

North Central Cancer Treatment Group

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

Addendum 2 – January 22, 2009

**Summary**

- Administrative/editorial changes.

**A replacement protocol is provided. Please replace the current copy with the one attached. Please keep this addendum with your protocol**

**Title page** Updated to reflect the addition of Addendum 2 and revised NCI version date.

**Section 4.0** **Test Schedule**

Page 11: Footnote #5 has been revised for clarification as follows:  
Submission of blood for mandatory translational research will be collected: Baseline (i.e.,  $\leq 2$  weeks before start of therapy); Cycle 1 Day 3 ( $\pm 1$  day); prior to treatment Cycle 2; prior to treatment Cycle 3; prior to treatment every 4 weeks thereafter x 5 (i.e., Cycles 5, 7, 9, 11, and 13). Kits are required for this collection. See Section 14.0.

**Section 14.0** **Body Fluid Biospecimens**

Page 30: The heading for column 6 in Section 14.241 has been revised for clarification as follows:

Cycle 1, Day 3 ( $\pm 1$  day)<sup>1</sup>

Footnote #1 in Section 14.241 has been revised for clarification as follows:

The blood sample taken on Cycle 1, Day 3 ( $\pm 1$  day) may be done at the patient's local lab. The blood draw kit should be sent with the patient to be used by that local lab.

Page 31: The first sentence of the first paragraph in Section 14.411 has been revised for clarification as follows:

Analysis of circulating endothelial cells (CECs) and circulating endothelial progenitor cells (CEPCs) will be performed at baseline, Cycle 1 Day 3 ( $\pm 1$  day), prior to treatment Cycle 2, prior to treatment Cycle 3, and prior to treatment every 4 weeks thereafter x 5 (i.e., prior to treatment Cycles 5, 7, 9, 11, and 13).

Page 32: The first sentence in Section 14.412 has been revised for clarification as follows:  
Measurement of angiogenic proteins in plasma will be performed at baseline, Cycle 1 Day 3 ( $\pm 1$  day), prior to treatment cycle 2, prior to treatment Cycle 3, and prior to treatment every 4 weeks thereafter x 5 (i.e., prior to treatment Cycles 5, 7, 9, 11, and 13).

Page 32: The first sentence in Section 14.413 has been revised for clarification as follows:

DNA will be extracted at baseline and buffy coat will be collected after Cycle 1 Day 3 ( $\pm 1$  day) and four weeks of treatment (prior to treatment Cycle 3) from whole blood collected in one 10 mL EDTA tube. DNA and buffy coat will be stored frozen at  $-80^{\circ}\text{C}$  by BAP, for future pharmacogenetic research according to patient consent information (see Section 6.24).

**Section 18.0**

Page 60:

**Records and Data Collection Procedures**

Footnote #9 has been revised for clarification as follows:

$\leq 2$  weeks before start of treatment, Cycle 1 Day 3 ( $\pm 1$  day), before treatment Cycle 2, before treatment Cycle 3, and then before treatment every 4 weeks thereafter x 5 (i.e., Cycles 5, 7, 9, 11, and 13).

**Appendix VII**

Page 1:

**Research Base Instructions for Biospecimen Processing in BAP Laboratory**

The heading in the fifth column has been revised for clarification as follows:

Cycle 1, Day 3 ( $\pm 1$  day)