Southwest
Oncology Group
A National Clinical Research Group

MEMORANDUM

TO: Members of the Southwest Oncology Group

FROM: SWOG Operations Office

DATE: May 2010

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 23 **Serious Adverse Events**

The section titled Reporting Serious Adverse Events for Phase I, Phase II and III Studies has been changed to Reporting Serious Adverse Events for SWOG Studies. The following information was added to this section:

The "CTEP Active Version" of the Common Terminology Criteria for Adverse Events (CTCAE) will be used in reporting SAEs on a given protocol. Newly activated studies are in CTCAE version 4.0 and many open studies are being converted to version 4.0. Version 4.0 is a major reorganization of adverse event taxonomy, done to conform to the international standard, Medical Dictionary for Regulatory Activities (MedDRA). Because of some changes and additions in this reorganization the following guidance for SWOG studies will be followed:

Deaths due to progressive disease that cannot be classified with a more specific Grade 5 adverse event should be reported as Death, NOS.

"Surgical and medical procedures" should be not be reported as SAEs or adverse events unless explicitly so directed in a protocol.

"Surgical and medical procedures," "falls," and "infusion site extravasation" should not be reported in an expedited manner as SAEs unless clearly associated with other reportable SAEs.

"Neoplasms benign, malignant and unspecified (incl. cysts and polyps)" should not be reported as SAEs unless possibly, probably, or definitely attributable to protocol treatment. (Per NCI policy, occurrences of AML, CML and MDS in patients who are or have been on NCI protocols should be reported only on the NCI/CTEP Secondary AML/MDS Report Form.)

Policy 30 **Responsibility for Patient Follow-Up**

A new section 9 was added and reads, "If a patient withdraws consent after registration, the institution must make a distinction with the patient to see if 1) they no longer wish to be treated, 2) they no longer wish to be followed, or both. Withdrawing consent to participate in a study does not necessarily mean they also withdraw consent to be followed. This distinction must be clearly noted on the Off Treatment Notice or Follow-Up form.

A new section 10 was added and reads, "If SWOG has made the decision to discontinue follow-up for a given protocol, the study will be added to the "List of Protocols with No Required Follow-Up" available on the CRA Workbench, under "Reports".

Policy 35 **Conflict of Interest**

Page 4: Section #5 was added to state that the Conflict of Interest Subcommittee reserves the right to review public domain resource information to confirm any involvement for any investigator.

Page 4: Management Plan: Added clarification of Management Plan reporting and subsequent reviewing.

Page 5: Management Plan (continued): Added verbiage that does not automatically preclude a role in authorship although a Management Plan is in place.

Page 5: Group Leadership Disclosures: Added additional levels of review.

Page 7: Declaration Form: The form has been converted to allow typed responses. A Conflict of Interest email account has been established to allow completed, signed and scanned forms to be emailed directly to a confidential email account.

The following policies had minor editorial (non-substantive changes):

Policy 3 Guidelines for Full Group Institutional Membership in the Southwest Oncology Group

Policy 5 Affiliate Program Membership

Policy 7 New Investigator Nomination Process

Policy 9 Investigator/Clinical Research Associate/Nurse Contribution Sheets

Policy 11 Job Description of a Study Coordinator

Policy 12 Registration and Treatment Policies

Policy 18 Data Evaluation Policy and Procedure

Policy 19 Quality Assurance Program

Policy 20 New Agent Studies and Safety Monitoring

Policy 24 Procedural Guidelines for all Southwest Oncology Group Publications

Policy 25 Drug Ordering Policy

Policy 31 Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule Policy

Policy 32 Conduct of Non-Therapeutic Studies - *DELETED*

Policy 37 Certification of Education in the Protection of Human Subjects

Policy 39 Acquisition, Maintenance and Use in Research of Tissue and Other Biologic Patient Specimens

Policy 41 Debarment, Suspension or other Administrative Actions and the Handling of Allegations of Research Misconduct

Policy 42 Policy on Advertising for Subject Recruitment