

North Central Cancer Treatment Group

N0572: A Phase I/II Trial of Sorafenib and CCI-779 in Patients with Recurrent Glioblastoma

Addendum 2 – October 6, 2006

**Summary**

**Scientific:**

- CCI-779 can cause bleeding including intratumoral, intracerebral, or subarachnoid bleeding. Therefore an additional exclusion criteria has been added to the Patient Eligibility section of the protocol.

**Editorial:**

- Administrative changes.
- Protocol resource personnel updates.

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

**Title page** Reflects the addition of Addendum 2 and revised NCI version date.

**Protocol Resource Page**

Page 2: **Christine R. Maszk** has been added as NCCTG *Research Base* Pathology Coordinator.

Contact information has been revised as follows for the NCCTG *Research Base* Data Management Specialist:

**Rachel Rathmann**

NCCTG *Research Base* Data Management Specialist

Phone: 507/284-5928 4357

Fax: 507/538-0906

E-mail: [rrathmann@mayo.edu](mailto:rrathmann@mayo.edu) [dmsinbox@mayo.edu](mailto:dmsinbox@mayo.edu)

**Section 3.0**

**Patient Eligibility**

Page 20: Section 3.39g has been added as an exclusion criteria as follows due to the possibility of bleeding with the use of CCI-779:

**Significant intratumoral, intracerebral, or subarachnoid hemorrhage on baseline MRI or CT, or other history of significant intratumoral, intracerebral, or subarachnoid hemorrhage.**

**Section 8.0**

**Dosage Modification Based on Adverse Events**

Page 28: The ANC and Platelets counts have been corrected in Section 8.1 as follows:

ANC  $\geq 1,000/\text{mL}$   $\text{mm}^3$

Platelets  $\geq 100,000/\text{mL}$   $\text{mm}^3$