

North Central Cancer Treatment Group

NCCTG 94-72-52: "Diagnostic and Prognostic Markers in Anaplastic Astrocytoma and Anaplastic Oligoastrocytoma"

Addendum 2 - April 10, 1998

Summary of Change

1. Protocol Resource page has been updated.
2. Index page has been modified.
3. The protocol has been repaginated.
4. Goals, Eligibility, and Procedures for Procurement and Handling of Paraffin Blocks, have been updated to include Grade 4 astrocytomas. Also, the Statistical Considerations Section 9.0 has been rewritten.
5. Four markers have been added: Appendix I (Spontaneous Apoptosis in CNS Tumors), Appendix II (Superoxide Dismutase Expression in CNS Tumors), Appendix III (Nitric Oxide Synthase in CNS Tumors), and Appendix IV (p16 Deletion Analysis).

It will be necessary to have proof of the IRB approval of this addendum prior to prospectively registering any blocks.

Due to extensive changes, a replacement protocol is included.

Title page: Reflects addition of Addendum 2.

Protocol Resource Page: Jenny K. Malecha (507/266-0724) replaces Tommie S. Siemek (507/284-1623) as Pathology Coordinator.

Index: Appendices I, II, III, and IV have been added.

Schema: At the top of the schema the following has been deleted and replaced: "Previous NCCTG/Mayo Clinical Trials" replaces "Retrospective 79-72-51, 85-72-51, 88-72-52" and "Present and Future NCCTG and Mayo Clinical Trials" replaces "Prospective NCCTG and Mayo studies."

- Pages 16, 17 Sections 1.9d through 1.9g have been added to the background to add the evaluation of tissue from Grade 4 astrocytoma (glioblastoma multiforme or GBM) patients enrolled in Mayo/NCCTG high-grade glioma trials conducted since 1979.
- Pages 17 Study Goals have been expanded to include analysis of tissue from Grade 4 astrocytoma patients enrolled in Mayo/NCCTG since 1979; additional markers identified by the Glioma Markers Network; and comparison of incidence of markers in the major histologic subtypes and their correlation in the total group, as well as within each of the subtypes. The original study goals have been replaced with new Sections 2.1, 2.11, 2.12, 2.13, 2.14, 2.2, and 2.3.
- Page 18 Sections 3.1 (“Paraffin-embedded tumor tissue blocks of patients enrolled in NCCTG 79-72-51, 85-72-51, or 88-72-52 who had the diagnosis of grade 3 astrocytoma or grade 3 or 4 oligoastrocytoma.”) and Section 3.2 (“Patients who have the diagnosis of grade 3 astrocytoma or grade 3 or 4 oligoastrocytoma with an available paraffin-embedded tumor tissue block enrolled in prospective NCCTG and Mayo studies.”) have been deleted and replaced with “Paraffin-embedded tumor tissue blocks 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; previous and current trials.” Also Sections 3.11 and 3.12 have been added to identify these trials.
- Page 18 “79-72-51, 85-72-51, 88-72-51 has been deleted from Section 5.1.
- Page 18-20 Block submission parameters have been added to Section 5.0 to accommodate the addition of Grade 4 astrocytoma patients. Old Sections 5.2, 5.21, 5.211, 5.212, 5.213, 5.214 and 5.22 have been renumbered as 5.3, 5.31, 5.32, 5.33, 5.34 and 5.35 respectively. Titles of Sections 5.1, 5.2, and 5.3 have been identified as: “Previous Clinical Trials,” “Future and Current NCCTG/Mayo High-Grade Glioma Clinical Trials,” and “GBM Specimens from Previous Clinical Trials,” respectively.
- Page 20 The Section 6.0 title, “Procedures for Procurement and Handling of Blood Samples for Prospective NCCTG and Mayo Anaplastic Astrocytoma and Anaplastic Oligoastrocytoma Studies” has been changed to, “Procedures for Procurement and Handling of Blood Samples for On-Going NCCTG and Mayo High-Grade Glioma Clinical Trials

Page 31-36 The entire Statistical Considerations Section 9.0 has been rewritten to permit the inclusion of markers identified by the Glioma Markers Network.

Appendix I: Molecular marker “Spontaneous Apoptosis in CNS Tumors” has been added as Appendix I.

Appendix II: Molecular marker “Superoxide Dismutase Expression in CNS Tumors” has been added as Appendix II.

Appendix III: Molecular marker “Nitric Oxide Synthase in CNS Tumors” has been added as Appendix III.

Appendix IV: Molecular marker “p16 Deletion Analysis” has been added as Appendix IV.