Pharmaceutical Management Branch
Cancer Therapy Evaluation Program, DCTD, NCI

Policy and Guidelines for
INVESTIGATIONAL AGENT DISTRIBUTION

Policy:

The Pharmaceutical Management Branch (PMB) provides investigational agents for use in DCTD approved protocols to eligible investigators with an active CTEP investigator registration status. Orders will only be shipped to the shipping address indicated on the investigator's current Supplemental Investigator Data Form (IDF).

Guidelines:

- Investigational agents are shipped from PMB to the investigator's designated shipping address only. Investigators can only have one designated shipping address.
- PMB supplied investigational agents must NOT be re-shipped by mail or overnight delivery services to another institution, site, or study subject.
- PMB supplied investigational agents must NOT be transferred to another institution or site without PMB approval.
- PMB allows investigational agents to be received by a Control Dispensing Area/Pharmacy and then transported to a Satellite Dispensing Area/Pharmacy given the following:
    - Control Dispensing Areas/Pharmacies support Satellite Dispensing Areas/Pharmacies either within a single institution, within a medical center complex consisting of two or more institutions, or to local community based investigators.
    - Agents must be transported to Satellite Dispensing Area/Pharmacy via staff or institutional courier using appropriate temperature controls and hazardous/infectious transportation procedures according to written institutional policies.
    - Control Dispensing Areas/Pharmacies are responsible for overall inventory control and must provide copies of all accountability records during any CTEP directed audit.

- PMB strongly recommends that all participating investigators at an institution use the same shipping (pharmacy) address by establishing a Primary Shipping Designee (PSD) with PMB (email ctepreghelp@ctep.nci.nih.gov for creation and maintenance).

- When a number of investigators are participating on the same clinical study at the same institution, one investigator should be designated the ordering investigator under whom all investigational agents for that protocol are ordered.

- In accordance with the FDA Guidelines on Good Clinical Practice and The Joint Commission, whenever possible, the pharmacy department should be responsible for agent receipt, storage, accountability, and preparation.

Questions or comments regarding investigational agent distribution 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.