

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

**Policy and Guidelines for
TRANSFER OF DCTD SUPPLIED INVESTIGATIONAL AGENTS**

Policy:

DCTD supplied investigational agents may be transferred within an institution (intra-institutional transfer) from a completed DCTD sponsored protocol to another DCTD approved protocol that utilizes the same agent and formulation.

Guidelines:

- An NCI Investigational Agent Transfer Form must be completed and submitted by fax (301-402-0429) to the Pharmaceutical Management Branch (PMB) for each agent transfer. Transfer forms should be submitted within 72 hours of the actual transfer. A copy should be retained for your records.
- The transfer of DCTD supplied investigational agents from an active protocol requires prior PMB approval, (PMB should be notified the next working day if emergent transfers are required during weekends or holidays). Transfer of investigational agents from an active protocol should be restricted to the following situations: excessive inventory for a protocol; investigational agent has short dating; or medical emergency.
- The transfer of DCTD supplied agents to non-DCTD approved protocols is NOT permitted under DCTD, NCI, and FDA policies and regulations.
- The transfer of DCTD supplied agents for commercial use is both **prohibited and illegal**. Replacement of DCTD supplied agents with commercial agents is also **prohibited and illegal**.
- The transfer of DCTD supplied agents shall only be made between registered active NCI investigators.
- The "transferring" investigator must be the investigator who originally ordered the agent or the investigator to whom the agent was previously transferred (i.e., "double transfer").
- The "receiving" investigator must be an active participant on the trial to which the agent is being transferred.
- "Borrowing" of investigational agents is prohibited. All transfers must be documented. Investigational agents should NOT be ordered for one protocol to replace what was "borrowed" from another protocol.
- All DCTD investigational agents shall be stored and accounted for separately by protocol. If an agent is used for more than one protocol, there should be separate physical storage and accountability for each protocol. PMB provides and accounts for agents on a protocol by protocol basis.
- Blinded studies -
 - Agents for blinded studies should NEVER be transferred between protocols.
 - Agents for blinded studies may be transferred between investigators with prior PMB approval.

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