SUMMARY OF CHANGES
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RTOG 85-31 PHASE III STUDY OF ZOLADEX ADJUVANT TO RADIOTHERAPY IN UNFAVORABLE PROGNOSIS CARCINOMA OF THE PROSTATE

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RTOG 85-31 has been amended, as required by NCI, to incorporate the revised NCI Adverse Event Reporting Guidelines as follows:

Section 6.6: This new section was added to address Radiation Adverse Event Reporting via the AdEERS RT-only pathway.

Section 7.3.1: In the first sentence, “known and unknown” were deleted, and the following two definitions of these terms were deleted as well, for consistency with the new NCI AE Reporting Guidelines.

Sections 7.3.1.1 through 7.3.1.6: The text in old sections 7.3.1.1, 7.3.1.2, and 7.3.1.3 was deleted and replaced by new text. New sections, 7.3.1.4 and 7.3.1.5 were added. Original Section 7.3.1.4 was renumbered as Section 7.3.1.6 as a result.

Appendix VI, Index: The original Appendix VI “NCI Adverse Reaction Form for Investigational Agents” was deleted from the protocol and from the Index as it is no longer necessary with the AdEERS report. The subsequent appendix was renumbered.

Appendix VII: The original Appendix VII has been renumbered as Appendix VI in the protocol and in the Index.

Note: Appendix VI, “Combined Radiosensitizer/Radioprotector/Chemotherapy Toxicity Criteria” is a separate PDF document.