



MEMORANDUM

TO: Members of the Southwest Oncology Group
FROM: Operations Office
DATE: May 9, 2005
SUBJECT: Policy Revisions

Five Southwest Oncology Group Policies have recently been revised. The revisions 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 #12 The Southwest Oncology Group Registration and Treatment Policy was revised extensively in Item 1, second paragraph, to strongly encourage institutions to register patients online via the Group Web Registration Program. If an institution is unable to access the online registration program for registrations to SWOG-coordinated non-randomized studies on holidays and weekends, or after regular business hours, the institution must call the Data Operations Center to leave a voice mail message on the day treatment is to begin.

Policy #18 The Quality Control Policy and Procedures Policy outlines the procedures the Statistical Center takes on initial forms set for patients registered to Phase II or Phase III protocols, and some Phase I protocols. On page one of the policy, under Procedures, the following information has been added: The composition of the Initial Forms Set (IFS) varies among protocols. Most require submission of the prestudy form, and a copy of Section 5 of the protocol, as well as a baseline abnormalities form for studies involving an Investigational New Drug.

Some protocols also require copies of prestudy operative reports, pathology reports and other ancillary forms. Some forms (including prestudy and baseline abnormalities forms) may be submitted online from the CRA Workbench at www.swog.org. Others (e.g., the operative reports and pathology reports) still require mailing. Thus the Statistical Center's Expectation System allows seven days for mailing so that all required forms arrive at the Statistical Center Data Operation's Office within 21 days of registration to be considered within the required time limit.

Additionally, all references to initial flow sheets have been deleted from the policy as they are no longer used.

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Policy #19 The Quality Assurance Program Policy was revised on page one, Item 3, to state that each member affiliate registering less than thirty subjects (changed from forty subjects) in three years may be reviewed (changed from will be reviewed) at the same time as the cases from the member institution with which the affiliate is associated. Also, affiliates registering greater than thirty patients (changed from forty patients) in three years will be reviewed separately on site.

Additionally, the second paragraph in Item 4 was changed to state that Affiliate and UCOP sites will have on-site Pharmacy audits conducted at least once every other audit cycle if time and budget constraints allow.

Policy #26 The Southwest Oncology Group Radiation Therapy Quality Assurance Committee Policy was extensively revamped and revised with all revisions approved by the members of the Board of Governors at their April 8, 2005, meeting. The revised policy meets the Quality Assurance Review Center (QARC) guidelines and structure. QARC was founded in 1980, and collects and reviews radiation therapy and diagnostic imaging data in support of cancer clinical trials for many of the NCI cooperative groups. The revised policy and forms can be found on the Group web site at <http://swog.org/Visitors/Policies.asp>.

Policy #30 The Responsibility for Patient Follow-Up Policy was revised to include (page two, Item 8) the location of the Patient Transfer Form on the Group's web site (www.swog.org, CRA Workbench, 'Tools of the Trade').

A second paragraph in Item 9c, page two of the policy, was added to show the location of the "Lost to Follow-Up form at www.swog.org, CRA Workbench, under 'Tools of the Trade'.

OM/ja

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