SUMMARY OF CHANGES
Amendment 5, Version Date: May 26, 2005

RTOG 0225, “A Phase II Study of Intensity Modulated Radiation Therapy (IMRT) +/- Chemotherapy for Nasopharyngeal Cancer”

Study Chair: Nancy Lee, M.D., (212) 639-3342, leen2@mskcc.org

RTOG 0225 has been amended as follows:

Section 4.5: The timeframe for all pretreatment radiologic studies was amended from 4 to 6 weeks.

Section 5.0 was amended to current RTOG standard and for web registration: The heading, “Pre-Registration Requirements”, was added to Section 5.1; the heading, “Registration”, was added to Section 5.2; instructions for web registration were added as Section 5.2.1 and the prior paragraph concerning dial-in registration” was deleted. The last paragraph on page two of the Eligibility Checklist was amended to be consistent with the changes in Section 5.0.

Section 6.11: “Radiation Adverse Event Reporting”: The prior text in Sections 6.11.3 through 6.11.5 was deleted. Section 6.11.3 now refers sites to the current adverse event reporting requirements in Sections 7.5 and 7.6.

Section 7.5 was amended to current RTOG standard.

Section 7.6, “AdEERS Expedited Reporting Requirements”, was added as mandated by NCI, and the prior text concerning adverse event reporting was deleted.

Section 11.1, footnote “d”: The timeframe for the pretreatment MRI was amended from 4 to 6 weeks to correspond to Section 4.5.

An amended protocol is available (no password required) on the RTOG Web site, http://www.rtog.org
RTOG 0225, “A Phase II Study of Intensity Modulated Radiation Therapy (IMRT) +/- Chemotherapy for Nasopharyngeal Cancer”

Study Chair: Nancy Lee, M.D., (212) 639-3342, leen2@mskcc.org

RTOG 0225 has been amended as follows:

A pre-treatment EKG is not required for all patients; however, patients receiving chemotherapy should have an EKG prior to chemotherapy. The following sections were amended to clarify this:

Section 11.1: In the table, the EKG was deleted from the “Prestudy” column and added under the “CTX” column. In footnote “c”, the sentence, “An EKG should be done prior to chemotherapy”, was added. In Appendix 1, under “What Is Involved In The Study?”, the EKG prior to study entry was deleted, and an EKG was added “Prior to chemotherapy, if you receive chemotherapy”.

Other changes:

Section 7.4.3.3.5: A definition of “recovery” was added for clarity.

The address for RTOG Headquarters was updated in Sections 7.5.3.6, 7.5.5, and 12.0.

An amended protocol is available (no password required) on the RTOG Web site, http://www.rtog.org
SUMMARY OF CHANGES  
Revision 3, Version Date: August 6, 2004

RTOG 0225, “A Phase II Study of Intensity Modulated Radiation Therapy (IMRT) +/- Chemotherapy for Nasopharyngeal Cancer”

Study Chair: Nancy Lee, M.D., (212) 639-3342, leen2@mskcc.org

RTOG 0225 has been revised as follows:

Sections 4.5, 11.1, and Appendix I were revised to clarify that an MRI of the head and neck is required 4 weeks prior to study entry, at 2 and 4 months after RT, and every 6 months during the first 3 years of follow up. If an MRI is medically contraindicated (e.g. pacemaker patients), a CT scan can be substituted for the MRI prior to study entry and in follow up.

A revised protocol is available (no password required) on the RTOG Web site, http://www.rtog.org
RTOG 0225, “A Phase II Study of Intensity Modulated Radiation Therapy (IMRT) +/- Chemotherapy for Nasopharyngeal Cancer”

Study Chair: Nancy Lee, M.D., (212) 639-3342, leen2@mskcc.org

RTOG 0225 has been revised as follows:

Patients must be ≥ 18 years of age to be eligible for this study. Section 3.1.3 and Question 5 on page 1 of the Eligibility Checklist were added to explicitly reflect this (and subsequent sections/questions were renumbered appropriately). This criterion also was added to the Eligibility list on the Schema page.

For stage T1-2 N0 patients, treating physicians can elect not to cover level one and/or submandibular lymph nodes. Section 6.3.2 was revised to reflect this.

Section 11.1: In follow up, an MRI of the head and neck is sufficient; a CT scan does not need to be done. Footnote “h” was revised accordingly, and corresponding changes were made in Appendix I, the sample consent, in the procedures listed under “What Is Involved In The Study?”.

Appendix I: The timeframe of radiation therapy was corrected to correspond to Section 6.4.2.3 under “What Is Involved In The Study?” and “How Long Will I Be In The Study?”.

A revised protocol is available (no password required) on the RTOG Web site, http://www.rtog.org
SUMMARY OF CHANGES
Revision 1, Version Date: August 19, 2003

RTOG 0225, “A Phase II Study of Intensity Modulated Radiation Therapy (IMRT) +/- Chemotherapy for Nasopharyngeal Cancer”

Study Chair: Nancy Lee, M.D., (212) 639-3342, FAX (212) 794-3188, leen2@mskcc.org

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

RTOG 0225 has been revised as follows:

Section 11.1 — Changed CT/MRI Scan to ≤ 6 weeks (42 days) prior to study entry because the time frame of 28 days was too short.

Section 13.2 — Deleted the last sentence in paragraphs 1 and 2 because Dr. Lee is no longer at the institution mentioned in those sentences.

A revised protocol is available (no password required) on the RTOG web site, http://www.rtog.org
RTOG 0225, “A Phase II Study of Intensity Modulated Radiation Therapy (IMRT) +/- Chemotherapy for Nasopharyngeal Cancer”

Study Chair: Nancy Lee, M.D., (212) 639-3342, FAX (212) 794-3188, leen2@mskcc.org

RTOG 0225 has been updated as follows:

Eligibility Checklist – Question #18 has been added to the operational/demographic portion of the checklist.

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”.