

North Central Cancer Treatment Group

N0321: Phase I/II Study of PS-341 in Combination with Paclitaxel, Carboplatin, and Concurrent Thoracic Radiation Therapy for Non-small Cell Lung Cancer (NSCLC)

Addendum 5 – February 2, 2007

Summary

- Administrative changes to the consent form.
- Additional editorial/administrative changes.

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

Title page: Dr. Adjei's contact information has been updated as follows:
Alex A. Adjei, M.D., Ph.D. (Research Base)*
~~Mayo Clinic~~ **Roswell Park Cancer Institute**
~~200 First Street, SW~~ **Elm & Carlton Streets**
~~Rochester, MN 55905~~ **Buffalo, NY 14263**
~~507/284-2511~~ **266-0268**
507/284-5280 (FAX)
alex.adjei@roswellpark.org

Updated to reflect Addendum 5 and revised NCI version date.

Protocol Resource Page

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

“**Paraffin-embedded Tissue** Pathology” is now reflected under the “Questions” column for the NCCTG Pathology Coordinators.

Jacqueline M. Lafky has been added as the NCCTG Biospecimen Resource Manager.

Section 14.0 Translational/Pharmacologic Studies (Optional)

Page 38: The contact information in Section 14.3 has been updated as follows:
NCCTG Operations Office
ATTN: NCCTG Research Coordinator
~~RO_FF_03_24-CC/NW Clinic 3-24~~
200 First Street SW
Rochester, MN 55905
~~ATTN: Helen Tollefson~~

Page 38: The contact information for the TACMA lab in the second paragraph following the bulleted items in Section 14.3 has been updated as follows:

The blocks/slides will be forwarded by ~~Helen Tollefson~~ **the NCCTG Research Coordinator** to the TACMA Biospecimen Laboratory, ~~Guggenheim 1034 Stable 13-10~~, Mayo Clinic Rochester.

Appendices IA and IB Consent Forms

Pages 5-6: Per Addendum 4, an updated CAEPR listing was received and appropriate revisions were made to the consent forms. It was noted that there were inconsistencies between the addendum summary and the consent forms. Therefore, the following revisions/clarifications have been made:

- ~~Lowering of the blood cell counts with an increased risk of infection~~ should have been deleted from the “Likely related side effects” section for both IA and IB consent forms as this was moved to the “Less likely related side effects” section.
- In consent form IA, the entry for “Change in walking stride or function” has been expended to read “Change in walking stride or function (**walking with a limp**).”
- In consent form IB, the entry for “Walking with a limp” has been expended to read “**Change in walking stride or function** (walking with a limp).”
- In consent form IB, the entry for “kidney damage or failure” has been expended to read “**Decrease in kidney function**, kidney damage or failure.”

Appendix V Carboplatin Dosing Worksheet

The protocol number has been corrected directly under the title as follows:
NCCTG protocol ~~N0222~~ **N0321**