

## MEMORANDUM

**TO:** Members of the Southwest Oncology Group

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

**DATE:** May 1, 2003

**SUBJECT:** **Group Policy Revisions**

Since May of last year, eight Southwest Oncology Group Policies have been revised as outlined below. Also, two new policies have been developed and implemented (#40 - "Membership of Non-United States Institutions" and #41 - "Misconduct, Debarment or Other Administrative Action"). We ask that you download and print revised and new policies to place in your Policy Book for future reference.

Policies can be found on the Group web site at <http://swog.org/Visitors/Policies.asp>.

### Revision Summations

Group History The Group History has been updated.

Policy #2 This policy, "Constitution/Bylaws" now lists the newly established Early Therapeutics Committee as a Standing Committee within the Group (page 8, Standing Committees), and formally recognizes the name change of the Committee on Women and Special Populations to the *Committee on Special Populations* (page 8, Standing Committees).

Policy #3 This policy, "Guidelines for Full Group Institutional Membership in the Southwest Oncology Group" was expanded by adding item #4 (Probationary Period and Criteria for Full Member Status) and item #5 (Criteria for Continued Participation).

Policy #5 Wording in the "Affiliate Program Membership" was changed in the Mailing Policy section on page 2 to reflect how affiliate institutions receive protocols.

Policy #8 The "Committee Membership Nominations" policy was revised in the first two paragraphs to include detailed information about eligibility for committee membership and the documentation needed in the Operations Office before approval can be granted.

Policy #10 The "Job Description of Disease Committee Chair" policy was revised by deleting item #15, "Documents proceedings of all Disease Committee meetings for the Group Minutes." As of October 2002, committees having established chapters in the *Report of Studies* are no longer required to submit formal minutes for documentation of meeting proceedings at Group Meetings.

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### Operations Office

- Policy #13 Forms in the "Protocol Guidelines" policy have been updated (i.e., Capsule Summary; Investigational Drug Trial Letter of Intent; Clinical Investigations Branch Phase III Trial Concept Submission form), plus references to "Flow Sheets" have been replaced by references to "Study Forms".
- Policy #21 The "Data and Safety Monitoring Policy" was revised to reflect there are now three non-voting representatives from the NCI on the committee rather than two and will monitor both treatment and prevention trials.
- Policy #29 This policy, "Roster of Investigators Maintenance Policies and Procedures" was revised in paragraphs three, four and five by adding "or suspended" - showing that institution's patient registration status can be terminated or suspended. Under the heading "Documentation Required" on page two, terminology was added detailing what items for documentation must be submitted to the Operations Office.
- Policy #39 A policy regarding the acquisition, maintenance and use of tissue and other biologic patient specimen for research has being drafted but is not yet considered a final document.
- Policy #40 The new "Membership of Non-United States Institutions" policy lists procedures and guidelines the Group has put in place for institutions outside the U.S. that have a interest in associating with the Group as a research base.
- Policy #41 The new "Misconduct, Debarment or Other Administrative Actions Policy" outlines steps the Operations Office takes to monitor misconduct, debarment or other administrative actions taken against Southwest Oncology Group investigators.

OM/ja

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