SUMMARY OF CHANGES
Amendment #1, Version Date: May 25, 2007

RTOG 0611, Urinary VEGF and MMP Levels in Patients Receiving Radiation Therapy for Glioblastoma Multiforme: Prospective Determination of a Predictive Value for Recurrence

Study Chair: Kevin Camphausen, MD; 301-496-5457; camphauk@mail.nih.gov

RTOG 0611 has been amended as follows:

When the protocol was designed, the targeted sample size was 130 patients in order to obtain 100 patients with all three urine specimens of sufficient quality for protocol analysis of the tumor markers. In May 2007, the urine specimen data with respect to the submission and quality was evaluated in the first 84 patient entries. These patients had potentially been on study sufficiently long enough for all three specimens to have been collected. All three usable specimens had been received for only 47 (54%) patients. Since the rate of patients with unusable specimens was higher than expected (30% vs 46%), the targeted sample size will be increased to 200 patients, assuming conservatively that all three usable specimens will be received for half of future patients. Once all three usable specimens have been received for 100 patients, the protocol will be closed to new patients even if less than 200 patients have been enrolled.

As a result, changes were made to the following sections:

- **Section 10.5:** A definition of usable urine specimen for the protocol analysis was added to the second and third sentences of the last paragraph.
- **Section 13.2:** The target sample size was recalculated following the analysis of urine specimen submission in the first 84 patients. The last sentence of the paragraph was deleted and was replaced with the last four sentences.
- **Section 13.3:** The projected gender and ethnicity accruals were adjusted to reflect the new sample size.
- **Appendix I/Sample Consent, How many people will take part in the study?:** 130 patients was changed to 200 patients.

In addition, the following other changes were made:

- **Appendix I/Sample Consent, What other choices do I have if I do not take part in this study?:** The first bullet (getting treatment or care for your cancer without being in a study) was because it is not applicable to this protocol.
- **Appendix I/Sample Consent, Will my medical records be kept private?:** The first sentence was added per current RTOG standard.
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**SUMMARY OF CHANGES**  
Update Date: May 4, 2006

**RTOG 0611** has been updated as follows:

**Entire protocol:** The protocol was repaginated to conform with the RTOG standard of having page 1 start at the first page of the Introduction (Section 1.0.), with no page numbers included on the Title Page, Schema Page, and Eligibility Checklist.

**Eligibility Checklist:** The protocol number was added to the left side of both checklist pages because it was inadvertently omitted.

**Section 12.1:** The A5 was deleted because it is not needed for this protocol. Enrolling sites will complete an A5 per the patient's RTOG GBM treatment protocol.

**Appendix I/Sample Consent, second paragraph, last line:** "Genetic" was changed to "protein" for increased clarity.

**Appendix I/Sample Consent, "What will happen if I take part in this research study?," last line:** "Genetic" was changed to "protein" for increased clarity.

NOTE: These are editorial/administrative changes to the protocol. NCI now requires that these changes be documented on the protocol title page with the date of the update noted as "Update Date," not as an amendment.

An updated protocol is available on the RTOG website: [www.rtog.org](http://www.rtog.org)
SUMMARY OF CHANGES
Update Date: February 2, 2006

RTOG 0611, Urinary VEGF and MMP Levels in Patients Receiving Radiation Therapy for Glioblastoma Multiforme: Prospective Determination of a Predictive Value for Recurrence

Study Chair: Kevin Camphausen, MD; 301-496-5457; camphauk@mail.nih.gov

RTOG 0611 has been updated as follows:

**Index and Section 4.0** - "s" was added to the end of the heading for Section 4.0 because it was inadvertently omitted. The correct heading is "Pre-Treatment Evaluations."

**Section 10.2.2** - Instructions were added to direct phone calls and shipments to the clinic nurse.

**Section 10.5** - The last paragraph was updated to state that institutions will receive $1000 for submitting all three urine samples.

**Section 13.5.2** - CDUS information was added as the last paragraph based on NCI's current analysis plan.

NOTE: These are editorial/administrative changes to the protocol. NCI now requires that these changes be documented on the protocol title page with the date of the update noted as "Update Date," not as an amendment.

An updated protocol is available on the RTOG website: www.rtog.org