

North Central Cancer Treatment Group

N0177: Pilot and Phase II Trial of OSI-774 and Radiation in Glioblastoma Multiforme Patients

Addendum 3 – August 1, 2003

Summary

- Paraffin blocks will no longer be sent to Dr. Robert B. Jenkins' laboratory, but will be sent to the Pathology Coordinator at the NCCTG Operations Office.
- Footnote #3 in Section 18.0 (Records and Data Collection Procedures) has been revised to reflect that CT/MRI scans used for treatment planning will also be submitted.
- The number of patients to be enrolled in each of the 3 studies has been corrected in the protocol and the consent forms.
- Editorial/administrative changes.

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

Title page: Reflects addition of Addendum 3.

Page 2: The Protocol Resource page has been revised to reflect that Brenda J. Booth replaces Wanda Rhodes as the Laboratory contact person.

Page 38: Section 14.161 (Ancillary Studies) has been revised as follows:
~~For Paraffin blocks submitted from outside hospitals besides Mayo Clinic Rochester should be sent to the NCCTG pathology coordinator at the following address: will forward the material to: Dr. Robert B. Jenkins' laboratory at Mayo Clinic Rochester.~~

**NCCTG Operations Office
Plummer 4
200 First Street SW
Rochester, MN 5905
ATTN: Pathology Coordinator**

The Pathology Coordinator will forward the materials to Dr. Robert B. Jenkins' laboratory at Mayo Clinic Rochester.

This tissue repository of brain tumor specimens will serve as the principal source for the tissue required for the analyses of EGFR amplification/mutation/phosphorylation status. Also, see section 18.2 footnotes 1 and 2.

Page 42: Section 16.12 (Statistical Considerations and Methodology), the second sentence has been revised and reads as follows:
A minimum of 6 patients will enter Study 2; and ~~24~~ **42** or more may be needed if anti-convulsants radically reduce the effective levels of the study drug.

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Page 50: Section 18.0 (Records and Data Collection Procedures), footnote #3 has been revised as follows:

For patients who do not receive any scheduled radiation therapy, submit a radiation therapy reporting form explaining why radiation was not given. For patients who receive partial or complete radiation therapy, submit the following within two weeks after the last day of radiation:

- a) RT reporting form.
- b) Daily treatment records.
- c) Dosimetry calculations and isodose curves.
- d) Copies of representative simulation films of all treated fields.
- e) Copies of representative port films of all treated fields.
- f) **Copies of CT/MRI scans used for treatment planning (indicate whether pre-op or post-op)**

Appendix IA: Consent form, under the section titled “How many people will take part in the study?” has been revised and reads as follows:

~~About~~ **Up to 22 18** people will take part in this study.

Appendix IB: Consent form, under the section titled “How many people will take part in the study?” has been revised and reads as follows:

~~About~~ **Up to 33 42** people will take part in this study.

Appendix IC: Consent form, under the section titled “How many people will take part in the study?” has been revised and reads as follows:

~~About~~ **Up to 97 93** people will take part in this study.