

SWOG
REGISTRATION AND STUDY INTERVENTION

1. Registrations

Participants must be registered with the Statistics and Data Management Center (SDMC) within the timeframe as specified in the protocol. If radiation and/or surgery is a part of randomized protocol treatment, scheduling will take place immediately following registration with the SDMC. If scheduling cannot be done immediately (e.g., participant unsure when they will be available, surgeon out of town for extended time), registration should be delayed. Participant registration through the Oncology Patient Enrollment Network (OPEN) must be performed by NCTN and NCORP Members and Affiliates (with permission of their Member). OPEN is available at all times with the exception of scheduled maintenance periods.

Late registrations (after start of study intervention) will not be accepted. 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 participant scheduling without exceeding the guidelines. **If the target date (e.g., Day 28) 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, participant registrations may be cancelled. Cancellations are approved at the discretion of the Group Statistician.

4. Non-SWOG Studies

These registration policies apply to all participants registered on studies managed by the SWOG SDMC, regardless of who is registering the participant. For studies managed by another SDMC within the National Clinical Trials Network (NCTN) or the NCI Community Oncology Research Program (NCORP), 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 participant's protocol intervention, monitoring and dose modifications, as well as for providing adequate documentation of all treatment, toxicities, response and follow-up. The registering

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investigator is also responsible for all quality assurance requirements and drug accountability record forms.

Participants 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 participant receive care from a non-SWOG clinician. 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.