 days prior to registration) ___/___/____ ____ No. If No, MRI date (≤ 21 days prior to registration) ___/___/____ • Patients undergoing surgery will have a post surgical MRI performed somewhere between ≥ 7 days after surgery but ≤ 28 days after surgery. 	____	____	____
All required baseline symptoms must be documented and graded.	____	____	____
Study drug availability checked.	____	____	____

All responses in above section must be “Yes.”

At the time of registration, the following will also be recorded:	____	____	____
<ul style="list-style-type: none"> • Patient has given permission to keep tissue sample(s) for use in future research to learn about, prevent, or treat cancer. 	____	____	____
<ul style="list-style-type: none"> • Patient has given permission to keep tissue 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). 	____	____	____
<ul style="list-style-type: none"> • Patient has given NCCTG permission to give tissue sample(s) to outside researchers. 	____	____	____
<ul style="list-style-type: none"> • Patient has given NCCTG permission to be contacted in the future to take part in more research. 	____	____	____
Patient has agreed to be enrolled on N0392.	____	____	____
Patient has agreed to be enrolled on 94-72-52.	____	____	____

All responses in above section may be “Yes” or “No.”

Patient study ID number _____

Grouping Factor

Arm

____ A (Patients not undergoing surgery)

____ B (Patients undergoing surgery at time of recurrence)

Subgroup code (for CTEP reporting)

____ SG1 (Patients not undergoing surgery – Patients in Arm A)

____ SG2 (Patients undergoing surgery at time of recurrence – Patients in Arm B)

Assigned Treatment

____ A) (**Patients not Undergoing Surgery**) - Vorinostat + Bortezomib

____ B) (**Patients Undergoing Surgery at Time of Recurrence**) - Vorinostat + Bortezomib

Person registering Signature _____ Registration Office specialist initials _____

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

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N0779

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

**PREREGISTRATION
SCREENING FAILURE FORM**

ALL ITEMS MUST BE COMPLETED

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

Date aware of preregistration screening failure: (*mm/dd/yyyy*) ___/___/_____

Primary reason screening failed? (*check one*)

- 3 Did not meet eligibility criteria
- 1 Investigator decision
- 2 Patient decision
- 4 Other reason, specify _____

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N0779

ON-STUDY FORM

Pg. 1 of 2

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

ALL ITEMS MUST BE COMPLETED

Institution: _____

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

Disease History

Date of Initial Diagnosis: (mm/dd/yyyy) ___/___/_____

Date of Diagnosis of (current) Recurrence: (mm/dd/yyyy) ___/___/_____

Date of Diagnosis of (prior) Recurrence(s): (mm/dd/yyyy) ___/___/_____

(mm/dd/yyyy) ___/___/_____

(NOTE: Send pathology material and pathology reporting form for the initial procedure and procedure(s) at recurrence)

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

Extent of primary resection: (check one)

1 None 2 Biopsy 3 Subtotal resection 4 Gross total resection

Location of (current) Recurrent 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 (current) Recurrent Tumor (check one)

1 Right 2 Left 3 Midline 4 Bilateral

Extent of resection at (current) recurrence: (check one)

1 None 2 Biopsy 3 Subtotal resection 4 Gross total resection

Multifocal Tumors

1 Yes 2 No

Any Previous Cancer

1 Yes 2 No



Site: _____ Date Diagnosis: ___/___/_____ Treatment: _____

PLACE LABEL HERE

Protocol Number: N0779

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

NORTH CENTRAL CANCER TREATMENT GROUP

ON-STUDY FORM

Pg. 2 of 2

ALL ITEMS MUST BE COMPLETED

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

Descriptive Factors:

Age (years): (check one) 1 <40 2 40-60 3 >60

Prior nitrosoureas: (check one) 1 Yes 2 No

Prior temozolomide: (check one) 1 None 2 Adjuvant 3 Recurrent 4 Both

Prior Avastin: (check one) 1 Yes 2 No

Interval since end of RT (months): _____

Corticosteroid therapy at study entry: (check one) 1 Yes 2 No

Family history of brain tumor: (check one) 1 Yes 2 No

If Yes, check all that apply:

