

North Central Cancer Treatment Group

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

Addendum 3 – January 22, 2009

Summary

- Oxcarbazepine is not considered a major inducer or inhibitor of CYP3A4 or CYP2A6. Therefore, reference to Oxcarbazepine has been deleted from the eligibility criteria (Section 3.34).
- 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 3 and revised NCI version date.

Section 3.0 **Patient Eligibility**
Page 8: Reference to Oxcarbazepine has been deleted from Section 3.34 as follows as this drug is not considered a major inducer or inhibitor of CYP3A4 or CYP2A6:
Receiving enzyme-inducing antiepileptic drugs (EIACs; *e.g.*, phenytoin, fosphenytoin, carbamazepine, ~~oxcarbazepine~~, phenobarbital, or primidone) or any other potent CYP3A4 inducer such as rifampin or St. John’s wort.

Appendix IV **Comprehensive List6 of Drugs That May Have Potential Interactions**
Page 1: Reference to Oxcarbazepine has been deleted in the table as follows as this drug is not considered a major inducer or inhibitor of CYP3A4 or CYP2A6:

<i>Inducers</i>			
Aminoglutethimide	Nevirapine	Phenytoin	Rifapentine
Carbamazepine	Oxcarbazepine	Primidone	
Fosphenytoin	Pentobarbital	Rifabutin	
St. John’s wort	Phenobarbital	Rifampin	

Appendix VII **Research Base Instructions for Biospecimen Processing in BAP Laboratory**
Page 2: Footnote #4 has been corrected as follows:
For “baseline” sample, DNA will be isolated from one EDTA tube using the protocol entitled “Extracting Samples on the AutoGenPure LS”.