



NCCTG

NORTH CENTRAL CANCER TREATMENT GROUP

Operations Office

Date: November 4, 2008

To: Medical Oncologists
Primary Clinical Research Associates

From: Sara M. Braun
Research Protocol Specialist III

Re: **Temozolomide dose modification error in protocol N0775**, A Randomized Phase II Trial of Temozolomide (TMZ) and Avastin® or ABI-007/Carboplatin (CBDCA) and Avastin® in Patients with Unresectable Stage IV Malignant Melanoma

It has come to our attention that the temozolomide dose modification table in Section 8.5 of protocol N0775 contains the following error:

8.5 Dose modifications for Temozolomide

Use Common Terminology Criteria for Adverse Events (CTCAE) v3.0 unless otherwise specified.			
CTCAE CATEGORY	ADVERSE EVENT	AGENT	DOSAGE CHANGE
<i>BASED ON INTERVAL ADVERSE EVENT</i>			
Blood/Bone Marrow	Hematologic: ANC <1000 or PLT <75,000	TMZ	Reduce dose by one dose level.
<i>AT SCHEDULED RETREATMENT</i>			
Blood/Bone Marrow	Hematologic: ANC <1500 or PLT <75,000	TMZ	Hold Rx until blood counts are above these levels then reduce by one dose level. If not recovered in 4 weeks, proceed to observation and then event monitoring
Other	Grade 3 or 4		Hold Rx until resolved to ≤ grade 1 then reduce by one dose level. If not resolved in 4 weeks, proceed to observation and then event monitoring.

Please implement this change immediately and retain a copy of this memo with your protocol documentation. An addendum to correct this error is in process.