- Father
- Mother
- Brother/Sister
- Child
- Other (List: _____)

Primary indicator: (check one) 1 Measurable disease 2 Evaluable disease

Number of prior chemotherapy regimens for progressive/recurrent disease: (check one) 1 0 2 1 3 ≥2 (≥2 Arm B only)

Height (cm): _____

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

NCCTG Protocol Number: N0779

NCCTG Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

FOLSTEIN MINI MENTAL STATE

APPENDIX IV

Date: (mm/dd/yyyy) ___/___/_____

___/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."

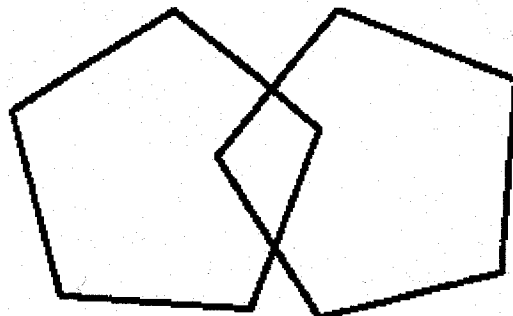
___/1 Read and obey: "Close your eyes."

___/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.



PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N0779

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

**BASELINE
ADVERSE EVENTS 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)

Required Baseline Adverse Events from Section 10.0 of Protocol

CTC Adverse Events Term	MedDRA Code (v. 10.0)	CTC Adverse Event Grade
Baseline number of stools per day: _____		
Fatigue (asthenia, lethargy, malaise)	10016256	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Anorexia	10002646	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Dehydration	10012174	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Nausea	10028813	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Taste alteration (dysgeusia)	10043125	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2
Vomiting	10047700	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Pain - <i>Select</i>		
- Abdomen NOS	10000081	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N0779

Patient ID: _____ Patient Initials: _____
L F M

Institution Number: _____

Institution: _____

**PRETREATMENT
MEASUREMENT FORM**

ALL ITEMS MUST BE COMPLETED

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

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

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

- 2 CT
- 4 MRI

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N0779

**ACTIVE MONITORING
MEASUREMENT FORM**

Patient ID: _____ Patient Initials: _____
L F M

Institution Number: _____

Institution: _____

ALL ITEMS MUST BE COMPLETED

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

Current Cycle Number: ____

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)	1 <input type="checkbox"/> CR 2 <input type="checkbox"/> PR 3 <input type="checkbox"/> REGR	5 <input type="checkbox"/> SD 6 <input type="checkbox"/> PD 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)	1 <input type="checkbox"/> CR 2 <input type="checkbox"/> PR 3 <input type="checkbox"/> REGR	5 <input type="checkbox"/> SD 6 <input type="checkbox"/> PD 8 <input type="checkbox"/> UNKN

① CT/MRI SCAN SCORE (compared to pretreatment exam)

CR = complete disappearance of all tumor
 PR = ≥50% reduction of L x W of 1° lesions; no new lesion
 REGR = Unequivocal decrease in size of contrast enhancement or in mass effect and no new lesion
 SD = failure to qualify for CR, PR, Regr or Prog
 PD = ≥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				
	CR	PR	REGR	SD	PD
Better					UNKN*
Same	CR	PR	REGR	SD	PD
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				
	CR	PR	REGR	SD	PD
Better					PD
Same	CR	PR	REGR	SD	
Worse					

PLACE LABEL HERE

Protocol Number: N0779

Patient ID: _____ Patient Initials: _____
L F M

Institution Number: _____

Institution: _____

NORTH CENTRAL CANCER TREATMENT GROUP

**EVALUATION/TREATMENT FORM
(ARM A - ALL CYCLES/ARM B - CYCLES ≥2)**

Pg. 1 of 2

ALL ITEMS MUST BE COMPLETED

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

Use one form per cycle, one column per agent.

