Southwest
Oncology Group
A National Clinical Research Group

MEMORANDUM

TO: Members of the Southwest Oncology Group

FROM: SWOG Operations Office

DATE: June 2008

SUBJECT: Policy Revisions

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

Revision Summations

Policy #2 –Constitution/Bylaws

In March 2008, a Bylaws Review Committee was identified by the Group Chair's Office to review Southwest Oncology Group Bylaws, to recommend amendments for adding the newly restructured Cancer Control and Prevention Program into the Bylaws, and to identify and integrate other new committees. Deputy Group Chair Richard Fisher chaired the Review Committee. Others appointed committee members were Jackie Benedetti from the Statistical Center, Marjorie Godfrey from the Operations Office, Anne Schott, Executive Officer in the Group Chair's Office, Jim Wade from the Central Illinois CCOP, and George Yoo from Wayne State University and Chair of the Surgery Committee.

The Board approved the committee's recommendations with the majority of revisions in ARTICLE IV – BOARD OF GOVERNORS, OFFICER AND COMMITTEES – SECTION 1 – BOARD OF GOVERNORS.

Members of the Board of Governors (*as revised*) now consist of:

1. The Group Chair, who shall preside, the Deputy Group Chair, the Group Statistician, the Associate Chair for Cancer Control and Prevention, and the Chair Elect (if applicable).
2. All Principal Investigators from Member institutions in Good Standing.
3. All Principal Investigators from the Community Clinical Oncology Program (CCOP) that choose SWOG as their primary research base.
4. The Chair of each active Disease and Research Committee. In the case of Co-chairs, only one will serve.
5. The Chairs of the Clinical Research Associates Committee, Nurse Oncologist Committee, Radiation Therapy Committee, Surgery Committee, and Pharmacy Committee.
6. One Affiliate Program representative elected by the Affiliate Program.
7. The UCOP Chair.
8. The Executive Officer(s) of the Group who serve as non-voting members.
9. Two associate statisticians, who serve as non-voting members.

In the case of overlap of membership roles (for example, the Chair of a Disease and Research Committee is also a Principal Investigator of a Member institution), the member to whom overlap applies can choose the role for which they will serve as a Board of Governors member, and will appoint a representative to fill the additional role(s).

Section 3, Committees, the third paragraph under A. Disease and Research Committee now reads "A Disease and Research Committee Vice-Chair shall be selected by and serves at the pleasure of the Disease and Research Committee Chair. His/her duty is to assist the Chair in carrying out duties. In the event of vacancy between Group Meetings, the Vice-Chair or Co-Chair will serve as the interim Committee Chair until a national search can be convened and a new Committee Chair identified. Disease and Research Committee Membership shall be constituted from among the interested and qualified members and associate members".

Additional Changes to the Bylaws

On the last page of the Bylaws, changes were made in the Group Committee roster with deletion of the following committees: Head and Neck, Special Populations, and the Intergroup Coalition against Sarcomas (ICAS) Committee.

Added to the Disease and Research Committees were: Gynecologic, Cancer Survivors, Health Disparities and Outcomes, Molecular Epidemiology, Prevention, and Symptom Control and Quality of Life.

The Bone Marrow and Stem Cell Transplantation Committee was moved from the Disease and Research Committees to an Administrative Committee.

The Cancer Control Research Committee was deleted from the Administrative Committees.

Policy 10 – Job Description of Disease and Research Committee Chair

Policy 10 was revised by adding the following sentence to the first paragraph, "These responsibilities also apply in a general fashion to Chairs of Administrative Committees".

Under Specific Responsibilities, item number nine, the sentence now reads, "Maintains a direct liaison with the other Committee Chairs, and the designated Executive Officer in the development and management of protocols".

Inserted at the end of the policy, paragraph twenty now states "When resigning from the Committee Chair position, the Chair is responsible for ensuring that the Group Chair is informed of this decision and that the co-chair or vice-chair of the committee is willing to serve temporarily as Interim Chair of the Committee until a national search is conducted".

