NCCTG's Data Monitoring Committee Report rcvd 6/11/04

The National Cancer Institute has requested that each cooperative group Data Monitoring Committee (DMC) provide DMC recommendations to institutional review boards. For intergroup studies coordinated by NCCTG, the Operations Office of each participating group will receive a report of the NCCTG DMC's recommendations. The cooperative group will be responsible for making the information available to its member institutions.

Below is SWOG's report:

<u>##N9831</u> - Adjuvant AC + Paclitaxel +/- Trastuzumab in HER-2 Overexpressing Node-Positive Breast Cancer

• Action: The committee voted unanimously to continue accrual per protocol. The DMC noted that it has no objection to the concept of pooling this trial with the NSABP B-31 trial, provided a final plan for analysis is provided for DMC review, including a justification that the trials are sufficiently similar to be pooled. The adverse event data were reviewed and no issues were found.

<u>#N9841</u> - A Randomized Phase III Equivalence Trial Irinotecan (CPT-11) vs Oxaliplatin (OXAL)/5-Fluorouracil (5-FU)/Leucovorin (CF) in Patients with Advanced Colorectal Carcinoma Previously Treated with 5-FU

• *Action:* The committee voted unanimously to continue accrual per protocol. The adverse event data were reviewed and no issues were found.