Current Cycle Number: _____

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

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

BSA(m²): (used for this cycle) _____

Was this cycle of treatment held (omitted) (Day 1)? (check one)

1 Yes, planned 2 No 3 Yes, unplanned

If Yes, planned or unplanned; Primary reason treatment held: (check one)

35 Hematologic
38 Any non-hematologic adverse event
99 Other (not per protocol), specify _____

Agent	Vorinostat (SAHA)	Bortezomib (PS-341)
Agent Start Date this cycle (mm/dd/yyyy)	___/___/___	___/___/___
Dose Level day one this cycle (If agent was not given this cycle, enter the dose level received on last day of treatment.)	mg	mg/m ²
Total Dose this cycle (If agent was not given this cycle, enter 0 for total dose.)	mg	mg
Was DOSE LEVEL adjusted (Day 1-14; Day 1, 4, 8, or 11) from previous cycle? (mg - mg/m ²)	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No
If Yes, PRIMARY REASON for Dose Adjustment per Section 8.0. Not BSA changes. (Check one)	35 <input type="checkbox"/> Hematologic 38 <input type="checkbox"/> Any non-hematologic adverse event 99 <input type="checkbox"/> Other (not per protocol), specify _____ 500 <input type="checkbox"/> Increased per protocol	35 <input type="checkbox"/> Hematologic 70 <input type="checkbox"/> Neuropathy: Motor and Sensory 38 <input type="checkbox"/> Any non-hematologic adverse event 99 <input type="checkbox"/> Other (not per protocol), specify _____ 500 <input type="checkbox"/> Increased per protocol

PLACE LABEL HERE

Protocol Number: N0779

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

NORTH CENTRAL CANCER TREATMENT GROUP

**EVALUATION/TREATMENT FORM
(ARM A - ALL CYCLES/ARM B - CYCLES \geq 2)**

ALL ITEMS MUST BE COMPLETED

Pg. 2 of 2

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

Current Cycle Number: _____

Agent: Bortezomib (PS-341)

Was dose omitted (day 1)? (check one)

1 Yes. If Yes, primary reason dose omitted: (check one)

35 Hematologic

38 Any non-hematologic adverse event

99 Other (not per protocol), specify _____

2 No. If No, was dose level adjusted? (check one) 1 Yes 2 No

If Yes, primary reason: (check one)

35 Hematologic

38 Any non-hematologic adverse event

70 Neuropathy: Motor and Sensory

99 Other (not per protocol), specify _____

3 NA (PS-341 has been discontinued; primary reason previously recorded) (End form)

Was dose omitted (day 4)? (check one)

1 Yes. If Yes, primary reason dose omitted: (check one)

35 Hematologic

38 Any non-hematologic adverse event

99 Other (not per protocol), specify _____

2 No. If No, was dose level adjusted? (check one) 1 Yes 2 No

If Yes, primary reason: (check one)

35 Hematologic

38 Any non-hematologic adverse event

70 Neuropathy: Motor and Sensory

99 Other (not per protocol), specify _____

3 NA (PS-341 has been discontinued; primary reason previously recorded) (End form)

Was dose omitted (day 8)? (check one)

1 Yes. If Yes, primary reason dose omitted: (check one)

35 Hematologic

38 Any non-hematologic adverse event

99 Other (not per protocol), specify _____

2 No. If No, was dose level adjusted? (check one) 1 Yes 2 No

If Yes, primary reason: (check one)

35 Hematologic

38 Any non-hematologic adverse event

70 Neuropathy: Motor and Sensory

99 Other (not per protocol), specify _____

3 NA (PS-341 has been discontinued; primary reason previously recorded) (End form)

Was dose omitted (day 11)? (check one)

1 Yes. If Yes, primary reason dose omitted: (check one)

35 Hematologic

38 Any non-hematologic adverse event

99 Other (not per protocol), specify _____

2 No. If No, was dose level adjusted? (check one) 1 Yes 2 No

If Yes, primary reason: (check one)

35 Hematologic

38 Any non-hematologic adverse event

70 Neuropathy: Motor and Sensory

99 Other (not per protocol), specify _____

3 NA (PS-341 has been discontinued; primary reason previously recorded) (End form)

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

**EVALUATION/TREATMENT FORM
(ARM B - CYCLE 1)**

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: N0779

Patient ID: _____ Patient Initials: _____
L F M

Institution Number: _____

Institution: _____

Use one form per cycle, one column per agent.

