

North Central Cancer Treatment Group

N0177: A Pilot and Phase II Study of OSI-774 and Temozolomide in Combination with Radiation Therapy in Glioblastoma Multiforme

Addendum 11 – August 25, 2006

**Summary**

- The University of Virginia will now be participating in Study 2.
- Administrative changes.

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

**Title page:** Now reflects Addendum 11 and revised NCI version date.

Under “Study Participants” the **University of Virginia** has been added as a limited participant.

**Protocol Resource Page**

Page 2: **Janis A. Wobschall** replaces ~~Lori K. Bratvold~~ as the NCCTG *Research Base* Protocol Development Coordinator.

**Section 10.0 Adverse Event (AE) Reporting and Monitoring**

Page 32: Section 10.23 table has been administratively revised as follows to reflect that the other grade 4 or 5 events will now be entered through the remote data entry system:

Other Grade 4 or 5 Events and/or Any Hospitalizations During Treatment Not Otherwise Warranting an Expedited Report	<p><del>Complete a Notification Form: Grade 4 or 5 Non-AER Reportable Events/Hospitalization Form within 5 working days.</del></p> <p>If an ADEERS report has been submitted, this form does not need to be submitted.</p> <p><del>Fax or mail to the NCCTG SAE Coordinator, NCCTG Operations Office, 200 First Street SW, Rochester, MN 55905, Fax (507)284-9628.</del></p> <p><b>Enter into the remote data entry system within 5 working days of notification.</b></p>
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**Section 18.0 Records and Data Collection Procedures**

Page 56: This study is now available for remote data entry; therefore, the opening statement in Section 18.2 has been revised as follows:

Submission Timetable (~~All materials are forwarded to the NCCTG Operations Office unless otherwise indicated.~~)

Page 57: Block submission is not required at the time of pre-registration; therefore, the following corrections have been made to footnote #1:

- The fourth bullet now reads “**ALL** (not selective) diagnostic slides ~~and blocks~~ (H & E stained and smears, if available)”
- The last paragraph now reads “If the patient does not enter the study, all slides, ~~blocks~~, and forms will be returned to the submitting institution.”