

**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 maintained by investigators in their clinical trial program. Investigators may delegate responsibility for agent ordering, storage, accountability and preparation to his/her designee(s). However, the investigator is ultimately responsible for all agents shipped in his/her name. The intent of agent accountability is to assure that NCI-supplied agents are administered only to patients enrolled on approved NCI trials and to track complete disposition of the agent.

**Guidelines:**

- Agent disposition (receipt, dispensing, transfer, return or authorized local destruction of un-dispensed agent) shall be documented on the NCI Investigational Agent (Drug) Accountability Record (DARF) or the NCI Investigational Agent Accountability Record for Oral Agents (Oral DARF) as appropriate.
  - NCI DARFs are approved by the Office of Management and Budget (OMB) and contain an OMB number and expiration date. Sites must transition existing agent inventory to renewed DARFs with a new expiration date within 90 calendar days of the expiration date of expired DARFs.
  - Electronic accountability systems may be used. Paper printouts of electronic DARFs must be identical to the NCI DARFs. Electronic accountability system database limitations are not valid reasons for improper accountability documentation according to NCI policy.
- Maintain separate NCI DARFs for each protocol, agent, strength, formulation and ordering investigator.
- Maintain separate NCI DARFs for each study participant on patient-specific supply studies as dictated by the protocol.
- Control NCI DARFs must be maintained at the location that directly receives agent from the NCI.

- Satellite NCI DARFs must be maintained at each location that receives NCI-supplied agent from a Control Dispensing Area/Pharmacy and stores an agent for more than one day.
- Store NCI-supplied investigational agents in a secure location which is only accessible to authorized personnel.
- Store each agent separately by protocol, strength, formulation and ordering investigator.
- Store agents under proper environmental conditions with documentation of temperature monitoring.

*Questions or comments regarding accountability and storage of investigational agents 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.*