



ETCTN Agent Ordering Information Sheet

1. Introduction

The Cancer Therapy Evaluation Program's (CTEP) Pharmaceutical Management Branch (PMB) handles the pharmaceutical support for clinical trials sponsored by CTEP, including those conducted within the ETCTN. Amongst other tasks, the PMB:

- Provides pharmaceutical information about CTEP Investigational New Drug (IND) agents;
- Manages the registration of study personnel participating in CTEP clinical trials and maintains all registration records. Refer to <u>PMB Person Registration</u> and <u>NCI Registration and Credential</u> <u>Repository</u> for additional information;
- Provides access to IND agent Investigator Brochures for NCI-sponsored clinical trials. Refer to <u>PMB Investigator Brochure</u> page for additional information; and
- Authorizes and distributes all CTEP-sponsored IND agents to eligible investigators.

Active CTEP-registered investigators and investigator-designated shipping designees and ordering designees can submit agent requests through PMB's Inventory Management System, <u>AURORA</u>. For questions about drug orders, transfers, returns, or accountability, call (240) 276-6575 Monday through Friday between 8:30 am and 4:30 pm (ET) or email <u>PMBAfterHours@mail.nih.gov</u> at any time.

For more information, visit the **PMB AURORA** webpage.

2. Use of PMB, CTEP Inventory Management System: AURORA

2.1 Access

The following requirements must be met to access AURORA:

- The ordering investigator must be registered with PMB and have an active person registration status and credentials necessary to access secure NCI/CTSU Information Technology (IT) systems; and
- If an *ordering designee* or *shipping designee* (i.e., a non-physician staff member authorized on the investigator's Agent Shipment Form to order and receive agent) is placing an order on behalf of an investigator, they too must have an *active* person registration status and credentials necessary to access secure NCI/CTSU IT systems.

2.2 Submitting a Drug Request

The following requirements must be met to order agent through AURORA:

• The ordering investigator must be claimed on an ETCTN grantee [i.e., Lead Academic Organization (LAO)] roster and must have an *active* person registration status.

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- The grantee organization (LAO) must be listed as the lead or participating organization on the protocol cover page for the study for which the investigator is ordering agent.
- The participating institution under the lead or participating organization must have an *active* site registration status.

3. Questions and Support

For questions related to PMB and the AURORA application, please contact PMB.

• PMB Contact Information: (240) 276-6575; pmbafterhours@mail.nih.gov.

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