SUMMARY OF CHANGES
Update Date: May 13, 2003

RTOG 99-11, “Phase II Study of Paclitaxel and Cisplatin in Combination with Split Course Concomitant Hyperfractionated Re-irradiation in Patients with Recurrent Squamous Cell Cancer of the Head and Neck”

Study Chair: Corey J. Langer, M.D., (215) 728-2985, FAX (215) 728-3639, cj_langer@fccc.edu

RTOG 99-11 has been updated as follows:

Appendix IX — Updated Dr. Gillin’s contact information.

NOTE: This is an editorial/administrative change 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”.

An updated protocol is available (no password required) on the RTOG website: http://www.rtog.org/
SUMMARY OF CHANGES
Revision 3, December 13, 2002

RTOG 99-11, “Phase II Study of Paclitaxel and Cisplatin in Combination with Split Course Concomitant Hyperfractionated Re-irradiation in Patients with Recurrent Squamous Cell Cancer of the Head and Neck”

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IRB Review Requirements:
(X) Full board review required
( ) Expedited review allowed
( ) No review required

RTOG 99-11 has been revised as follows:

Cover Page — “Current Edition” has been replaced with “Version Date” to comply with recent NCI guidelines; the fax number for Dr. Horwitz has been changed.

Schema Page — “(if available)” has been added after “Radiation records, including simulation and portal films”.

Eligibility Questions — Question #15 has been changed to “(≥ 1.5)” for the granulocyte count to be consistent with the Schema Page and Section 3.1.10. In question #21, “(See Section 3.1.12 for requirements)” has been added.

Section 3.1.12 — The wording in parentheses has been changed to (simulation and portal films, “if available”).

Sections 6.5.5.1, 7.5.6 — These sections have been added to include the risk of carotid rupture in patients whose tumors overlap the carotid artery. This information has also been incorporated in Appendix I, under “What are the Risks of the Study?”, in the section entitled “Bleeding Risk”.

Section 11.1 — The fourth and fifth column headers have been clarified by the addition of “(First Follow-up)” and “(Subsequent Follow-ups)” respectively.

Section 12.1 — “Prior Radiotherapy Materials (TM)” has been added.

Section 12.2 — Radiotherapy records (and films “if available”) has been added; “(Simulation and portal films should be submitted if available; all other records are mandatory)” has also been added.

Appendix I — Under “What Are My Rights As A Participant”, the paragraph about the
Data and Safety Monitoring Board has been replaced with “A group of experts………..”

A revised protocol is available (no password required) on the RTOG website at http://www.rtog.org/
SUMMARY OF CHANGES

RTOG 99-11, Head and Neck

The following changes have been made:

Section 7.3.6.1 — G-CSF (Filgrastim) is now available from UintaVision, and contact/ordering information has been updated. This information also was updated in Appendices VI and VII.

Appendix IX — An IMRT questionnaire has been added for those institutions planning to use IMRT treatment techniques for this protocol.
SUMMARY OF CHANGES

RTOG 99-11, Head and Neck

The following changes are in effect:

**Eligibility Checklist** - "Is this patient going to receive IMRT?" has been added.

**Section 6.0** - The allowable treatment approaches for this protocol now include 3D-CRT and IMRT. Additional information is required if an IMRT treatment planning or a 3D-CRT delivery approach is used.

**Section 6.1** - Additional information has been added for scheduling missed treatments. "On the alternate week, i.e., the week the patient is on break" has been deleted.

**Section 6.3.2** - Treatment planning CT scans are required if a 3D-CRT or IMRT treatment approach is used. "The tumor volume should be clearly marked" has been deleted.

**Section 6.3.5.1** - Requirements for isodose calculations in the axial, sagittal, or coronal planes and dose volume histograms if a 3D-CRT or IMRT approach is used have been added.

**Sections 6.5.5, 6.6, and 6.7** - have been added.

**Section 7.3.1** - Additional information has been added about the dosing schedule of Filgrastim for four cycles as well as the dosing schedule of Filgrastim if chemoradiation treatments are missed. The sentence "If missed radiation doses (see Section 6.1) are given during a "break" week, G-CSF should be continued" has been deleted.

**Section 7.5.2.1** - "or 1 dose level" has been deleted.

**Section 8.1** - "Surgery of the recurrent head and neck primary or regional nodes subsequent to protocol therapy must be reported on the Surgery Form" has been deleted.

**Section 11.1** - The follow-up schedule has been changed in the table (d) to match 12.1.

**Section 12.1** - The requirement for "Prior Radiotherapy Materials" (TM) has been deleted. Requirement for Dose Volume Histograms (DVH) has been added to "Final Dosimetry Information".

**Section 13.2** - The last four sentences have been added regarding the addition of IMRT to
the protocol.

**Appendix I, Consent Form** - Under "What is Involved in the Study", three cycles of G-CSF has been changed to four cycles; the follow-up schedule has been changed to match 11.1 and 12.1