

**Pharmaceutical Management Branch  
Cancer Therapy Evaluation Program, DCTD, NCI**

**Policy and Guidelines for  
INVESTIGATIONAL AGENT RETURNS**

**Policy:**

Investigators/Designees should make every effort to minimize the amount of agent ordered and returned unused, (e.g. limit inventories to an 8 week supply or less). Investigators/Designees must return unused DCTD supplied investigational agent to the NCI clinical repository when:

- The agent is no longer required because the study is completed or discontinued and the agent cannot be transferred to another DCTD sponsored protocol. Whenever possible DCTD supplied investigational agents should be transferred to another DCTD-sponsored trial that utilizes the same investigational agent, form, and strength. All policies and procedures regarding investigational agent transfer should be followed.
- Agent is outdated. Investigators/designees should only return outdated agents with a firm expiration date or if they have received written notification from PMB that an agent has expired and should be returned.
- The agent is damaged or unfit for use. Investigators/designees should contact the PMB prior to returning investigational agents because of stability concerns, (e.g. loss of refrigeration or exposure to elevated temperatures). Do **NOT** return broken vials. Broken vials should be destroyed at the clinical site. Follow the appropriate agent accountability guidelines.

**General Guidelines:**

- Regulations require that all agents received from the DCTD, NCI be returned to the DCTD, NCI for accountability and disposition.
- Return only unused vials/bottles. Do **NOT** return opened or partially used vials/bottles unless specifically requested otherwise in the protocol.
- Return only DCTD supplied agents to the NCI Clinical Repository. Do **NOT** ship agents received from other sources to the NCI Clinical Repository.

**Procedure:**

- Complete the Return Drug List. All information must be accurate and complete, (e.g. protocol numbers and investigator numbers).
- Double check quantities and lot numbers prior to shipment.

- All instructions on the Return Drug List must be followed.
- Enclose the Return Drug List with the returned agents. Keep a copy for your records.
- Package the agents securely to prevent breakage. Breakage of vials on route to the NCI Clinical Repository is a potential health hazard. To minimize the risk to couriers and the NCI Clinical Repository staff, we recommend that all return agents be double bagged.
- Ship agent returns at room temperature. Refrigerated shipment is **NOT** required.
- Send agent returns to the address indicated on the Return Drug List.
- Express delivery (e.g. next day air) is NOT necessary for agent returns.
- The investigator/designee is responsible for the cost of shipment. "Collect" or C.O.D. shipments will **NOT** be accepted.
- Return receipt - Investigators/designees must complete the return receipt section of the Return Drug List for confirmation of a agent return.

*Questions or comments regarding investigational agent returns should be addressed to the Pharmaceutical Management Branch by telephone (301-496-5725) or fax (301-402-0429).*