



# NCCTG

NORTH CENTRAL CANCER TREATMENT GROUP

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**Date:** March 28, 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

**The following are form revisions generated by Addendum 3:**

**Arm A - Cycle 1 only Evaluation/Treatment Form:**

- **Title change from:** Cycles 1 and 3 Evaluation/Treatment Form **To:** Arm A - Cycle 1 only Evaluation/Treatment Form
- **Read:** Cycle: **Reads:** Cycle: 1
- Added another "Primary Reason" under "Was this cycle of treatment held?" of 154=Metabolic/Laboratory
- Added another "**PRIMARY REASON** for Dose Adjustment ..." of 154=Metabolic/Laboratory under CCI-779 column

**Arms A and B Evaluation Form For End of 4-6 Week Rest Period:**

- **Title change from:** Evaluation Form For End of 4-6 Week Rest Period **To:** Arms A and B Evaluation Form For End of 4-6 Week Rest Period

**Arm A - Cycles 3 through 8 / Arm B - Cycles 1 and 3 through 8 Evaluation/Treatment Form:**

- **Title change from:** Cycles 3 through 8 Evaluation/Treatment Form **To:** Arm A - Cycles 3 through 8 / Arm B - Cycles 1 and 3 through 8 Evaluation/Treatment Form
- Removed column for CCI-779

**Baseline Blood Specimen Submission:**

- New form

**Mayo Clinic Rochester Only At MTD Active Monitoring Blood Specimen Submission Form:**

- This form was deleted and replaced with "Mayo Clinic Rochester Only Active Monitoring Blood Specimen Submission Form" and has been completely reformatted to reflect data collection time points described in section 14. Collection will be done during dose escalation and at MTD.

**End of Active Treatment/Cancel Notification Form:**

- Added "(Arm A only)" after 1=Observation to clarify that Arm B does not have an observation phase

CTEP Report Variables Form:

- Addition of Treatment Assignment Code (including valid values)

**The following form revisions were not generated by Addendum 3 but are current formatting corrections:**

Arm A - Cycle 1 only Evaluation/Treatment Form:

- Deleted "Treatment" box
- Added specific measure of units under CCI-779 and TMZ columns instead of under "Agent" column in rows for Dose Level and Total Dose.
- **Read:** Was **DOSE LEVEL** adjusted this cycle? (*i.e. mg/m<sup>2</sup>*) **Reads:** Was **DOSE LEVEL** adjusted from previous cycle? (*mg - mg/m<sup>2</sup>*)
- To match protocol verbiage the "**PRIMARY REASON** for Dose Adjustment ..." column:
  - **Read:** 38=Non hematologic adverse event **Reads:** 38=Other nonhematologic adverse event

Arm A - Cycles 3 through 8 / Arm B - Cycles 1 and 3 through 8 Evaluation/Treatment Form:

- Deleted "Treatment" box
- Added specific measure of units under TMZ column instead of under "Agent" column in rows for Dose Level and Total Dose.
- **Read:** Was **DOSE LEVEL** adjusted this cycle? (*i.e. mg/m<sup>2</sup>*) **Reads:** Was **DOSE LEVEL** adjusted from previous cycle? (*mg/m<sup>2</sup>*)
- To match protocol verbiage the "**PRIMARY REASON** for Dose Adjustment ..." column:
  - **Read:** 38=Nonhematologic adverse event **Reads:** 38=Other nonhematologic adverse event

End of Active Treatment/Cancel Notification Form:

- This form was reformatted into the current verbiage and format

Pathology Reporting Form Brain Tumor:

- Sections I and II margins updated to current formatting:
  - **Read:** I. Data Manager **Reads:** I. CRA/RN
  - **Read:** II. Information obtained from pathology report **Reads:** II. Completed by the NCCTG Central Pathology reviewer
- Section III. Signatures section updated to current formatting:
  - **Read:** Reviewer **Reads:** NCCTG Pathology Reviewer
  - **Read:** Committee Chairman **Reads:** Chairperson
  - NCCTG Pathology Reviewer; Research Base Advisor; and Committee Chairperson result choices:
    - **Read:** 1. Agree with diagnosis; 2. Minor disagreement; 3. Substantial disagreement **Reads:** 1. Agree with original local diagnosis; 2. Minor disagreement with original local diagnosis; 3. Substantial disagreement with original local diagnosis

If you have any questions, please feel free to contact me at 507/266-3549.

JW/dg  
Enclosure