SUMMARY OF CHANGES

RTOG 94-13 Prostate September 8, 1998

The following changes are in effect:

**Cover Page** Dr. Roach’s telephone number is (415) 476-5228, fax number is (415) 502-0192.

**Eligibility Checklist** Added whether any care will be given at a VA or military facility.
SUMMARY OF CHANGES

RTOG 94-13 Prostate

The following changes are in effect:

Pathological lymph-node-positive patients (eligible for RTOG 96-08) are excluded from RTOG 94-13. This change affects the Schema, Eligibility Checklist (Q4), Sections 3.1.2, 3.2.9 (new) and 6.4.1 (line 3).

The option of using Lupron was also added to the Schema and to the Consent form. This is a correction, not a change. See Summary of Changes #2, 3/1/96.

Section 3.1.6.1 Corrected atrophy to hypertrophy.

Section 3.1.6.2 Added "testosterone effect . . . by 90 days" as clarification (NCI recommendation).

Section 6.4.1 Highlighted line 4 for emphasis.

Section 6.4.2 Sentences 2-3 are new.

Section 6.6.2 Added

Rectal blocks should be used on lateral fields.

Section 7.1.2.2 (new) In place of four single doses, a 3-month depot of Zoladex or Lupron plus one single dose depot is allowed.

Section 10.0 Pathology materials will be sent to the RTOG Tissue Bank at LDS Hospital (also affects Section 12.0, the P6 and P7 requests were dropped).

Section 11.1 Item "f" was expanded to include all PSA's.
The following corrections are in effect:

**Section 3.1.6** Prior finasteride ($\geq 60$ days) and testosterone ($\geq 90$ days) are allowed (also affects Section 3.2.4).

**Section 3.1.9** Treatment may begin up to 6 weeks after randomization. The prior 3 week limit excluded our Canadian members.

**Section 3.2.5** Prior cancer ($\geq 5$ years ago) does not exclude the patient from this study.

**Section 6.4.1** Urethrogram will be used as part of the simulation of both prostate only and whole pelvis fields.

**Section 13.4** Was added to address the *Inclusion of Women and Minorities*.

The changes to Section 3.0 also affect the Schema and the Eligibility Checklist

*Replacement pages are attached.*