MEMORANDUM

TO: Members of the Southwest Oncology Group

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

DATE: June 1, 2001

SUBJECT: Policy Revisions

Since May of last year, eleven Southwest Oncology Group Policies have been revised as outlined below. In addition, a new policy has been created and implemented within the Group (**Policy No. 37 – Certification of Education in the Protection of Human Subjects**).

We ask that you download and print from the web (http://swog.org/Visitors/Policies.asp) each of the policies mentioned below, toss out your old copies, and insert the new ones in your Policy Book for future references.

Revision Summations

Policy #5 The Affiliate Program Membership policy was revised in the second section (Criteria for Selection) by deleting reference to Multiple Project Assurance and to reiterate institutional and investigator credentialing.

Policy #7 The policy regarding the new investigator nomination process has been revised to show that a copy of the *Certification of Education in the Protection of Human Subject* is now required in order to process a new investigator nomination (please see new Policy #37).

Policy #9 In the first paragraph of the Investigator/CRA/Nurse Contribution Sheets policy, CGOP was changed to Affiliate. On page two under SPECIAL POSITIONS, items 7 and 8 were added as follows:

7. PCPT/SELECT Special meetings – 3 points

8. Young Investigators Workshop – 3 points

Policy # 11 In the job description of a study coordinator, the following clarifications have been added to Section C, page 3:

> Additionally, prompt Study Coordinator review of patient outcome is critical to the conduct of two-stage designs that rely on response information to determine total accrual goals. However, as specified in Section A.2, outcome information should not be reported until the study has closed, and the data have been approved for release.
>
> There is no formal data and safety monitoring committee for Phase II studies. Toxicity and accrual monitoring are routinely done by the study coordinator, study statistician, and the disease committee chair. Response monitoring is done by the study statistician and study coordinator.

Also, added to Section D, page 3:

> A Phase III trial is developed and monitored as described for other Group trials. In addition to the toxicity and accrual monitoring that is conducted by the study coordinator and study statistician, Phase III trials are monitored by the Data and Safety Monitoring Committee, whose members and responsibility are outlined in Policy No. 21.

Policy #12 The Southwest Oncology Group policy regarding patient registration and treatment has been revised to include a statement that direct patient registration via the web may be performed by Members, CCOPs, UCOPs, Affiliates (with permission of their Member), and some Special Members, at any time with the exception of scheduled maintenance periods (policy page 1, item 1).

A sentence was added that Affiliate registrations must be performed through the Member institution unless the Affiliate has been designated a "free-standing" affiliate, or has been given direct registration privileges via the web by its Member Institution (policy page 2, item 4).

For clarification purposes a statement was added to the treatment section of the policy that patients must not be registered if they will not be seen at the institution reported as the 'treating institution' (policy page 2, Item 6).

Policy #13 The Protocol Guidelines policy was revised on page 15 by changing the wording to state that Priority Lists are no longer mailed but are distributed.

Also, on page 20 of the policy, Section 5.17, second paragraph, the standard wording has been revised to read:

> At the time of patient registration, the treating institution's name and ID number must be provided to the Statistical Center in order to ensure that the current (within 365 days) date of institutional review board approval for this study has been entered into the data base.

Policy #18 In the Quality Control Policy and Procedure policy, references to registration forms have been deleted. Additionally the first two paragraphs under Flow Sheet (page 2 of the policy) have been revised to read:

> The Data Coordinator will determine that the correct flow sheet has been completed. Eligibility criteria are documented in Section 5.0 of the protocol, the initial flow sheet and/or the eligibility checklist (for older studies).
>
> Dates of required prestudy tests must be documented on the flow sheet, or Section 5.0 of the protocol (or the eligibility checklist on older studies). For most studies, these tests must have been performed within the timing guidelines listed below.

Policy #19 Group policy regarding the Quality Assurance Program has been revised to show that a minimum of three cases from each member affiliate registering less than forty patients in three years will be reviewed at the same time as the cases from the member institution with which the affiliate is associated. Affiliates registering greater than forty patients in three years will be reviewed separately on-site (policy page 1, item 3).

An audit resulting in an assessment of *acceptable, but needs follow-up* is defined as multiple lesser deficiencies identified, or major deficiencies identified that were not corrected and/or addressed prior to the audit. As before, an *acceptable but needs follow-up* audit requires a written response and/or corrective action plan (policy page 2, 12b).

An *unacceptable* audit is defined as multiple major deficiencies, a single flagrant deficiency, or an excessive number of lesser deficiencies. As before, an *unacceptable* audit requires (as a minimum) a written response and/or corrective action plan and a reaudit of any component rated as unacceptable (policy page 3, 12c).

Policy #24 This policy regarding Southwest Oncology Group manuscript submissions and publications has been revised to clarify that prior to submitting a manuscript to a journal, the primary author must request a final review of the manuscript and receive written approval to submit the manuscript from the appropriate **Disease Committee Chair**.

When the primary author submits the manuscript to a journal, a copy of the Disease Committee Chair's final approval, letter of submission to the journal, and a clean copy of the final manuscript must be sent to the Operations Office (policy page 2, item 4).

Policy #30 This policy regarding follow-up of patients registered to Group protocols has been revised to more clearly state who is responsible for follow-up when investigators move from one institution to another. These guidelines apply to Member Institutions, CCOPs, Stand-Alone UCOPs, Affiliates and Free-Standing Affiliates. See revisions on policy pages 1 and 2, items 6 and 7 and new item 8 for notification of transfer of follow-up responsibilities.

Policy #31 The last sentence in the first paragraph of Policy 31 regarding use of full patient name was deleted (~~If the patient name cannot be provided, the registration will be refused~~).

→ Policy #37 The Certification of Education in the Protection of Human Subjects policy is a newly created and implemented policy within the Group. This policy is applicable to all scientist, investigators, Group personnel and others who are identified as key personnel in any proposed Group research, grant or contract.

OM/ja

cc: Peter M. Ravdin, Ph.D., M.D.
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SOUTHWEST ONCOLOGY GROUP
POLICY BOOK

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