

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

**Policy and Guidelines for  
INVESTIGATIONAL AGENT RETURNS**

**Policy:**

Investigators/Designees must return un-dispensed PMB supplied investigational agent to the NCI Clinical Repository.

**Guidelines:**

- PMB requires that all PMB supplied investigational agents received from the DCTD, NCI be returned to the DCTD, NCI for accountability and final disposition.
- Return only PMB supplied agents to the NCI Clinical Repository. Do NOT return agents received from other sources.
- Complete all sections of the Return Drug List neatly and accurately to receive credit for the return.
  - See FAQ: “Returning agent to NCI Clinical Repository” for detailed instructions
- If the agent is considered a dangerous good (DG) or infectious substance for shipping purposes (as noted by **\*\*DG\*\*** on the Shipping Record), sites may request local destruction authorization.
  - See “Policy and Guidelines for Investigational Agent Local Destruction”

PMB supplied agents should be returned when:

- The agent is no longer required for the study and the agent cannot be transferred to another DCTD sponsored protocol.
  - Whenever possible, PMB supplied investigational agents should be transferred to another DCTD sponsored protocol that utilizes the same agent, strength, and formulation.
  - See “Policy and Guidelines for Investigational Agent Transfers”
- The agent is unsuitable for clinical use.
  - Investigators/designees should contact the PMB prior to returning investigational agents because of stability concerns due to temperature excursions.
  - Do NOT return broken containers. Broken containers should be destroyed at the clinical site per institutional procedures.

- Investigators/designees have received written stock recovery notification from PMB.
- Un-dispensed patient specific agent should be returned at the time the patient completes therapy.

*Questions or comments regarding investigational agent returns 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](mailto:PMBAfterHours@mail.nih.gov) anytime.*