Current Cycle Number: 1

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

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

BSA(m²): *(used for this cycle)* ____ . ____ ____

Was this cycle of treatment held (Day 1)? *(check one)*

1 Yes, planned 2 No 3 Yes, unplanned

If Yes, planned or unplanned; Primary reason treatment held: *(check one)*

35 Hematologic
38 Any non-hematologic adverse event
99 Other (not per protocol), specify _____

Date of surgery: *(mm/dd/yyyy)* ____ / ____ / ____

Was surgery delayed 10 or more days? *(check one)* 1 Yes 2 No

If Yes, reason for delay: *(check all that apply)* Adverse Event possibly, probably, or definitely related to study treatment
 Other, specify _____

Agent	Vorinostat (SAHA)	Bortezomib (PS-341)
Agent Start Date this cycle <i>(mm/dd/yyyy)</i>	____ / ____ / ____	____ / ____ / ____
Dose Level day one this cycle <i>(If agent was not given this cycle, enter the dose level received on last day of treatment.)</i>	mg	mg/m ²
Total Dose this cycle <i>(If agent was not given this cycle, enter 0 for total dose.)</i>	mg	mg
Was DOSE LEVEL adjusted <i>(Day 1 or 2; Day 1)?</i> <i>(mg - mg/m²)</i>	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No
If Yes, PRIMARY REASON for Dose Adjustment per Section 8.0. Not BSA changes. <i>(Check one)</i>	35 <input type="checkbox"/> Hematologic 38 <input type="checkbox"/> Any non-hematologic adverse event 99 <input type="checkbox"/> Other (not per protocol), specify _____	35 <input type="checkbox"/> Hematologic 70 <input type="checkbox"/> Neuropathy: Motor and Sensory 38 <input type="checkbox"/> Any non-hematologic adverse event 99 <input type="checkbox"/> Other (not per protocol), specify _____

PLACE LABEL HERE

Protocol Number: N0779

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

NORTH CENTRAL CANCER TREATMENT GROUP

NADIR/ADVERSE EVENT FORM

ALL ITEMS MUST BE COMPLETED

Pg. 1 of 3

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

Current Cycle Number (nadir/adverse events associated with this cycle): _____

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

Test	Date of Nadir (Date of lab test) (mm/dd/yyyy)	Nadir Value (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.)	Is this nadir below the LLN? (check one)	CTC AE Attribution Code (If Grade >0) 1 = Unrelated 2 = Unlikely 3 = Possible 4 = Probable 5 = Definite	Has an adverse event expedited report been submitted?*(Enter 1 for Yes or 2 for No)
PLT K/uL or 10 ⁹ /L	___/___/_____	_____	1 <input type="checkbox"/> Yes → 2 <input type="checkbox"/> No → (Go to WBC)	1 2 3 4 5	___
WBC K/uL or 10 ⁹ /L	___/___/_____	_____	1 <input type="checkbox"/> Yes → 2 <input type="checkbox"/> No → (Go to Hgb)	1 2 3 4 5	___
Hgb g/dL	___/___/_____	_____	1 <input type="checkbox"/> Yes → 2 <input type="checkbox"/> No → (Go to ANC)	1 2 3 4 5	___
ANC K/uL or 10 ⁹ /L	___/___/_____	_____	1 <input type="checkbox"/> Yes → 2 <input type="checkbox"/> No → (Go to Adverse Event)	1 2 3 4 5	___

CTC Adverse Event Term	MedDRA Code (v. 10.0) (must be completed)	CTC Adverse Event Grade (highest grade this cycle) INCLUDE GRADE 0's	CTC AE Attribution Code (If Grade > 0) 1 = Unrelated 2 = Unlikely 3 = Possible 4 = Probable 5 = Definite	Has an adverse event expedited report been submitted?*(Enter 1 for Yes or 2 for No)

Required Adverse Events from Section 10.0 of Protocol

Fatigue (asthenia, lethargy, malaise)	10016256	0 1 2 3 4	1 2 3 4 5	___
Anorexia	10002646	0 1 2 3 4 5 (death)	1 2 3 4 5	___
Dehydration	10012174	0 1 2 3 4 5 (death)	1 2 3 4 5	___
Diarrhea	10012727	0 1 2 3 4 5 (death)	1 2 3 4 5	___
Nausea	10028813	0 1 2 3 4 5 (death)	1 2 3 4 5	___

* See Section 10.0 of the protocol.

