MEMORANDUM

TO: Members of the Southwest Oncology Group

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

DATE: December 10, 2004

SUBJECT: Policy Revisions

At the October 2004 Board of Governors meeting, five revised Southwest Oncology Group Policies were presented for discussion and approved as revised. The revision are summarized below. All Group policies can be viewed and printed from the web at http://swog.org/Visitors/Policies.asp.

Revision Summations

Policy #30 The following item number nine has been added to Policy #30, regarding patients lost to follow-up:

9. An institution may identify a patient as "lost to follow-up" if **all** of the following criteria are met:

   a) The last contact date for a patient has exceeded two years.

   b) Since the last contact date, the institution can document at least three telephone attempts to contact the patient and/or a certified letter to the last known address has either been returned, or not answered.

   c) The institution has attempted to find a date of death through the National Death Index (NDI). (This may be accomplished either through a NDI search at the institution, or via a request to the Southwest Oncology Group Statistical Center to include the patient in a periodic Group-wide search of the NDI).

Policy #31 This policy was previously titled "Use of Full Patient Name," but has been changed to the "Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule Policy." The HIPAA Privacy Rule went into effect April 14, 2003, and places restrictions on how covered entities may use and disclose Protected Health Information (PHI). This policy will serve to document the policies and procedures developed within the Southwest Oncology Group to acknowledge this regulation.

Policy #38 On page 2 of Policy #38, under Item 3, the following clarification has been made regarding dose recalculations based on weight change:

3. Dose Modification During Treatment

Subsequent doses should be escalated or reduced based on toxicity. The dose modification should be based on a percentage escalation or reduction. Patients will be weighed prior to initiation of a new cycle of treatment. Dose recalculation based on weight change must be done if the patient experiences more than 10 lbs. weight gain or weight loss from baseline This will be done prior to any further dosing.

Policy #39 The policy for the acquisition, maintenance and use in research of tissue and other biologic patient specimens was revised with recommendations by Drs. Cecilia Fenoglio-Preiser and Daniel Hayes and was approved by the Board of Governors at their October 2004 meeting in Kansas City. Changes in the policy include use of the term biospecimen banks rather than repositories; and, in items six and seven on page two of the policy, it now states that materials will not be processed within or removed from biospecimen banks without authorization of the Group Chair and the Chair of the Correlative Science Specimens Use Committee, changed from the necessary authorization approval coming from the appropriate disease chair.

On page three of the policy, item number 7b has been changed to read:

b. The authorization for materials from studies done solely by the Southwest Oncology Group can be obtained by applying for permission for the use of the specimens to the Group Chair. He will pass this request on to the Correlative Science Specimen Use Committee and the appropriate disease specific correlative science committee. The leader for this committee will have the responsibility of organizing reviews and communicating on an annual basis in writing to the Group Chair the results of the reviews, and the current status of approved projects.

Lastly, Appendix A and a model consent form has been deleted from the revised policy and the appropriate NCI website referenced (http://ctep.cancer.gov/guidelines/consent.html). This website should be accessed for downloading NCI Informed Consent Templates that can then be modified.

Policy #41 The policy regarding misconduct, debarment or other administrative actions was revised by adding two introductory paragraphs to emphasis that the Southwest Oncology Group expects the highest standards of integrity be observed in the research it conducts. Additionally, the following paragraph has been added at the end of the policy regarding the identification of scientific misconduct:

"Any data irregularities or findings suspicious of intentional misrepresentation of data and/or disregard for regulatory safeguards

identified through quality control procedures at the Data Operations Office or the Quality Assurance Audit Program, or allegations of misconduct reported by any staff member or institution participating in Southwest Oncology Group research, should immediately be reported to the Group Chair. The Group Chair decides whether further action is warranted. If a reasonable level of suspicion of misconduct is identified, the Group Chair will immediately notify the Clinical Trials Monitoring Branch, Cancer Therapy Evaluation Program, National Cancer Institute by phone at (301) 496-0510."

OM/ja

cc: Dana B. Sparks, M.A.T.
Marjorie A. Godfrey