**POLICY**

The Upstate Carolina NCORP (UC-NCORP) Principal Investigators and delegated Research Staff are responsible for handling study provided investigational agents. UC-NCORP Investigators and Research Staff are responsible for being aware of the most current NCI Pharmaceutical Management Branch (PMB) Guidelines and policies for compliance and patient safety. The following policy is to help assure knowledge and adherence to the current policies.

**DEFINITIONS**

**PMB:** The Pharmaceutical Management Branch (PMB) is charged with providing pharmaceutical support for clinical trials sponsored by the National Cancer Institute’s (NCI) Cancer Therapy Evaluation Program (CTEP). This support includes provision of pharmaceutical information about CTEP IND agents:

* [Agent Management](https://ctep.cancer.gov/branches/pmb/agent_management.htm)
* [Investigator Brochure (IB)](https://ctep.cancer.gov/branches/pmb/ib_list.htm)
* [Material Safety Data Sheet (MSDS)](https://ctep.cancer.gov/branches/pmb/msds/default.htm)
* [Patient/Caregiver Ad Hoc Education Template](https://ctep.cancer.gov/branches/pmb/patient_caregiver_education.htm)

**RESPONSIBILITY**

Principal Investigator and Delegated Research Staff (including Pharmacist)

**GUIDELINES**

* Active CTEP registered investigators or their authorized shipping designees and ordering designees may order agents from the PMB for NCI- sponsored or funded clinical trials using PMB-supplied agents
* If a number of Investigators are participating on a clinical study at the same institution, one Investigator should be considered or designated the Principal Investigator under whom all Investigational Agents for that protocol are ordered
* An eight-week supply should be ordered per enrolled study subject or as specified by the protocol
* It is recommended that sites consolidate order submission requests

**PROCEDURES**

UC-NCORP QA Coordinator will review each affiliate site’s pharmacy Policies & Procedures for compliance of NCI PMB Investigational Agent requirements

Affiliate Site responsibilities:

1. Each site is required to have policies in place regarding the handling of research provided Investigational Agents
2. All delegated Research Pharmacy and Research Staff who are responsible for ordering agent supplies, signing drug in or out must have completed the NCI-PMB Investigational Agent Training
3. All Investigational Agents will be stored in a limited access secured location, accessible only to authorized personnel
4. All Investigational Agents will be appropriately stored at the designated temperature to ensure the stability and integrity of the agent
5. Logs are to be maintained documenting temperatures of each storage location (ambient room temperature, refrigerator logs, etc.)
6. Each Investigational Agent will be stored separately by protocol and drug strength
7. Investigational Agents that are ordered by multiple Investigators must be stored separately by each Investigator
8. The NCI-PMB log (or its equivalent) will be maintained for all study supplied agents
9. Study Agent ordering, reorders and receipt documents are to be maintained
10. Dispensing is only allowed by an approved Investigator or Pharmacist
11. Transportation of Investigational Agents must meet the NCI-PMB requirements
12. Destructions and Returns of Investigational Agent must follow PMB and/or sponsor requirements and must be documented
13. Each site must have a written process for ensuring an ordering physician is an active approved Investigator on specific trial
14. USP 800 pharmacy requirements should be in effect at each institution no later than the deadline of 12-1-2019

**REFERENCE:**

* Pharmaceutical Management Branch Cancer Therapy Evaluation Program, DCTD, NCI, Policy and Guidelines for INVESTIGATIONAL AGENT ORDERING, 09/15

[*https://ctep.cancer.gov/protocoldevelopment/requisition\_agents/docs/Investigational\_Agent\_Ordering.pdf*](https://ctep.cancer.gov/protocoldevelopment/requisition_agents/docs/Investigational_Agent_Ordering.pdf)

* Pharmaceutical Management Branch (PMB)

[*https://ctep.cancer.gov/branches/pmb/default.htm*](https://ctep.cancer.gov/branches/pmb/default.htm)

**ASSOCIATED FORMS:**

*Access current NCI PMB forms from the PMB website:* [*https://ctep.cancer.gov/branches/pmb/default.htm*](https://ctep.cancer.gov/branches/pmb/default.htm)

Forms available include:

* NCI Investigational Accountability Record Form
* NCI Oral Agents Investigational Accountability Record Form
* NCI Transfer Investigational Agent Form
* NCI Return Investigational Agent Form

**COMMITTEE APPROVAL:**

UC NCORP Policy and Procedure Committee