

SOUTHWEST ONCOLOGY GROUP

Group Chair's Office
24 Frank Lloyd Wright Drive
P.O. Box 483
Ann Arbor, Michigan 48106

Operations Office
4201 Medical Drive, Suite 250
San Antonio, Texas 78229

Policy Memorandum No. 12
Subject: Registration and Treatment Policies
Departments Affected: All

Page 1 of 2 pages
Original Release Date: July 1985
Revision Date: April 2010

SOUTHWEST ONCOLOGY GROUP REGISTRATION AND TREATMENT POLICIES

1. Registrations

Patients must be registered with the Statistical Center Data Operations Center prior to initiation of treatment. Registration must take place no more than one working day prior to the planned start of treatment except for studies in which surgery or radiation therapy are the first treatment modalities following registration (including studies requiring placement of a Hickman or port catheter) or as otherwise stated in the protocol. Allowances are made for scheduling for these procedures. However, actual scheduling of radiotherapy or surgery should take place immediately following registration with the Statistical Center. If scheduling cannot be done immediately (e.g., patient unsure when they will be available, surgeon out of town for extended time), registration should be delayed. Direct patient registration via the web must 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.

Late registrations (after start of treatment) will not be accepted. It is required that institutions register patients online via the Southwest Oncology Group Web Registration Program to avoid any possible delays. For registrations to SWOG-coordinated non-randomized studies on holidays and weekends (or after regular business hours) and/or the site is unable to access the online registration program, the institution must call the Data Operations Center leaving a voice mail message **on the day treatment is to begin**. The caller must state the name of the institution, investigator, CRA, patient initials, disease site and study number. A call must then be placed to the Data Operations Center on the **next working day** to register these cases.

In calculating days of tests and measurements, the day a test or measurement is done is considered Day 0. Therefore, if a test is done on a Monday, the Monday four weeks later would be considered Day 28. This allows for efficient patient scheduling without exceeding the guidelines. **If Day 28 (the target date) falls on a weekend or holiday, the limit may be extended to the next working day.**

2. Eligibility Exceptions

The Statistical Center will make no exceptions to the eligibility criteria as written in the protocol without a written amendment to the protocol from the Operations Office. Amendments must be recommended by the Study Coordinator, approved by the Disease Committee Chair, the Operations Office Executive Officer, the Statistician of record, and the NCI. Once approved at all levels, the amendment to the protocol is circulated to the Group and the Statistical Center modifies their registration routine. **No one** in the Group is authorized to make exceptions to eligibility criteria unless an error is discovered in the protocol relating to the exception.

3. Cancellations

Under rare circumstances, patient registrations may be cancelled. Cancellations are approved at the discretion of the Group Statistician.

4. Affiliate

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.

5. Intergroup Studies

These registration policies apply to all patients registered on studies managed by the Southwest Oncology Group Statistical Center, regardless of the cooperative group registering the patient. For intergroup studies managed by another group, the registration policies of that group take precedence; however, if exceptions to the eligibility criteria as written in the protocol are made by the other group, the appropriate representative of the group must telephone the Southwest Oncology Group Statistical Center (or the CTSU if applicable) to grant approval before the registration will be accepted.

6. Treatment

The registering investigator must accept full responsibility for each patient's treatment, monitoring and dose modifications, as well as for providing adequate documentation of all treatment, toxicities, response and follow-up. The registering investigator is also responsible for all quality assurance requirements and drug accountability record forms.

Patients must not be registered if they will not be seen at the institution reported as the 'treating institution'. In rare cases, circumstances developing after registration may require that a patient receive care from a non-Southwest Oncology Group physician. This does not release the registering investigator from the responsibilities noted above.

The treating institution is responsible for performing Institutional Review Board functions, i.e., initial and continuing review, consent form, and adverse drug reaction reporting.