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 anytime.