Pharmaceutical Management Branch
Cancer Therapy Evaluation Program, DCTD, NCI

Policy and Guidelines for use of the NCI Investigational Agent Accountability Record for Oral Agents (Oral DARF)

Policy:

Use of the NCI Investigational Agent Accountability Record for Oral Agents (Oral DARF) is mandatory effective March 1, 2014.

Guidelines:

- Agent disposition (receipt, dispensing, transfer, return or authorized local destruction of un-dispensed agent) of NCI-supplied oral agent formulations must be documented on the NCI Oral DARF. Accountability of all other agent formulations will continue to be maintained on the current version of the original NCI Investigational Agent (Drug) Accountability Record (DARF).

- For existing studies, sites have the option to start a new page of the accountability record using the Oral DARF, or may continue to use the existing original DARF until all lines of the page have been completed. When a new page number is started, the Oral DARF must be implemented.

- Patient returns of dispensed oral agents should only be documented on the Oral DARF if dispensing was documented on the Oral DARF.
    - See FAQ: ñPatient Returns of Oral Clinical Suppliesò for guidance on patient return documentation

Questions or comments regarding accountability and storage of investigational agents should be addressed to the Pharmaceutical Management Branch by telephone (240-276-6575) or email (PMBafterhours@mail.nih.gov).