

**SWOG**  
**REGISTRATION AND TREATMENT POLICIES**

1. Registrations

Patients must be registered with the Statistics and Data Management Center (SDMC) within the timeframe as specified in the protocol. Scheduling of radiotherapy or surgery should take place immediately following registration with the SDMC. 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. Patient registration through the Oncology Patient Enrollment Network (OPEN) must be performed by NCTN and NCORP Members and Affiliates (with permission of their Member), and some Special Members. OPEN is available at all times with the exception of scheduled maintenance periods.

Late registrations (after start of treatment) will not be accepted. For registrations to SWOG-coordinated non-randomized studies and the site is unable to access the online registration program, the institution must call the SWOG Statistics and Data Management Center (SDMC) 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 SDMC on the **next working day** to register these patients.

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 SDMC 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 Chair, approved by the Disease Committee Chair, the Committee's 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.

3. Cancellations

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

4. Non-SWOG Studies

These registration policies apply to all patients registered on studies managed by the SWOG SDMC, regardless of who is registering the patient. For studies managed by another SDMC within the National Clinical Trials Network, the registration policies of that SDMC take precedence; however, if exceptions to the eligibility criteria as written in the protocol are made by the other SDMC, the institution must obtain this in writing and maintain as a part of their source documentation so it is available should it be questioned during audit.

5. 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-SWOG physician. This does not release the registering investigator from the responsibilities noted above.

The treating institution is responsible for ensuring Institutional Review Board functions, i.e., initial and continuing review, consent form, and adverse drug reactions are performed and reported.