The following update (CALGB Update #9) is in effect:

**REVISION:**

Cover page: Phone and fax numbers have been updated for Dr. Kevin Hughes, Study Chair. Email address has been updated for Ms. Judith Wheeler, Data Coordinator.

This study has met its Accrual goal; effective Friday, February 26, 1999 at 5 pm ET, this study will permanently close to further accrual.
SUMMARY OF CHANGES

RTOG 97-02 Breast (CALGB 9343)  April 20, 1998

The following changes (CALGB Update #8) are in effect:

REVISIONS:

Cover page: Phone and fax numbers have been updated for Dr. Barbara Smith, Breast Surgery Sub-Committee Chair.

Section 5.4, Data Submission: Title of C-294 form has been corrected.

Section 5.5, Histologic Studies: Reference to CALGB Form C-350 has been changed to Form C-490.

*Appendix II cover page: Title of Form C-294 has been corrected, and Form C-490 has been added. Form C-490 with instructions is included for insertion into the forms package.

AMENDMENT:

Section 4.1, Eligibility: Estrogen receptor positivity by immunohistochemistry will be defined as greater than or equal to 10% of cells staining positive (previously 20%).

* These changes were made to the RTOG Forms Pack. Revised C-490, T1, and TF are included with this mailing.
The following changes are in effect:

- Spelling of "axillary" was corrected on the cover page and the Consent Form titles.
- Treatment start dates will be collected on the Randomization Worksheet (15)
SUMMARY OF CHANGES

RTOG 97-02 Breast (CALGB 9343)        April 28, 1997

The following changes (CALGB #7) are in effect:

**Cover Page** Dr. Barbara L. Smith has been added as the Chair of the CALGB Breast Surgery Subcommittee. Phone and fax numbers have been updated for Dr. Thomas J. Smith, ECOG Study Coordinator.

**Section 8.0** Information regarding ocular toxicity of tamoxifen has been updated.

**Model Consent** Has been revised to update ocular toxicity of tamoxifen. *This revision requires IRB review and approval.*

**PLEASE NOTE:** All patients currently taking tamoxifen as part of this trial must sign an Information Update (attached) at the time of their next scheduled visit. The signed Information Update must be stored in the patient's research record at the treating institution. Those patients who are no longer taking tamoxifen but are still being followed must be provided notification of this new toxicity; however, notification of receipt of this information is not required. The Information Update or a newsletter may be used for notification of patients no longer receiving tamoxifen. A "Model Newsletter" that can be modified for institutional use is included in the "Tamoxifen-Associated Eye Toxicity" memorandum in this mailing.

Until a revised consent form has received institutional human subjects approval, patients enrolling on this trial should sign the information update in addition to the current institutional consent form. Please see the "Tamoxifen-Associated Eye Toxicity" memorandum included in the CALGB March 15, 1997 protocol mailing for further information.

**Appendices A and B** No changes have been made, but copies are provided for those institutions who received protocols without these appendices.