

Pharmaceutical Management Branch Cancer Therapy Evaluation Program, DCTD, NCI

Policy and Guidelines for INVESTIGATIONAL AGENT ORDERING

Policy:

Active CTEP registered investigators or their authorized shipping designees and ordering designees may order agents from the Pharmaceutical Management Branch (PMB), CTEP for NCI- sponsored or funded clinical trials using PMB-supplied agents.

Active CTEP-registered investigators and investigator-designated shipping designees and ordering designees should submit agent requests through the PMB Online Agent Order Processing (OAOP) application < <https://eapps-ctep.nci.nih.gov/OAOP/pages/login.jsp> >. Access to OAOP requires the establishment of a CTEP Identity and Access Management (IAM) account < <https://eapps-ctep.nci.nih.gov/iam/> > and the maintenance of an %active+account status and a %current+password.

- **Routine Orders:** Normal PMB processing time is two (2) business days. Non-expedited, room temperature shipments are shipped via FedEx Ground which may take up to five (5) business days to arrive once the order is shipped. Agents requiring special shipping conditions are sent Monday through Thursday for next day delivery.
- **Patient-Specific Orders:** Orders require additional processing time and are not available for next day delivery.
- **Expedited Orders:** PMB provides next day delivery to registered investigators to meet "emergency" or urgent needs. **Requests for next day delivery must be received at PMB by 2:00 p.m. Eastern Time.** The requirement for next day delivery must be stated on the order request and an express courier account number provided.
- **International Orders:** Orders require additional processing time and are not available for next day delivery.

Guidelines:

- **Protocol-Specific Orders:** When a number of investigators are participating on a clinical study at the same institution, one investigator should be considered or designated the principal or lead investigator under whom all investigational agents for that protocol should be ordered.
- **Patient-Specific Orders:** Initial orders are submitted by the lead organization of the protocol and cannot be entered through OAOP. Subsequent orders must be submitted through OAOP, or as specified by the protocol, under the name of the investigator from the initial order.

- Orders will only be shipped to the investigator's designated shipping address. Investigators may only have a single shipping address. All changes to the investigator's shipping address must be in writing by submission of an updated Supplemental Investigator Data Form signed by the investigator or by submission of an updated Primary Shipping Address and Designee (PSD) Worksheet if applicable.
- Changes or additions to investigator-designated shipping designees and ordering designees must be in writing by submission of an updated Supplemental Investigator Data Form signed by the investigator or by submission of an updated Primary Shipping Address and Designee (PSD) Worksheet if applicable.
- The ordering designee submitting the order and the shipping designee will receive a confirmation e-mail of successful order submission. Order status may be viewed any time through the OAOP application. Upon shipment, a confirmation e-mail is sent which includes the order details and tracking information.
- Limit agent requests to an eight week supply or as specified by the protocol.

Questions or comments regarding investigational agent ordering should be addressed to the Pharmaceutical Management Branch by telephone (240-276-6575) Monday through Friday between 8:30 am and 4:30 pm (ET) or email PMBAfterHours@mail.nih.gov anytime.