PLACE LABEL HERE

Protocol Number: N0779

Patient ID: _____ Patient Initials: _____
L F M

Institution Number: _____

Institution: _____

NORTH CENTRAL CANCER TREATMENT GROUP

NADIR/ADVERSE EVENT FORM

ALL ITEMS MUST BE COMPLETED

Pg. 2 of 3

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

Current Cycle Number (nadir/adverse events associated with this cycle): _____

CTC Adverse Event Term	MedDRA Code (v. 10.0) (must be completed)	CTC Adverse Event Grade (highest grade this cycle) INCLUDE GRADE 0's	CTC AE Attribution Code (If Grade > 0) 1 = Unrelated 2 = Unlikely 3 = Possible 4 = Probable 5 = Definite	Has an adverse event expedited report been submitted?*(Enter 1 for Yes or 2 for No)
Required Adverse Events from Section 10.0 of Protocol				
Taste alteration (dysgeusia)	10043125	0 1 2	1 2 3 4 5	—
Vomiting	10047700	0 1 2 3 4 5 (death)	1 2 3 4 5	—
Pain - Select				
- Abdomen NOS	10000081	0 1 2 3 4	1 2 3 4 5	—

* See Section 10.0 of the protocol.

PLACE LABEL HERE

Protocol Number: N0779

Patient ID: _____ Patient Initials: _____
L F M

Institution Number: _____

Institution: _____

NORTH CENTRAL CANCER TREATMENT GROUP

NADIR/ADVERSE EVENT FORM

ALL ITEMS MUST BE COMPLETED

Pg. 3 of 3

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

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

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

1 Yes, and reportable adverse events occurred

3 Yes, but no reportable adverse events occurred (Stop here)

2 No (Stop here)



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 CTC Adverse Event Terms not listed	MedDRA Code (v. 10.0) (must be completed)	CTC Adverse Event Grade (highest grade this cycle)	CTC AE Attribution Code (If Grade > 0) 1 = Unrelated 2 = Unlikely 3 = Possible 4 = Probable 5 = Definite	Has an adverse event expedited report been submitted?*(Enter 1 for Yes or 2 for No)
	<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"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	—
	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<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	—
	<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"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	—
	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<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	—
	<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"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	—
	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<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	—
	<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"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	—
	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<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	—
	<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"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	—
	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<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	—
	<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"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	—

* 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 Number: N0779

**CONCURRENT TREATMENT FORM
(BASELINE)**

Patient ID: _____ Patient Initials: _____
L F M

Institution Number: _____

ALL ITEMS MUST BE COMPLETED

Institution: _____

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

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

Concomitant medications? (check one)

1 Yes 2 No (Stop here)

If Yes, enter all medications (including prescription, over-the-counter, and alternative medications) Exceptions: Steroids, anti-convulsants, and antiemetics are to be reported on the Concurrent Steroid and Anticonvulsant Treatment Form (Baseline).

Concomitant Treatment	Total Daily Dose and Schedule

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N0779

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

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

ALL ITEMS MUST BE COMPLETED

Institution: _____

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

Current Cycle Number: _____

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

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

1 Yes 2 No (Stop here)

If Yes, enter medications (including prescription, over-the-counter, and alternative medications) that have not been previously reported, no longer being taken or have a dose and/or schedule change. Exceptions: Steroids, anticonvulsants, and antiemetics are to be reported on the Concurrent Steroid and Anticonvulsant Treatment Form (Active Monitoring).

