SUMMARY OF CHANGES
Amendment 1: August 17, 2011
(Broadcast: August 25, 2011)

RTOG 0822, A PHASE II EVALUATION OF PREOPERATIVE CHEMORADIOThERAPY UTILIZING INTENSITY MODULATED RADIATION THERAPY (IMRT) IN COMBINATION WITH CAPECITABINE AND OXALIPLATIN FOR PATIENTS WITH LOCALLY ADVANCED RECTAL CANCER

Study Chair: Michael Garofalo, MD, 410-328-6080, mgarofalo@umm.edu

RTOG 0822 has been amended as follows:

As mandated by CTEP, this study will utilize CTCAE version 4.0 for AdEERS reporting of adverse events beginning October 1, 2011. Related changes were made to Section 7.6.

All AE reporting on the study case report forms will continue to use CTCAE version 3.0.

Note: References to CTCAE, version 3.0, may remain in the protocol. These are appropriate, as treatment decision for patients enrolled on this study were based on that version.

Other Changes
Global: All weblinks and related descriptions to sub-pages of the RTOG website were updated.

Title Page: The Document Version History table was added per current RTOG standard

Section 7.6.3: Text referring to AML/MDS paper report forms has been removed since AdEERS will now be used for reporting AML or MDS and additional notification to CTEP is no longer required. Instructions for submitting a hard copy of the report, including the RTOG HQ address, have also been deleted per current RTOG standard
SUMMARY OF CHANGES
Update: March 30, 2010

RTOG 0822, A PHASE II EVALUATION OF PREOPERATIVE CHEMORADIOThERAPY UTILIZING INTENSITY MODULATED RADIATION THERAPY (IMRT) IN COMBINATION WITH CAPECITABINE AND OXALIPLATIN FOR PATIENTS WITH LOCALLY ADVANCED RECTAL CANCER

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RTOG 0822 has been revised as follows:

Title Page:

- E-mail address for Dr. Hong was updated.

Section 12.2, "Summary of Dosimetry Digital Data Submission", "Hard copy isodose distributions for total dose plan", removed reference to QA guidelines

Appendix II, Study Parameters Table, typographical error removed: "≤ 28 days wks prior to study entry" changed to "≤ 28 days prior to study entry"

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", not as an amendment.