

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

**Policy and Guidelines for
INVESTIGATIONAL AGENT TRANSFERS**

Policy:

PMB supplied investigational agents may be transferred from a DCTD sponsored protocol to another DCTD sponsored protocol or between eligible investigators within an institution (intra-institutional transfer) if the protocol utilizes the same agent, strength and formulation supplied by PMB.

Guidelines:

- An NCI Investigational Agent Transfer Form must be submitted by fax (240-276-7893) or email (PMBAfterhours@mail.nih.gov) to obtain prior approval for each agent transfer. Transfer forms for urgent medical need should be submitted within 72 hours of the actual transfer.
 - Transfer of supplied agents shall only be made between registered active CTEP investigators.
 - The "transferring" investigator must be the investigator who originally ordered the agent or the investigator to whom the agent was previously transferred.
 - The "receiving" investigator must be an eligible participant on the trial to which the agent is being transferred.
 - Transfers must be documented on the Control DARF and written documentation of NCI authorization must be retained as part of the accountability records.
 - Only whole containers can be transferred.
- Transfer of PMB supplied investigational agents between protocols:
 - Example situations: notification of protocol status change (e.g., closed to accrual and treatment or complete), excessive inventory for a protocol, investigational agent has short dating, or urgent medical need.
- Transfer of PMB supplied investigational agents between eligible investigators:
 - Example situations: orders placed for multiple investigators within the same protocol, or change of investigator at the site (e.g., ordering investigator leaves institution).
- Transfer of PMB supplied agents when the Control Pharmacy/Dispensing Area relocates requires prior approval.

- Transfer of PMB supplied agents to non-DCTD approved protocols is NOT permitted under DCTD, NCI, and FDA policies and regulations.
- Transfer of PMB supplied agents for commercial use is both prohibited and illegal. Replacement of PMB supplied agents with commercial agents is also prohibited and illegal.
- "Borrowing" of investigational agents is prohibited. All transfers must be documented. Investigational agents can NOT be ordered for one protocol to replace what was "borrowed" from another protocol.
- Patient specific supplies should NEVER be transferred between protocols or between patients.
 - Patient specific agent may be transferred between investigators within the same protocol with prior PMB approval.

Questions or comments regarding investigational agent transfers 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.