**POLICY**

PMB advises investigators on specific requirements and updates of requirements in relation to investigational drug management that the FDA and NCI may mandate.

This policy is to ensure current practices and requirements of the PMB, related to the use of investigational agents, are reviewed and utilized at all UC NCORP participating sites.

**RESPONSIBILITY**

Principal Investigator or his/her delegated Pharmacy staff and Research staff

**GUIDELINES**

 **Per the PMB website the following items are support PMB provides:**

* Provision of pharmaceutical information about CTEP IND agents
* Registration of all investigators and associates participating in CTEP clinical trials and the maintenance of all registration records
* A Treatment Referral Center (TRC) for handling special CTEP clinical agent initiatives, referrals to high priority clinical trials and the coordination, authorization, and processing of all requests for Special Exception and Treatment Referral Center protocol agent use
* Authorization and distribution of all CTEP-sponsored Investigational New Drug (IND) agents to eligible investigators
* Provision of agent forecasting, agent acquisition, and inventory management of all IND agents distributed by CTEP for clinical trials
* Provision and management of high priority double blind, randomized clinical trials
* Distribution of agents to investigators for non-human (preclinical) use
* Additional details on each of the above items is in the provided link at the bottom in the reference section

**PROCEDURES:**

1. Each site is responsible for adherence with NCI/DCTD/CTEP requirements for storage and accounting for investigational agents, including complying with NCI/DHHS Drug Accountability Records (DAR) procedures as described in the DCTD Investigators' Handbook.
2. The PMB Investigational Drug Accountability Training Videos will be viewed annually by research staff delegated to perform any task associated with the ordering, receipt, dispensing of study provided agents, or drug accountability log completion
3. Dates of completion are to be maintained by each affiliate and sub-affiliate site and made available as requested during site monitoring visits by the QA Coordinator.

 4. The UC NCORP QA coordinator will review for adherence to PMB requirements during monitoring visits

**REFERENCE:**

<https://ctep.cancer.gov/branches/pmb/default.htm>

**ASSOCIATED FORMS:**

*Notice: To assure the most current forms are in use all PMB forms will be accessed from the website above noted under the heading “CTEP Forms, Templates and Documents”*

**COMMITTEE APPROVAL:**

UC Policy and Procedure Committee