

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

**Policy and Guidelines for
ACCOUNTABILITY AND STORAGE OF INVESTIGATIONAL AGENTS**

Policy:

FDA regulations require investigators to establish a record of the receipt, use, and disposition of all investigational agents. The NCI as a sponsor of investigational trials has the responsibility to assure the FDA that systems for agent accountability are being maintained by investigators in their clinical trial program. Investigators may delegate responsibility for agent ordering, storage, accountability and preparation to his/her designee. However, **the investigator is ultimately responsible for all agents shipped in his/her name.** The intent of agent accountability is to assure that DCTD supplied agents are only used for patients enrolled on an approved DCTD trial.

Guidelines:

- Agent disposition (receipt, transfer, dispensing or return) shall be maintained on the NCI Investigational Drug Accountability Record. Alternative accountability records, either manual or electronic, may be used if they include all the information required on the NCI Investigational Drug Accountability Record and if the paper printout is identical to the NCI accountability record.
- A NCI Investigational Drug Accountability Record must be maintained at each location at which an agent is stored (e.g. main pharmacy, satellite pharmacy).
- DCTD supplied investigational agents should be stored in a secure location which is only accessible to authorized personnel.
- Each agent should be stored and accounted for separately by protocol.
- There shall be a separate NCI Investigational Drug Accountability Record for each protocol.
- If a protocol uses more than one DCTD supplied agent or more than one strength or formulation of the same agent, there shall be a separate storage area and NCI Investigational Drug Accountability Record for each agent, strength, and formulation.

Questions or comments regarding accountability and storage of investigational agents should be addressed to the Pharmaceutical Management Branch by telephone (301-496-5725) or fax (301-402-0429).