Concomitant Treatment	Reason for entry: 1= New medication 2= Medication no longer being taken 3= Dose and/or schedule change	Total Daily Dose and Schedule

PLACE LABEL HERE

Protocol Number: N0779

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

NORTH CENTRAL CANCER TREATMENT GROUP

**CONCURRENT STEROID AND ANTICONVULSANT
TREATMENT FORM**

(BASELINE)

ALL ITEMS MUST BE COMPLETED

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

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 → <i>(specify)</i> _____	
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 (ineligible) →	
Carbamazepine/Tegretol 2 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes (ineligible) →	
Valproic acid/Depakene 2 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes →	
Phenobarbital 2 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes (ineligible) →	
Keppra 2 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes →	
Other anticonvulsant 2 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes → <i>(specify)</i> _____	

Concomitant Treatment	Total Daily Dose
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 → <i>(specify)</i> _____	

PLACE LABEL HERE

Protocol Number: N0779

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

NORTH CENTRAL CANCER TREATMENT GROUP

END OF ACTIVE TREATMENT/CANCEL NOTIFICATION FORM

Submit Once Per Patient

ALL ITEMS MUST BE COMPLETED

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) Event Monitoring (follow Event Monitoring schedule)
(See Schema and Section 13.0 of the protocol) Off Study (cancels only)

Reason Treatment Ended <i>(check one)</i>	COMMENTS
1 <input type="checkbox"/> Treatment Completed Per Protocol Criteria	
2 <input type="checkbox"/> Patient Withdrawal/Refusal After Beginning Protocol Therapy	Specify:
24 <input type="checkbox"/> Patient Withdrawal/Refusal Prior To Beginning Protocol Therapy <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
10 <input type="checkbox"/> Disease Progression Before Active Treatment	
5 <input type="checkbox"/> Alternative Therapy	Specify:
6 <input type="checkbox"/> Patient Off-Treatment For Other Complicating Disease	Specify:
7 <input type="checkbox"/> Death On Study	Complete Event Monitoring Form
8 <input type="checkbox"/> Other	Specify:

* Submit documentation to verify progression. See Section 11.0 and Section 18.0 of protocol.

PLACE LABEL HERE

Protocol Number: N0779

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

NORTH CENTRAL CANCER TREATMENT GROUP

EVENT MONITORING FORM

ALL ITEMS MUST BE COMPLETED

Pg. 1 of 2

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

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

- 1 Yes. If Yes, complete rest of form.
- 2 No. If No, date of last attempt to contact patient: (mm/dd/yyyy) ___/___/_____ (End form)

Vital Status

1 Alive Date of last contact or date of death: (mm/dd/yyyy) ___/___/_____

2 Dead
 Primary Cause of Death: (check one) 1 Due to this disease 2 Due to other cause, specify _____
 4 Due to protocol treatment
 (adverse event related to treatment)

Disease Follow-up Status

Has the patient had a documented clinical assessment for this cancer (since submission of the last event monitoring form)?*

- 2 No. If No, Go to Notice of New Primary.
- 1 Yes. If Yes, Cancer Follow-up Status Date: (mm/dd/yyyy) ___/___/_____

Notice of First Relapse/Progression in the Event Monitoring Phase

Has the patient developed a first relapse or progression that has not been previously reported (in event monitoring phase)?

- 2 No 1 Yes. If Yes, Date of Relapse/Progression:** (mm/dd/yyyy) ___/___/_____

Site(s) of Relapse/Progression: (check all that apply)
 Primary Leptomeningeal spread
 New lesion(s) Periventricular enhancement
 Progressive T₂ signal abnormality Other, specify _____

Method (s) of Diagnosis: (check all that apply)
 CT Biopsy
 MRI Other, specify _____
 Clinical Progression

Notice of First Subsequent Treatment

Has the patient received subsequent treatment for this cancer that has not been previously reported?

- 2 No 3 Unknown 1 Yes. If Yes, Start date of subsequent treatment: (mm/dd/yyyy) ___/___/_____
- Subsequent treatment: Bevacizumab
 (check all that apply) Other, specify _____

Notice of New Primary

Has a new primary cancer or MDS (myelodysplastic syndrome) been diagnosed that has not been previously reported?

