Southwest
Oncology Group
A National Clinical Research Group

MEMORANDUM

TO: Members of the Southwest Oncology Group

FROM: Operations Office

DATE: September 1, 2006

SUBJECT: Policy Revisions

Twelve Southwest Oncology Group Policies have recently been revised and two new polices have been adopted. The revised and new policies are summarized below and 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 was expanded by adding the following mission statement: Conducts Phase I clinical trials to pursue novel treatment trials of both cytotoxic and targeted small molecules in special patient populations and disease groups appropriate to the Cooperative Group setting.

Policy #2 The Southwest Oncology Group Constitution / Bylaws policy was revised in Fall 2005 and again in Spring 2006. The Bylaws now recognize the positions of Executive Officer(s), Group Deputy Chair, and Associate Chair for Cancer Control and Prevention. A statement was added that special members of the Group must be reviewed by the Membership Committee before being approved for Group membership. References to the Professional Review Committee were deleted.

Per the NCI, former Group Disease Committees are now referred to as Disease and Research Committees while all other committees are Administrative Committees, as listed below:

DISEASE AND RESEARCH COMMITTEES
- Bone Marrow and Stem Cell Transplantation
- *Breast Cancer
- Committee on Special Populations
- Early Therapeutics
- *Gastrointestinal Cancer
- Genitourinary Cancer
- Head & Neck Cancer
- *Intergroup Coalition Against Sarcomas (ICAS)
- *Leukemia
- *Lung Cancer
- *Lymphoma
- *Melanoma
- Myeloma
- Translational Medicine

ADMINISTRATIVE COMMITTEES

Affiliate Program
*Cancer Control Research
Clinical Practices
*Clinical Research Associates
Membership
Nurse Oncologist
Pathology
Pharmacy
Professional Standards
Quality Assurance
*Radiation Therapy
Scientific Advisory Board
Surgery

*Indicates the Committee has a Working Group

Policy #5 Following preliminary membership approval, Affiliate Program participants are issued a roster identification number and password to access the Group website. The Operations Office no longer mails protocol information (activations, closures, amendments, etc.), as all protocol information is disseminated electronically. Participants are required to download all bi-monthly protocol information on the 1st and 15th of each month.

Policy #9 The Investigator/Clinical Research Associate/Nurse Contribution Sheets Policy details how the Southwest Oncology Group monitors the level of contribution each member makes to the Group through their position, committee participation, meeting attendance, protocol participation, proposed clinical trials, submission of manuscripts and abstracts, and meeting presentations. The number of points allotted for each actively has been restructured and will be used in future grants.

Policy #11 Policy 11 describes the job description of a study coordinator. On page two, section three of the policy, the following wording has been added:

The Study Coordinator must monitor the progress of the study regularly to determine need for protocol revisions and amendment. The Study Coordinator must provide explicit wording for revisions and amendment to the Protocol Coordinator to aid the amendment process.

Policy #23 On page two of the Serious Adverse Events (SAEs) Policy, under the section titled Reporting Methods to be Used, the second paragraph has been revised as follows:

> For patients who are enrolled in a study and have received investigational drug(s), commercial drugs(s), surgery, radiation therapy, or any combination of the above, all SAEs as defined in Protocol Section 16 must be reported via AdEERS. This is normally done on-line at the AdEERS Application page at http://ctep.cancer.gov/reporting/adeers.html.

Additionally, the number of days investigators have to send initial SAE reports to the Operations Office has been changed from seven to ten days.

Policy #24 Policy 24 is the procedural guidelines for all Southwest Oncology Group publications. At the Fall 2005 Board of Governors' meeting, the following paragraph (page two, section four, item D) was approved:

D. Final Acceptance by Journal: 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. 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. These manuscripts will be preserved permanently in the PMC archive for use by the public, health care providers, educators, scientists, and NIH.

Policy #28 The title of the policy on Guidelines for the Conduct of "Safety Review" and Pilot Protocols has been changed to The Guidelines for Conduct of "Developmental Strategy Review", Review of Correlative Science, and Pilot Protocols. The changes in the title are directly associated to the changes in the policy. There is also new information in the policy regarding CTEP reviews of correlative science proposals and links to where appropriate guidelines can be found on CTEP's website.

Policy #34 The opening two paragraphs of the Industrial Interaction Policy No. 34 now, in part, states that "to ensure the free flow of information and generation of public knowledge, the Group will not enter into or renew any industry contract that would restrain its freedom to disclose the existence of the document, the identity of any collaborator of the proposed research or the purpose and scope of the proposed research." Further, the Group does not accept grants, contracts, or agreements for research which restricts its members from publishing or otherwise disseminating the results of the research, consistent with Group Policy 24 and related policies.

Policy #35 Policy No. 35 - Conflict of Interest Policy - remains under revision. A draft policy was adopted by the Southwest Oncology Group's Board of Governors at the April 2006 meeting; however, the policy has not yet been through the approval process of the National Cancer Institute.

Policy #36 The Affirmation of Integrity Policy was revised in September 2005, by adding the following sentence: By signing the Affirmation of Integrity statement, each individual affirms awareness of and compliance with Southwest Oncology Group Policy #41, concerning integrity in the reporting of data.

Policy #41 Policy #41 - Debarment, Suspension or Other Administrative Actions and the Handling of All Allegations of Research Misconduct - was extensively expanded. It addresses key aspects and actions to ensure that the Group's scientific process maintains an environment and reputation of trust and integrity. The policy discusses the regular monitoring of Group investigators conducted through various federal agency website bulletins boards which post misconduct, debarment, suspension or other administrative actions against investigators, and addresses the procedures for, and handling of, allegations of scientific misconduct.

New Policies

Policy #42 The Policy on Advertising for Subject Recruitment was adopted by the Board of Governors at their October 2005 meeting. This policy addresses the handling of patient recruitment methods and materials concerning Southwest Oncology Group-coordinated or endorsed studies where such advertising will be part of the protocol package, amendment or used at any

additional time during the trial, and where these advertisements are either 1) distributed or funded by a pharmaceutical company for use by all sites, or 2) where Group funds are used for the cost of creating or employing study advertising. In addition to any Group review process, each Participating Investigator must submit subject recruitment information to his/her institution's IRB for review and approval. Member or affiliate sites may have policies or procedures that must be followed in addition to, or more restrictive than, this Group policy concerning advertising for subject recruitment. The policy also contains a list dos and don'ts for SWOG investigators.

Policy #43 — Policy #43 - Requests for Patient Data from Investigators and Pharmaceutical Companies - was approved at the Board of Governors meeting held April 21, 2006. The policy describes the Group's policies on providing individual patient data to investigators and pharmaceutical companies, and sets forth the procedures for processing such data requests.

OM/ja

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