Southwest
Oncology Group
A National Clinical Research Group

MEMORANDUM

TO: Members of the Southwest Oncology Group

FROM: SWOG Operations Office

DATE: December 2009

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 Summation

Policy 2 **Constitution/Bylaws**

The Early Therapeutics Committee is now a formal Southwest Oncology Group Disease and Research Committee.

Policy 3 **Guidelines for Full Group Institutional Membership in the Southwest Oncology Group – Inclusion of Criteria for continued Participation and Support**

The former Paragraph 5 titled Criteria for Continued Participation has been deleted and a new Paragraph 6 titled Criteria for Continuing Participation and Support was created. This new sections reads:

Each Member Institution will abide by the rules and performance criteria governing all Southwest Oncology Group members in regards to patient eligibility and evaluability, timeliness of data submission, acceptable quality assurance audits, and scientific contributions to the Group.

All Member Institutions in good standing and meeting the below listed Funded U10 Member criteria will be eligible to request Group Chair permission to compete for U10 funding during each Group grant renewal cycle.

There are two categories for Member Institutions: funded U10 Member Institutions and unfunded Member Institutions.

Funded U10 Member Institutions:
SWOG Member institutions with active U10 Cooperative Agreements with the National Cancer Institute are funded for their accrual, scientific contributions, and travel expenses through these grants. In addition, these institutions are paid on a "per case basis" for accrual over and above their individual accrual baseline. These institutions must maintain a three year average annual accrual of 50 initial registrations to SWOG endorsed treatment studies, plus management of their follow up responsibilities. These institutions have membership and voting privileges on the Group's Board of Governors. U10 funded institutions submit non-competing continuation applications annually during a grant cycle.

Unfunded Member Institutions:
SWOG unfunded Member institutions, those without U10 Cooperative Agreements, receive limited support through the Group Chair's Office. They are reimbursed on a "per case" basis for their accrual. They also receive limited travel support to attend Group Meetings. These institutions also have voting privileges with the Group's Board of Governors.

The Unfunded Member Institution, apart from its affiliates, must maintain a minimal accrual contribution of 20 initial registrations to Group and Group endorsed treatment studies. The accrual will be measured as an average annual accrual of the previous three (3) years. The accrual is reviewed annually.

Failure to meet the minimum accrual standard listed above will result in the site being put into a probationary period of one year and will lose the privileges associated with being a member-in-good standing.

SWOG unfunded Member institutions in on probation or in good-standing may be eligible for travel funding for participation in the bi-annual SWOG Group meetings, subject to the availability of funding.

#Accruals*	# funded trips at the Group rate
>/= 32	6 for the year
20-31	4 for the year
10-19	2 for the year
1-9	At the discretion of the Chair

Policy 4 **Community Clinical Oncology Program Guidelines – Inclusion of Criteria for Continued Participation and Support**

On page two of this policy, changes were made under the CRITERIA FOR FULL MEMBERSHIP FOR CCOPS section. Under item one, the accrual of at least 50 evaluable patients was changed from 50 to 20 patients. Wording at the end of the sections now reads 'to Group and Group endorsed treatment studies'.

The following paragraph titled COMPLIANCE WITH FEDERAL REGULATIONS was revised as follows:

COMPLIANCE WITH FEDERAL REGULATIONS
Each CCOP must comply with all applicable federal regulations governing the conduct and monitoring of clinical trials, to include ensuring compliance with the Code of Federal Regulations (45 CFR 46, 21 CFR 50, and 21 CFR 56) in the protection of human subject research and Institutional Review Board review and approval of research studies and consent forms, conducting research in compliance with the ethical principles embodied in The Belmont Report (respect for persons, beneficence and justice), and ensuring the confidentiality of patient data (e.g., the Health Insurance Portability and Accountability Act – HIPAA). Non-compliance with federal regulations may result in investigation or censure.

Below is the second new paragraph:

CRITERIA FOR CONTINUING PARTICIPATION AND SUPPORT
Each CCOP will abide by the rules and performance criteria governing all Southwest Oncology Group members in regards to patient eligibility and evaluability, timeliness of data submission, acceptable quality assurance audits, and scientific contributions to the Group.

The CCOPs must maintain a minimal accrual contribution of 20 initial registrations to Group and Group endorsed treatment studies. The accrual will be measured as an average annual accrual of the previous three (3) years. The accrual is reviewed annually.

Failure to meet the minimum accrual standard listed above will result in the site being put into a probationary period of one year and will lose the privileges associated with being a member-in-good standing.

Policy 15 **Applicability of IND Applications and Investigator Brochures/Support from Pharmaceutical Companies – Inclusive of IB Information and Contract Language**

The paragraphs of Policy 15 were replaced, restructured and more information than in the former policy. The Investigational New Drug Applications is the first paragraph of the policy with no changes. The following section titled Investigator's Brochures is new and applicability and source information for obtaining Investigator's Brochures for SWOG-led studies. The following and last section is titled Contract Negotiations for Protocol Support. This now includes information about required use of the SWOG contract template and provision of Report of Studies information to pharmaceutical companies.

Policy 45 **NEW Press Releases and Media Coverage – Newly Developed Policy for Press Releases**

This new policy states that press releases related to SWOG activities must be coordinated with the Group's communication and public relations manager. This manager will communicate, as needed, with the National Cancer Institute and/or pharmaceutical companies to ensure compliance with grant and contractual obligations for the public release of Group study findings or study information.