SWOG
Leading cancer research. Together.

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MEMORANDUM

TO: Members of the Southwest Oncology Group

FROM: SWOG Operations Office

DATE: November 2011

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 3 **Guidelines for Full Group Institutional Membership in SWOG**

This policy was updated to include guidelines for Translational Medicine Members joining SWOG. Specifically, the following paragraph was added to Section 1:

Institutions that apply to join SWOG as Translational Medicine Members should preferably be an NCI-designated Cancer Center and will be required to outline their proposed scientific contributions to SWOG in terms of planned numbers and types of formal proposals for retrospective use of specimens, plans for creating working relationships with research committees to explore prospective research collaborations, specific areas of applicable expertise of proposed individual member investigators, as well as the investigators' record of publication and an outline for plans for publication of SWOG collaborations.

The following sentence was added to Section 3:

For Translational Medicine Members, accrual will not be a component of funding decisions.

The following sentence was added to Section 4:

For Translational Medicine Members, projected minimal participation in five SWOG translational medicine research projects based over a three year period.

The following sentence was added to Section 6:

For Translational Medicine Members that are unfunded, travel approval is at the discretion of the Group Chair.

Policy 13 **Protocol Guidelines**

This policy was updated primarily to outline the role of committee patient advocates in the protocol development process, to adapt to NCI changes resulting from Operational Efficiency Working Group (OEWG)

recommendations, to add recommendations for capsule summary content, to delete the outdated protocol development PERT chart and priority slots, to re-organize and consolidate information and to add eligibility content and other recommendations resulting from the ongoing SWOG Quality Initiative efforts.

Policy 23 **Serious Adverse Events**

This policy was updated to incorporate decreased review responsibility for non-SWOG INDs. Specifically, the following wording has been incorporated:

For NCI-held IND studies and commercial drug studies, evaluations of SAEs will be done by the SAE Coordinator as AdEERS reports are received. A minimal review will be conducted to ensure all reported events meet the criteria outlined in Section 16 of the protocol and that all sections of the report are complete. If a previous AdEERS report was submitted for the same cycle of treatment, the site will be informed that the current report will be withdrawn and the previous report must be amended to include the new SAE**.** The exception will be any Grade 5 event that is not due to progressive disease or an unrelated event (e.g. car accident).

For SWOG-held IND studies and Grade 5 events described above for NCI-held studies and commercial drug studies, additional data is always required on submitted SAEs. An evaluation by the Physician Reviewer's will be completed on receipt of the required data.

The Physician Reviewer evaluates the report, the supporting data, and the reporting investigator's description of the event, adverse event code(s), grade(s), expectedness, and attribution(s). If the initial evaluation of a report suggests that a protocol violation may be implicated in the adverse event(s) being reported, the report and supporting data will be reviewed for protocol compliance by the SAE Coordinator. Based on this review, the Physician Reviewer may recommend changes in SAE code(s), grade(s), and attribution(s).

Policy 33 **Institutional Performance Review**

This policy has been revised to clarify inadequate performance and to tighten the definition of overdue follow-up.

Policy 42 **Policy on Advertising for Subject Recruitment and Trial Promotion**

A section for "Collaborating with Industry Partners on Trial Promotion" was added; a section on "Industry Interaction with SWOG Clinical Sites" was added; a section for "Industry Support for SWOG Educational and Promotional Efforts" was added.