Policy 12 – SWOG Registration and Treatment Policies

On page one of Policy 12, section 3. Cancellations, the revised paragraph reads as follows: "Under rare circumstances, patient registrations may be cancelled. Cancellations are approved at the discretion of the Group Statistician." *(Prior to this revision, patient registrations could not be canceled from a protocol once they enter, regardless of the circumstances surrounding that patient.)*

Policy 15 – Group Protocols Sponsored by Pharmaceutical Companies / IND Applications

The paragraph below has been added to Policy 15:

In order to provide the necessary non-grant funding for the costs of contract performance and scientific/administrative services related to pharmaceutical industry collaborations, a 25% administrative handling fee will be assessed to the total dollar budget. These fees will be delegated but not limited to the following costs which are directly associated with pharmaceutical contracts:

- Contract: negotiation, preparation, execution, government interaction, retention, modification, tracking
- Protocol: modification to accommodate pharmaceutical interaction, review, discussion, revision, coordination
- Administrative: Copying, supplies, computers, phones, mailing, study activation, website updates, communication with sites for initiation
- SAEs: reporting, database maintenance, communications

- Activation: communication with government, study review/discussion/triage, study specific conference calls
- Accounting costs - includes invoicing/tracking sponsor payments and creating of reports.

Policy 24 – Procedural Guidelines for all SWOG Publications

New and revised information has been inserted on pages three and four of the publications policy under paragraph 4.D and E. These sections now read:

D. Final Acceptance by Journal: In accordance with Division G, Title II, Section 218 of PL 110-161 (Consolidated Appropriations Act, 2008) the NIH Public Access Policy, previously voluntary, is now mandatory effective April 7, 2008. The Primary Author is responsible for submitting to the NIH National Library of Medicine's PubMed Central (PMC) an electronic version of the author's final manuscript, upon acceptance for publication, resulting from research supported in whole or in part with direct costs from NIH (via research grant and career development award mechanisms, cooperative group agreements or contracts). The author's final manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. Upon acceptance for publication, it must be made publicly available no later than 12 months after the official date of publication. The NIH Policy applies to all peer-reviewed journal articles, including research reports and review, but not including non-peer-reviewed materials, such as correspondence, book chapters, and editorials. Also effective April 7, 2008, authors of articles arising from NIH funds are responsible for insuring that publishing agreements allow for full compliance with this policy. These manuscripts will be preserved permanently in the PMC archive for use by the public, health care providers, educators, scientists, and NIH.

   Furthermore, beginning May 25, 2008, anyone submitting an application, proposal or progress report to the NIH must include the PMC or NIH Manuscript Submission reference number when citing application articles that arise from their NIH funded research. Non-compliance with the policy will have negative funding implications. The new NIH policy will have direct impact on all peer-reviewed articles resulting from Southwest Oncology Group studies. While the group's publication office, upon notification of manuscript acceptance, will remind the primary author regarding the NLM PubMed submission requirement, actual submission to NLM PubMed Central is the responsibility of the primary author. It will also be the responsibility of the primary author to notify the publications office of the PMC or NIH Manuscript Submission reference number, as well as article PDF file, when available. The following are links regarding the new policy which may be useful to the membership:

   http://publicaccess.nih.gov/
   http://publicaccess.nih.gov/FAQ.htm
   http://publicaccess.nih.gov/PublicAccess_training.ppt
   http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-033.html

E. Reprints: Inasmuch as most scientific journals now provide authors with a complimentary number of PDF copies of their published articles, reprints will only be ordered/dispensed by the Group Office if legitimate need can be demonstrated by the primary author.

Policy 30 – Responsibility for Patient Follow-Up

Item three on page one of the patient follow-up policy was revised to read as follows: If an Affiliate institution ceases to be affiliated with the Group, it retains responsibility for the treatment and clinical management of all patients currently receiving treatment and active follow-up, and should provide necessary data forms and follow-up information. The Member institution may, in some cases, be willing to assume responsibility for clinical follow-up once the patient is being seen annually (or less frequently) for study purposes.

The following paragraph 9.c has been **deleted**: 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).