



NCCTG

NORTH CENTRAL CANCER TREATMENT GROUP

Date: April 4, 2008

To: NCCTG Primary Clinical Research Associates

From: Janis Wobschall
Protocol Development Coordinator

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

Due to the status change notice which reflects that approval of Addendum 3 is required prior to further patient enrollment, the pre-registration eligibility checklist has been revised as follows.

Addendum 3 dated March 28, 2008 IRB approved?

Yes. If Yes, Addendum 3 approval date (mm/dd/yyyy) ___/___/___

No. If No, End form, Addendum 3 IRB approval required.

If you have any questions, please feel free to contact me at 507/284-4852.

JW/dg
Enclosure

North Central Cancer Treatment Group

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

Status Change – April 4, 2008

NOTICE OF STATUS CHANGE

As of Addendum 3, this study reopens. New enrollment will not be allowed until IRB approval of Addendum 3 is obtained.

Please retain this notice with the protocol.

April 4, 2008

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 (4/4/08)
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)
Concurrent steroid and anticonvulsant treatment log – active monitoring (12/14/05)
Concurrent steroid and anticonvulsant treatment log – baseline (12/14/05)
On-study form (12/14/05)
Baseline adverse events/symptoms (12/14/05)
Arm A – Cycle 1 evaluation/treatment form (3/17/08)
Arms A and B evaluation form for end of 4-6 week rest period (3/17/08)
Arm A - Cycles 3 through 8/ Arm B – Cycles and 3 evaluation/treatment form (3/17/08)
Evaluation/observation form (12/14/05)
Nadir/adverse event log (12/14/05)
Late effects of radiation therapy (12/14/05)
CTEP report variables (3/18/08)
Radiation therapy reporting form (12/14/05)
Pretreatment neuro measurement form (12/14/05)
Active monitoring neuro measurement form (12/14/05)
End of active treatment/cancel notification form (3/17/08)
Event monitoring form (12/15/05)
Pathology reporting form (3/17/08)
Baseline tissue specimen submission form (1/12/2007)
Baseline blood specimen submission form (3/17/08)
Mayo Rochester only active monitoring blood specimen submission form (3/17/08)
Grade 4 or 5 non-AER reportable events/hospitalization form (6/1/06)
Mini mental state examination (12/14/05)
Fax order form (12/12/05)

✓ 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
Open to Mayo Rochester, Jacksonville, Scottsdale, and University of Alabama at Birmingham only

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

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) <input type="checkbox"/> White <input type="checkbox"/> Black or African American <input type="checkbox"/> Native Hawaiian or Other Pacific Islander <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
Gender (check one) <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Unknown	
Date of birth (mm/dd/yyyy) ___/___/_____	
Zip code _____	
Country of Residence _____	
Method of payment (check one) <input type="checkbox"/> PI (Private Insurance) <input type="checkbox"/> MR (Medicare) <input type="checkbox"/> MRP (Medicare and Private Insurance) <input type="checkbox"/> MD (Medicaid) <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)	Ethnicity (check one) <input type="checkbox"/> Not Hispanic or Latino <input type="checkbox"/> Hispanic or Latino <input type="checkbox"/> Not reported: Refused or data not available <input type="checkbox"/> Unknown: Unsure of their ethnicity

Addendum 3 dated March 28, 2008 IRB approved?
 Yes. If Yes, Addendum 3 approval date (mm/dd/yyyy) ___/___/_____
 No. If No, End form, Addendum 3 IRB approval required.

NCCTG Pre-Registration Eligibility Checklist N027D
Open to Mayo Rochester, Jacksonville, Scottsdale, and University of Alabama at Birmingham only

04/04/2008
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*.

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.	____
Non-USA institution only (<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 _____ Registration Office specialist _____
Signature initials

Physician _____ M D Y
Signature