Southwest
Oncology Group
A National Clinical Research Group

MEMORANDUM

TO: Members of the Southwest Oncology Group

FROM: Charles A. Coltman, Jr., M.D.

DATE: June 15, 2004

SUBJECT: Policy Revisions

Since May of last year, 13 Southwest Oncology Group Policies and the Group History have been updated as outlined below. All Group policies can be viewed and printed from the web: http://swog.org/Visitors/Policies.asp.

Revision Summations

History — The History and Evolution of the Southwest Oncology Group has been updated to note that the PCPT trial was closed and published in 2003, and that a Group Chair Elect has been identified and will take over as Chairman in April 2005.

Policy #4 — The Community Clinical Oncology Program Guidelines Policy was revised to indicate that a CCOP physicians no longer has to submit an FDA 1572 form (Statement of Investigator) to the Operations Office, but rather that the 1572, and necessary supporting documents, are now sent directly to the NCI Pharmaceutical Management Branch.

Policy #7 — The New Investigator Nomination Process Policy and application form were revised to show that a nominated investigator is not required to submit an FDA 1572 form to the Operations Office for membership, nor required to submit a Voluntary Race, Ethnicity, Disability and Gender Data Survey.

Policy #11 — Additional information regarding Phase I studies and the involvement of the Early Therapeutics Committee has been added to section B. Phase I Studies (page 3) of the Job Description of a Study Coordinator Policy.

Policy #13 — The revised Protocol Guidelines Policy includes the following changes: information has been added under Capsule Summary Phase regarding steps recently put into place when new or amended protocols cross traditional committee boundaries (page 3); the Priority Slots graph has been updated (page 7); the Capsule Summary form (pages 8-9) has been restructured; and, additional information has been added regarding development of Phase I studies within the Group, including reference to the Early Therapeutics Committee (page 15).

Under Toxicities To Be Monitored and Dosage Modification (page 22), the policy now states that the NCI Common Terminology Criteria for Adverse Events (CTCAE) Version 3.0 is used, that a copy can be downloaded from CTEP home page (http://ctep.cancer.gov), and that RECIST criteria are now used for solid tumor disease assessment.

Policy #14 — Until the NCI updates its intergroup guidelines following the advent of CTSU and the CIRB, revisions to Southwest Oncology Group Policy #14 regarding conduct of intergroup trials will remain pending.

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Policy #19 Added on page one of the Quality Assurance Program Policy is the sentence, "Affiliate and UCOP sites will have an on-site Pharmacy audit conducted at least once every other audit cycle." Also on the first page, number five, the second sentence now reads, "The audit team will consist of at least one investigator **or nurse** and a Quality Assurance representative from the Operations Office."

Policy #23 The policy for reporting Serious Adverse Events (SAEs) has been revised (in multiple sections) to incorporate the recently implemented reporting methods of the National Cancer Institute's Adverse Event Expedited Reporting System (AdEERS). Also changed is the supporting data requirements from the traditional standardized set - pre-study forms, treatment/toxicity forms, and, as applicable, off-study and notice of death forms - to the specific source documentation, and that study forms are needed to document each SAE. Another change is that SAEs on non-SWOG-coordinated protocols are now reported directly to the coordinating group.

Policy #25 Our Drug Ordering Policy now states that all clinical drug requests for PMB-distributed agents must be signed by the investigator in whose name the agent is ordered, or by the shipping designee, or an ordering designee whom the investigator has listed on their most recent Supplemental Investigator Data Form (IDF) on file with PMB. The policy includes the pertinent CTEP web address for more information.

Policy #26 Changes to the Radiation Therapy Policy remain under revision.

Policy #27 The policy regarding bone marrow and stem cell transplantation has been revised to show that the Foundation for the Accreditation of Hematopoietic Cell Therapy (FAHCT) is now the Foundation for the Accreditation of Cellular Therapy (FACT). The policy states that guidelines and procedures for accreditation may be obtained via the Internet from the FACT web site (http://www.unmc.edu/Community/fahct/Default.htm).

Policy #31 Policy 31, "Use of Full Patient Name," has been re-titled "Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule Policy." The HIPAA Privacy Rule went into effect April 14, 2003, and places restrictions on how covered entities may use and disclose Protected Health Information (PHI). Revised Group Policy #31 serves to document the policies and procedures developed within the Southwest Oncology Group to acknowledge this regulation.

Policy #35 The Conflict of Interest Policy was reviewed by the Group's attorney and revised to meet current Federal regulations. Significant changes are:

The defined term "Research Product" is used consistently throughout the policy (changed from "Product"). The first line under Disclosure was moved to paragraph two, stating that all investigators and other listed parties must file disclosure statements annually.

The last paragraph on the Conflict of Interest Disclosure Form (page 6) immediately above the signature line was added. This provision is designed to coordinate the disclosures made to the Group with disclosures made by an investigator or other party to the institution with which he or she is affiliated. It also obligates the party who signs to supplement with additional information or provide a separate documentation with additional information needed for the Group to comply with regulations governing applications for grants or other funding.

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Policy #39 The Acquisition, Maintenance and Use in Research of Tissue and Other Biologic Patient Specimens Policy remains in *DRAFT* format at this time.

OM/ja

cc: Dana B. Sparks, M.A.T.
Marjorie A. Godfrey