

SWOG
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Policy Memorandum No. 25
Subject: Agent Ordering Policy
Departments Affected: All

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AGENT ORDERING POLICY

To order study agent, the Principal Investigator (PI) or authorized ordering designee must refer to the Agent Information Section of the protocol to identify the supplier of the study agent(s) and the method of ordering/procurement process.

All study agent orders for agents supplied through the Cancer Therapy Evaluation Program (CTEP), NCI must be submitted directly to the Pharmaceutical Management Branch (PMB) in accordance with the current PMB policies and procedures. For study agents that are not supplied by the CTEP, NCI, consult the protocol for agent ordering procedures.

Agent orders should not be routed through the SWOG Network Operations Center.

NCI, CTEP Supplied Agent(s)

NCI-supplied agents may be requested by eligible participating Investigators (or their authorized designee) at each participating institution. The CTEP assigned protocol number must be used for ordering all CTEP-supplied investigational agents. The eligible participating investigators at each participating institution must be registered with CTEP, DCTD through an annual submission of FDA Form 1572 (Statement of Investigator), NCI Biosketch, Agent Shipment Form, and Financial Disclosure Form (FDF). Refer to the NCI CTEP User Registration webpage for more information (<https://dctd.cancer.gov/research/ctep-trials/for-sites/registration>). If there are several participating investigators at one institution, CTEP-supplied investigational agents for the study should be ordered under the name of one lead participating investigator at that institution.

PMB AURORA Ordering System

Submit agent requests through the PMB AURORA application (<https://ctepcore.nci.nih.gov/aurora/login>). Access to AURORA requires the establishment of credentials necessary to access secure NCI Clinical Oncology Research Enterprise (CORE) systems, maintenance of an "active" account status, a "current" password, and active person registration status. For questions about agent orders, transfers, returns, or accountability, call or email PMB any time or use the dialog function in AURORA to communicate with PMB staff or refer to the protocol for current PMB contact information. Refer to the PMB's website for specific policies, guidelines and forms related to agent management (<https://dctd.cancer.gov/research/ctep-trials/for-sites/agent-management>).

Commercially Available Agents

For protocols where commercially available agents are being used, refer to the protocol to determine whether the agent is provided free-of-charge and, if so, to obtain ordering information. Agent accountability requirements, if applicable, will also be detailed. If commercial agent is not provided free-of-charge, routine institutional procurement procedures for commercial supply should be followed.