- 2 No 3 Unknown 1 Yes. If Yes, New Primary Cancer Date: (mm/dd/yyyy) ___/___/_____
- Site of New Primary: _____

Late Adverse Event (post completion of active monitoring)

Has the patient experienced (prior to treatment for progression or relapse or a second primary, and prior to non-protocol treatment) any severe (grade ≥3) long term toxicity that has not been previously reported:

- Adverse events at least possibly attributed to treatment on this study.
- Death within 30 days of treatment.
- Death any time at least possibly treatment related.

- 2 No 3 Unknown/Not evaluated 1 Yes. If Yes, Submit page 2 of the Event Monitoring Form for Late Adverse Event Reporting.

*If this is the first event monitoring form check yes, enter cancer follow-up status date and complete the rest of the form.

**Submit documentation to verify PD.

PLACE LABEL HERE

Protocol Number: N0779

Patient ID: _____ Patient Initials: _____
L F M

Institution Number: _____

Institution: _____

NORTH CENTRAL CANCER TREATMENT GROUP

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

ALL ITEMS MUST BE COMPLETED

Pg. 2 of 2

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

The CTC AE v.3.0 will be used to evaluate the following adverse events:

CTC Adverse Event Term	MedDRA Code (v. 10.0) (must be completed)	CTC Adverse Event Grade (Highest Grade)	CTC AE Attribution Code 1 = Unrelated 2 = Unlikely 3 = Possible 4 = Probable 5 = Definite	Late Adverse Event Onset Date (mm/dd/yyyy)
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PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

**BASELINE
TISSUE SPECIMEN COLLECTION FORM
(ALL PATIENTS)**

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: N0779

Patient ID: _____ Patient Initials: _____
L F M

Institution Number: _____

Institution: _____

INSTRUCTIONS:

- Complete this form **for all patients** and enter into the remote data entry system ≤ 30 days of study entry.
- See Section 17 of the protocol for specimen requirements and shipment.
- Include a copy of this form with tissue submission (see Section 17).

Was a research tissue specimen obtained (from the primary surgery)? (check one)

- 1 Yes. If Yes: Date of collection (**date of surgery**): (mm/dd/yyyy) ___/___/_____
Date Specimen Shipped: (mm/dd/yyyy) ___/___/_____
2 No. If No, reason: _____

Was a research tissue specimen obtained (from a first recurrent procedure)? (check one)

- 1 Yes. If Yes: Date of collection (**date of surgery**): (mm/dd/yyyy) ___/___/_____
Date Specimen Shipped: (mm/dd/yyyy) ___/___/_____
2 No. If No, reason: _____

Was a research tissue specimen obtained (from any other recurrent procedure)? (check one)

- 1 Yes. If Yes: Date of collection (**date of surgery**): (mm/dd/yyyy) ___/___/_____
Date Specimen Shipped: (mm/dd/yyyy) ___/___/_____
2 No. If No, reason: _____

Institution Contact Information: (Please Print)

Contact Person at Institution (CRA/Nurse):

Institution Name: _____

Street Address: _____

City: _____

State: _____

Zip Code: _____

Phone Number: _____

Fax Number: _____

E-mail Address: _____

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

**ACTIVE MONITORING
TISSUE SPECIMEN COLLECTION FORM
(ARM B PATIENTS - POST TREATMENT)**

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: N0779

Patient ID: _____ Patient Initials: _____
L F M

Institution Number: _____

Institution: _____

Current Cycle Number: 1

INSTRUCTIONS:

- Complete this form **for all Arm B patients** and enter into the remote data entry system within 7 days of specimen collection.
- See Section 17 of the protocol for specimen requirements and shipment.
- Include a copy of this form with tissue submission (see Section 17).

