As mandated by CTEP, RTOG 0241 has been amended to replace CTC version 2.0 with the CTEP Active Version of CTCAE. Changes were made to the following sections:

- Section 7.10.1
- Appendix V, Sections "B", "D", and "E"
RTOG 0241, “Phase I Study Of Irinotecan And Cisplatin In Combination With Twice Daily Thoracic Radiotherapy (45 Gy) Or Once Daily Thoracic Radiotherapy (70 Gy) For Patients With Limited Stage Small Cell Lung Cancer”

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

RTOG 0241 has been revised as follows:

Section 6.7, Prophylactic Cranial Radiotherapy (PCI), was revised to allow patients who achieve a complete tumor response to receive PCI in twice daily as well as once daily.

A revised protocol is available (no password required) on the RTOG Web site, http://www.rtog.org
SUMMARY OF CHANGES
Revision 4, Version Date: June 4, 2004

RTOG 0241, “Phase I Study Of Irinotecan And Cisplatin In Combination With Twice Daily Thoracic Radiotherapy (45 Gy) Or Once Daily Thoracic Radiotherapy (70 Gy) For Patients With Limited Stage Small Cell Lung Cancer”

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

RTOG 0241 has been revised as follows:

Dose limiting toxicities (DLTs) have been redefined to be more clinically relevant and to tighten the circumstances under which a DLT can be declared. The prior version of the protocol did not take into account grade 3 diarrhea and neutropenic fever that could be expected from either irinotecan or combination therapy and that would not necessarily interrupt concurrent chemoradiation. Sections 7.8, 13.1.1, and 13.2.1 were revised accordingly.

Other changes:

Section 7.4.5, “Toxicity”: The second paragraph was divided into two paragraphs; the heading “Special Precautions for Diarrhea” was added, and the dosage regimen for loperamide was revised.

Sections 7.7.1 and 7.7.2.2: The heading, “Dose Modification” was added to the upper left column of the tables for clarity.

A revised protocol is available (no password required) on the RTOG Web site, http://www.rtog.org
SUMMARY OF CHANGES
Revision 3, Version Date: March 31, 2004

RTOG 0241, “Phase I Study Of Irinotecan And Cisplatin In Combination With Twice Daily Thoracic Radiotherapy (45 Gy) Or Once Daily Thoracic Radiotherapy (70 Gy) For Patients With Limited Stage Small Cell Lung Cancer”

Study Chair: Corey J. Langer, M.D., (215) 728-2985, cj_langer@fccc.edu IRB Review Requirements:
(   ) Full board review required
(X) Expedited review allowed; however, site IRB requirements take precedence.
(   ) No review required

RTOG 0241 has been revised as follows:

Because this is a phase I trial in which esophagitis as well as other toxicities may very well occur, it is imperative that supportive therapy be as uniform as possible. Amifostine has yet to be proven to be protective against esophagitis (in locally advanced non-small cell lung cancer) and may potentially introduce other unique toxicities of its own. Therefore, amifostine is not permitted during chemoradiation. Sections 7.2.1 and 9.1 were revised accordingly.

Section 7.3.2 was deleted, as this information is provided in Sections 7.7.1 and 7.7.2.2.

Section 7.7.1: The text and table from Section 7.7.2.2 also was included in this section for clarity.

A revised protocol is available (no password required) on the RTOG Web site, http://www.rtog.org
SUMMARY OF CHANGES
Revision 2, Version Date: January 12, 2004

RTOG 0241, “Phase I Study Of Irinotecan And Cisplatin In Combination With Twice Daily Thoracic Radiotherapy (45 Gy) Or Once Daily Thoracic Radiotherapy (70 Gy) For Patients With Limited Stage Small Cell Lung Cancer”

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

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

RTOG 0241 has been revised as follows:
Details of dose escalation were revised for clarity: “sequences” were clarified as “arms”, levels within sequences were renumbered for consistency, and the “ping-pong” approach was described more clearly. The following sections were revised: Schema page, Sections 1.1 (the eleventh paragraph beginning “The current study design…”), 7.1.1, 7.1.2, 13.2.2, and 13.3. The method of dose escalation remains unchanged.

Other Changes
Sections 7.8, 13.1.1, and 13.2.1 were revised to provide consistent details of a dose limiting toxicity.

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 26, 2003

RTOG 0241, “Phase I Study Of Irinotecan And Cisplatin In Combination With Twice Daily Thoracic Radiotherapy (45 Gy) Or Once Daily Thoracic Radiotherapy (70 Gy) For Patients With Limited Stage Small Cell Lung Cancer”

Study Chair: Corey J. Langer, M.D., (215) 728-2985, cj_langer@fccc.edu IRB Review Requirements:
(   ) Full board review required
(X) Expedited review allowed
(   ) No review required

RTOG 0241 has been revised as follows:

Section 7.7.1.2 — In the heading of the table, the last word was revised from “alopecia” to “diarrhea”; the heading now reads, “Cisplatin and Irinotecan dose modifications for non-hematologic toxicity: (other than renal; diarrhea)”.

A revised protocol is available (no password required) on the RTOG Web site, http://www.rtog.org
SUMMARY OF CHANGES
Update Date: March 17, 2003

RTOG 0241, “Phase I Study Of Irinotecan And Cisplatin In Combination With Twice Daily Thoracic Radiotherapy (45 Gy) Or Once Daily Thoracic Radiotherapy (70 Gy) For Patients With Limited Stage Small Cell Lung Cancer”

Study Chair: Corey J. Langer, M.D., 215-728-2985, cj_langer@fccc.edu RTOG 0241 has been updated as follows:
Title page — At ECOG’s request, the logistics for ECOG institutions will be added to the protocol at a later date; the contact information for the ECOG chair was removed from the title page until the logistics are available.

Eligibility Checklist, page 3 — Questions 17, 18, and 19 were added to this operational/demographic portion of the checklist.

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 a revision.

An updated protocol is available (no password required) on the RTOG website: http://www.rtog.org/