Southwest
Oncology Group
A National Clinical Research Group

MEMORANDUM

TO: Members of the Southwest Oncology Group

FROM: SWOG Operations Office

DATE: June 1, 2007

SUBJECT: Policy Revisions

The following Southwest Oncology Group Policies have been revised as summarized below. All policies can be viewed and printed from the Group's web site at http://swog.org/Visitors/Policies.asp.

Revision Summations

Policy #1 — The Southwest Oncology Group Mission Statement has been expanded by including the following mission: Collects, stores and provides membership access to high-quality, well-annotated human specimens collected from and representative of the patient populations entered into the Group's NCI-funded clinical trials.

Policy #2 — In the Group's Constitution/Bylaws, all mention of the Pathology Committee, Head and Neck Committee, and the Intergroup Coalition Against Sarcomas (ICAS) have been deleted as these committees have been disbanded within the Southwest Oncology Group.

Policy #12 — Minor revisions have been made in Policy 12, Registration and Treatment Policies, to clarify that patient registrations are made through the Data Operations Office of the Statistical Center.

Policy #13 — The Protocol Guidelines Policy #13 now clearly states that a study coordinator must be a member of the Southwest Oncology Group and must have completed the Group's Study Coordinator Workshop. Additionally, the policy now states that the Group's Executive Committee will review development time for the top priority studies on a quarterly basis (or more often as particular situations warrant) and will recommend a corrective action plan involving action by the Protocol Coordinator, the Study Coordinator and/or the Committee – as needed – for any study where the Executive Committee identifies that intervention is needed. Also added to the policy is a statement that, by Group definition, coordinating a clinical trial means involvement from the capsule summary stage to the submission of a manuscript, and that Study Coordinators are required to submit a disclosure of any significant financial conflict of interest that they may have.

Another change is that the development of cancer control studies is now similar to the development of treatment protocols except that the concept is submitted to the NCI's Division of Cancer Prevention.

Policy #15 Policy 15 focuses on Group protocols sponsored by pharmaceutical companies and investigational new drug applications. The policy now states that "at no time prior to contract execution and study activation may the potential pharmaceutical collaborator advertise, publish or otherwise disclose information concerning the proposed trial to the public absent the review and approval of the Group's authorized officials".

Policy #17 The Cost Containment Policy has been extensively revised in the Study Parameter Guidelines section (page one) regarding imaging studies, studies that use "response rates" as primary endpoint, and criteria if "time to progression" is the primary endpoint. The revised policy states that SWOG does not collect and store data on clinical laboratory tests that are not directly related to an endpoint of the study. Laboratories used to indicate toxicity and validated markers of tumor response may be requested. The guiding principals are extensively outlined in the revised policy.

Policy #18 Language was added to the Quality Control Policy and Procedures Policy to clarify how the Statistical Center performs quality control on data submitted for patients registered to Phase II or Phase III protocols. A major focus of quality control is the initial forms required by protocols, and the policy now details when and how they are to be submitted.

Policy #19 SWOG's Quality Assurance Program was developed to enhance the reliability and validity of clinical trials from Group institutions through the use of routine monitoring procedures. Major changes in the QA policy are in sections 9, 10, 14 and 15 detailing how institutions should prepare for scheduled audits. The revised policy also includes overviews of subsequent assigned assessments.

Policy #21 The Data and Safety Monitoring (DSMC) Policy has been extensively revised and now states that the DSMC is responsible for considering all relevant information related to a given study and for providing a recommendation to the Group Chair concerning a study change or termination.

The DSMC monitors all SWOG Phase II and III therapeutic and cancer control trials, and outlines how large prevention trials, such as SELECT, are monitored. Procedures, recommendations, access to and release of data, conflict of interest and confidentiality, and intergroup trials guidelines have been updated on pages two, three and four of the revised policy. A new section – Institutional Responsibilities: Membership of DSMC (and attendance at sessions) – has been added regarding open, closed and executive sessions for DSMC voting members, non-voting CTEP committee members, study and Group statisticians, and members of the Group's executive leadership. The revised policy is consistent with the NCI's Cooperative Group Data Monitoring Policy.

Policy #24 The revised policy for Procedural Guidelines for All Southwest Oncology Group Publications has also been extensively revised, with additional information inserted for timely publications, abstracts, manuscripts, publications credit, data disclosure and reproduction of data, and reprints of articles produced by the Group Communications Program. The revised policy states that publication or oral presentations of work done via the Group's Cooperative Agreement requires appropriate acknowledgement of NCI support and is the responsibility of the primary study coordinator on any SWOG study to submit a manuscript for publication within one year after closure.

Policy #33 The Institutional Performance Review Policy outlines the Statistical Center's monthly monitoring responsibilities of institution submission of data collection forms, reports of timeliness of submission of initial forms, percent of patients overdue for follow-up while on protocol treatment, and percentage of patients overdue for follow-up once off treatment. Per policy, each Principal Investigator is provided with data pertinent to his or her institution's performance and to their affiliates, and an institution's registration privileges may be suspended when performance is inadequate. Explanations of inadequacies have been expanded in the revised policy.

Policy #34 The following paragraph has been added to the Industrial Interaction Policy:

In order to better ensure patient safety in Group clinical trials, at no time prior to contract execution and study activation may the industrial collaborator advertise, publish or otherwise disclose information concerning the proposed trial to the public, absent the review and approval of the Group's authorized officials. Further, assuming contract execution and trial activation occur, prior to issuing a press release that references the Study or its results, or that uses the other party's name or trademarks, the parties agree to provide reasonable prior review and comment by the other party. Both parties agree to comply with the request of the other party for the removal of confidential information, previously identified as such, from the press release prior to publication. Neither party shall reference the Study or its results or use the other party's name or trademarks for promotional or advertising purposes absent the other party's prior written consent.

Policy #39 In item #3 of the Acquisition, Maintenance and Use In Research of Tissue and Other Biologic Patient Specimen Policy, the following has been added for clarification: "Stored" biospecimens are collected for use that is defined at the time of sample submission. Collection of stored specimens is time-sensitive and will be audited during the course of the clinical study. "Banked" biospecimens refers to the use and distribution for future studies not specified at the time of collection.

Additionally, in item #5-j, the following has been added: Access to the laboratory and clinical outcomes data will be restricted to the SWOG Statistical Center and the Group Statistician. Only select personnel will have the ability to match the SWOG identification number with clinical endpoints. Results from the analysis of biospecimens shall not be published or presented in any manner that allows identification of any patients. Data generated from analysis of biospecimens submitted to SWOG repositories are considered the property of SWOG.

Other changes are made in item 7-b, 10 and the last paragraph of item 11.

Policy #42 The following paragraph has been added to the Policy on Advertising for Subject Recruitment: While it is common for investigators to discuss proposed or potential Southwest Oncology Group clinical trials with their patients, it is requested that investigators make no guarantees of trial activation. On occasion, Group clinical trials are not activated or have a delayed activation for various reasons including based on the Group's main concern for the safety of study participants.