Was a research tissue specimen obtained (*post treatment*)? (check one)

1 Yes. If Yes: Date of collection (**date of surgery**): (mm/dd/yyyy) ___/___/____

Date Specimen Shipped: (mm/dd/yyyy) ___/___/____

2 No. If No, reason: _____

Institution Contact Information: (Please Print)

Contact Person at Institution (*CRA/Nurse*):

Institution Name: _____

Street Address: _____

City: _____

State: _____

Zip Code: _____

Phone Number: _____

Fax Number: _____

E-mail Address: _____

PLACE LABEL HERE

Protocol Number: N0779

Patient ID: _____ Patient Initials: _____
L F M

Institution Number: _____

Institution: _____

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

Primary Pathologist: _____ No. of slides sent: _____

Clinic/Hospital: _____ Date sent: _____

Reviewer: _____ Slide No. _____ Sequence No. _____

I. CRA/RN

THIS REPORT IS FOR: (check one) 1 Primary 2 Recurrent

1. DATE OF OPERATIVE PROCEDURE

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

_____ to _____
_____ to _____

II. Completed by the NCCTG Pathology reviewer

2. 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 (For mixed tumors, specify by prevalence)

(number all that apply):

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

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 the following items after rebiopsy)

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

Vascular Changes:

Tissue Changes:

- Proliferation
- Atrophy/Gliosis
- Other (specify) _____
- Necrosis, thrombosis, sclerosis
- Necrosis

COMMENTS: _____

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

Protocol Number: N0779

Patient ID: Patient Initials: L F M

Institution Number:

Institution:

NOTIFICATION FORM
Grade 4 or 5 Non-AER Reportable Events/Hospitalization
ALL ITEMS MUST BE COMPLETED

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.
Verify reporting requirements listed within the study protocol, prior to entering into the remote data entry system.
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: (____) _____-

Current Cycle Number: Assigned Treatment Arm: _____

Event ≥ Grade 4: (check one) 1 Yes 2 No

Table with 4 columns: Date of First Occurrence of Adverse Event (mm/dd/yyyy), CTC Adverse Event Term (only one event per line), CTC Adverse Event Grade, and In your opinion, is this related to the study medication?*

*Answer YES if attribution is unlikely, possible, probable or definite; answer NO if unrelated; answer UNKNOWN if you are not sure. Verify if expedited reporting (e.g. ADEERS) is required (see protocol), based on relationship to study treatment.

Hospitalization: (check one) 1 Yes 2 No

If Yes: 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

Protocol Number: N0779

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

CTEP REPORT VARIABLES
PRIOR THERAPY

ALL ITEMS MUST BE COMPLETED

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

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 multiple agents systemic [10008452]
- Chemotherapy (NOS) [10050693]
- Chemotherapy non-cytotoxic [90003014]
- Drug and/or immunotherapy (e.g. interleukin-2, interferon) [90003006]
- Hormonal Therapy (e.g. tamoxifen, androgen deprivation) [10065646]
- Surgery [10042609]
- Radiation Therapy [10037770]
- Bone Marrow Transplant [10061730]
- Prior therapy NOS [90003010]
- Gene Transfer [90003004]
- Anti-retroviral Therapy [90003000]
- Antisense [90003002]
- Oncolytic Virotherapy [90003008]
- Vaccine [10021430]
- Therapy (NOS) [90003012]
- Hematopoietic stem cell Transplantation [10063581]
- Image Directed Local Therapy [90003016]

Number of prior chemotherapy regimens: _____

MedDRA disease code: 10018337 [*Glioblastoma multiforme*]

Treatment Assignment Arm: A Arm A (Patients not undergoing surgery)
B Arm B (Patients undergoing surgery at time of recurrence)

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

PATHOLOGY SUBMISSION FORM

Protocol Number: N0779

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

**** 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 W. Scheithauer and/or associates, Mayo Clinic Rochester - Rochester, MN

Number of slides sent: ___

Accession number(s) (on the slides sent):

_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

Number of blocks sent: ___

Accession number(s) (on the blocks sent):

_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

COMMENTS:

Institution Contact Information: (Please Print)

Contact Person at Institution (CRA/Nurse): _____

Institution Name: _____

Street Address: _____

City: _____

State: _____

Zip Code: _____

Phone Number: _____

Fax Number: _____

E-mail Address: _____