



NCCTG

NORTH CENTRAL CANCER TREATMENT GROUP

Date: March 27, 2009

To: Primary Clinical Research Associates

From: Janis Wobschall
Research Protocol Specialist

Re: PATIENT SAFETY ISSUE: N0776, Phase II Trial of Avastin® in Combination with Sorafenib in Recurrent Glioblastoma Multiforme

The following change needs to be implemented IMMEDIATELY. An official amendment will be issued in the near future. This change is for Section 8.3 Dose Modifications.

All other non-hematologic adverse events (excluding alopecia)	Grade 2-4 (excludes nausea/vomiting that has not been pre-medicated)	Sorafenib Avastin	Hold* responsible agent/agents until resolved to grade 0-1 adverse event, then decrease by one dose level. If no recovery after a 3-week delay, despite institution of all clinically appropriate symptomatic treatment, discontinue one or both agents according to attribution.
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If you have any questions, please feel free to contact me at 507-284-4852.