

North Central Cancer Treatment Group

N057K: Phase I/II Evaluation of Everolimus (RAD001), Radiation and Temozolomide (TMZ)  
Followed by Adjuvant Temozolomide and Everolimus in Newly Diagnosed Glioblastoma

Addendum 2 – December 5, 2008

**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 2 and revised NCI version date.

**Section 3.0** **Patient Eligibility (PHASE I and II)**  
Page 14: 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:  
Currently on enzyme inducing anti-convulsants (EIACs) or other strong inducers of CYP3A4. Note: For the purpose of this study, these drugs will be defined as carbamazepine, ~~oxcarbazepine~~, phenytoin, phenobarbital/primidone, rifabutin, rifampin or St. John's wort.

**Section 14.0** **Body Fluid Biospecimens**  
Page 44: The opening paragraph of Section 14.261 has been corrected as follows:  
Complete the ~~requisition~~ **NCCTG Research Blood Specimen #Form** (see Forms Packet) and confirm the specimens are correctly labeled. Be sure to indicate the appropriate visit on the ~~requisition~~ **NCCTG Research Blood Specimen #Form**. Ensure the following information is provided:

Page 45: Section 14.265 has been corrected as follows:  
At each time point, gently invert the EDTA (purple top) tubes 8-10 times. DO NOT shake or centrifuge ~~thisese~~ tubes. This blood requires no additional processing.

Page 45: Sections 14.2651 and 14.2652 have been revised to bold and underline the following text:  
14.2651 If applicable, place the mandatory **2 mL whole blood EDTA tube in the freezer** while packaging and shipping arrangements are made.

14.2652 If applicable, place the optional **10 mL whole blood EDTA in the refrigerator** while packaging and shipping arrangements are made.

Section 14.272 has been corrected as follows:

Photocopy the ~~requisition~~ **NCCTG Research Blood Specimen Form** for your records (**see Forms Packet**). Place the original ~~requisition~~ **NCCTG Research Blood Specimen Form** in a plastic bag and submit with the specimen.

Page 46: The following text has been bolded in the heading of Section 14.274:  
Optional whole blood for banking (**refrigerated** specimen)

**Section 17.0 Pathology Consideration/Tissue Biospecimens**

Page 62: The address in Section 17.262 has been updated as follows:  
NCCTG Operations Office  
Attn: NCCTG PC Office (**Study N057K**)  
RO\_FF\_03\_24-CC/NW Clinic  
200 First Street SW  
Rochester, MN 55905

Page 63: The address in Section 17.37 has been updated as follows:  
NCCTG Operations Office  
Attn: NCCTG PC Office (**Study N057K**)  
RO\_FF\_03\_24-CC/NW Clinic  
200 First Street SW  
Rochester, MN 55905

**Appendix V Selected Inhibitors, Inducers, and Substrates of Cytochrome P450**

Pages 1: Reference to Oxcarbazepine has been deleted from the ninth row of the third column as this drug is not considered a major inducer or inhibitor of CYP3A4 or CYP2A6.