Southwest
Oncology Group
A National Clinical Research Group

MEMORANDUM

TO: Members of the Southwest Oncology Group

FROM: Charles A. Coltman, Jr., M.D.

DATE: May 20, 2002

SUBJECT: **Policy Revisions**

Since May of last year, three Southwest Oncology Group Policies have been revised as outlined below. We ask that you download and print from the web (http://swog.org/Visitors/Policies.asp) each of the policies mentioned below, toss out your old copies, and insert the new ones in your Policy Book for future references.

Revision Summations

Policy #15 This policy, "Group Protocols Sponsored by Pharmaceutical Companies / Investigational New Drug Applications" was revised to include, in paragraph 2, mention that pharmaceutical firms may provide financial support for the collection of financial disclosure forms, in addition to the other items as listed.

Policy #22 This policy, "Ethical and Regulatory Considerations" was revised to more clearly detail FDA compliance regulations for the conduct and monitoring of clinical investigations. It also reflects that adverse drug reactions (ADRs) are now referred to as serious adverse events (SAEs).

Policy # #23 This policy, "Serious Adverse Events" was formerly titled "Adverse Event/Adverse Drug Reaction" but was revised to reflect FDA/NCI preferred terminology. This change in terminology was made throughout the policy.

OM/ja

cc: Peter M. Ravdin, Ph.D., M.D.
John J. Crowley, Ph.D.
Jacqueline Benedetti, Ph.D.
Marjorie A. Godfrey
Evonne Lackey