

North Central Cancer Treatment Group

N0776: Phase II Trial of Avastin® in Combination with Sorafenib in Recurrent Glioblastoma Multiforme

Addendum 8 – April 17, 2009

Summary

Administrative/editorial changes.

Replacement pages are included. Please incorporate into the protocol and keep this addendum with your protocol.

Title page Updated to reflect the addition of Addendum 8 revised NCI version date.

Protocol Resources

Page 2: **Helen J. Tollefson** replaces ~~Christine R. Maszk~~ as the NCCTG *Research Base* Pathology Coordinator.

The title for Roxann Neumann has been added “**RN, BSN, CCRP.**”

Section 8.0 **Dosage Modification Based on Adverse Events**

Page 19: For clarification purposes, the third column under the “All other non-hematologic adverse events” section in Section 8.3 has been revised as follows:

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 the agents according to attribution the event is clearly related to. If it cannot be determined to which agent the event is related to, discontinue treating, go to observation, and then to event monitoring.
	Grade 3-4 (excludes nausea/vomiting that has not been pre-medicated)		Discontinue the agent the event is clearly related to. If it cannot be determined to which agent the event is related to, discontinue treating, go to observation, and then to event monitoring.

Section 15.0 **Drug Information**

Page 44: The following statement has been updated in Sections 15.17 and 15.24:

~~Return any outdated or remaining drug to the research base pharmacy~~ **Outdated or remaining drug is to be destroyed on-site as per procedures in place at each institution.**

Section 18.0

Records and Data Collection Procedures

Page 63:

For clarification purposes, reference to footnote #5 has been added to the X located in the “At each evaluation” column for the Measurement Form.