

North Central Cancer Treatment Group

94-72-52: Diagnostic and Prognostic Markers in High-Grade Glioma

Addendum 6 – February 2, 2007

**Summary of Change**

- The protocol has been revised to reflect that 15 unstained slides may be submitted if an institution does not allow the release of tissue blocks.
- Statistician update.
- Protocol resource personnel update.

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

**Title page**      **Wenting Wu, Ph.D.** replaces ~~Karla V. Ballman, Ph.D.~~ as statistician for this study.

Updated to reflect Addendum 6 and revised NCI version date.

**Protocol Resource Page**

Page 2:      **Janis A. Wobschall** replaces ~~Lori K. Bratvold~~ as Administrative/document resource person.

**Schema**

Page 4:      The section “Present and Future NCCTG and Mayo studies” has been revised as follows in order to allow the submission of 15 unstained slides if tissue blocks are not available:

Paraffin blocks **or 15 unstained slides** of tumor specimen and blood samples submitted

**Section 3.0 Patient Eligibility**

Page 18:      This section has been revised as follows in order to allow the submission of 15 unstained slides if tissue blocks are not available:

Paraffin-embedded tumor tissue blocks **or 15 unstained slides** of patients enrolled in the Mayo/NCCTG clinical trials, conducted since 1979, which were designed to assess specific therapies in patients with newly diagnosed high-grade glioma.

**Section 5.0****Procedures for Procurement and Handling of Paraffin Blocks**

Page 19:

Section 5.2 has been revised as follows in order to allow the submission of slides if tissue blocks are not available:

- Section 5.211 now reads “Each patient’s block/**slides** should be placed in a plastic bag...”
- Section 5.212 now reads “Following patient registration, submit the packaged blocks/**slides** to the NCCTG Operations Office.”
- The second sentence in Section 5.213 now reads “At the completion of the study, remaining tissue blocks/**slides** will be retained...”
- The last sentence in Section 5.214 now reads “With confirmation of block/**slides** availability, you will be called...”
- Section 5.22 now reads “Blocks/**slides** will be routed...: