SUMMARY OF CHANGES
Revision 4, Version Date: July 7, 2004

RTOG 0022, Phase I/II Study Of Conformal And Intensity Modulated Irradiation For Oropharyngeal Cancer

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The protocol has been re-designated RTOG 0022 (formerly RTOG H-0022). The letter, “H” (for Head & Neck) that preceded the protocol number was deleted throughout the protocol to make the protocol designation consistent with current RTOG standards.

A revised protocol is available (no password required) on the RTOG Web site, http://www.rtog.org
RTOG H-0022, Phase I/II Study Of Conformal And Intensity Modulated Irradiation For Oropharyngeal Cancer

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IRB Review Requirements:
(   ) Full board review required
(X) Expedited review allowed; however, site IRB requirements take precedence
(   ) No review required

RTOG H-0022 has been revised as follows:

Section 4.1.5 — The requirement for liver CT and bone scan has been clarified: “in the presence of elevated alkaline phosphatase” has been replaced with “in the presence of elevation to more than twice the normal range of alkaline phosphatase”.

Section 5.1 — The previous wording “Prior to registering patients, institutions must submit a copy of IMRT approval to the CTSU Regulatory Office” is being changed to “The institutions must be pre-approved for IMRT studies by the IMRT QA Committee and the Image-Guided Therapy Center. See Appendix VI. A copy of IMRT approval will be forwarded to RTOG Headquarters from the Image-Guided Therapy Center. RTOG Headquarters will notify the CTSU Regulatory Office upon receipt of an institution’s IMRT approval.” This wording was changed because institutions are not the ones who send the IMRT approval to the CTSU Regulatory Office.

Section 6.9.4 — Added “PTV60” after “PTV66”.

Section 6.9.4.2, number 2 — Added as the second sentence, “The 52.0 Gy isodose surface covers no less than 99% of the PTV60, and the 60 Gy isodose surface covers no less than 90% of the PTV60.” In the last sentence, added “and PTV60 scoring” after “PTV54”.

Section 7.0 was revised for clarity and to be consistent with Section 3.2.6.

Section 12.2.3: Added Quality Assurance and Dry Run Guidelines

Appendix VI — Added the Corvus Data Transmission to ITC procedures for sending both CTV and PTV structures

The name of and the contact information for the RTOG 3D QA Center has been updated in the following sections of the protocol: 6.7, 6.8, 12.1, 12.2.1, 12.2.2, 12.2.3, and Appendix VI.
A revised protocol is available (no password required) on the RTOG website: http://www.rtog.org
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SUMMARY OF CHANGES

RTOG H-0022: Oropharyngeal Cancer, 3D/IMRT

January 15, 2002

The following change was made:

Section 6.9.4.2 — The last sentence of #2, “Minor variation” was revised to read, “The 72.6 Gy isodose surface (110% of PTV66 prescription dose) covers no more than 20% of the PTV54 (excepting coincident PTV66).

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

RTOG H-0022: Oropharyngeal Cancer, 3D/IMRT

The following change was made:

**Section 6.0** — Section 6.2.3: A parenthetical phrase was added to the first sentence; Section 6.3.1: In the second sentence, “PTV66” was substituted for “the PTVs”, in the third sentence “is the PTV54” was substituted for “are the PTVs”, and the last two sentences were added; Section 6.3.3: The second sentence was inserted; Section 6.4.2.1: The fourth sentence was revised to read, “No more than 1% or 1 cc of the tissue outside the PTVs…”; Section 6.4.2.2: “Subclinical disease (PTV54)” was substituted for “Subclinical disease (secondary PTVs)” in the third sentence, and “Subclinical PTV60” was substituted for “Subclinical PTV” in the fourth sentence; Section 6.4.3: “Glottic Larynx 2/3 below 50 Gy” was added to the top of the list, and the last sentence was added; Sections 6.4.4, 6.6, and 6.9.4 were revised; Sections 6.9.4.1, 6.9.4.2, and 6.9.4.3 were added.

**Section 11.1** — “MRI of head and neck” and item “i” were added to correspond to Section 4.1.5; “Endoscopic and/or mirror eval” was added to correspond to Section 11.2.1.

**Section 11.2.1** — In the first sentence, the phrase, “commencing one month” was deleted to correspond to item “c” in Section 11.1.

**Sections 11.3.2 and 11.3.3** were deleted.

**Section 13.2** — The second and third paragraphs were revised.

**Section 13.5.3** — The last two sentences were deleted.

**Appendix I** — Under “What Is Involved In The Study?”: The schedule for Endoscopic and/or Mirror Evaluation was revised to “At follow-up”; the schedule for MRI of the head and neck was revised to “Optional; Prior to study entry if indicated”; “Biopsy” and the schedule for biopsy were added to correspond to Section 11.2.3.

*A revised protocol is attached.*