


Pharmacy Manual

	Policy Name	Investigational Drug Service: General Description
	Policy Number	PHARM 0619
	Date this Version Effective	January 2014
	Responsible for Content	Pharmacy Operations Council

I. Description

Provides accountability, preparation and dispensing clinical trial materials to human subjects

II. Rationale

To comply with the standards set forth by The Joint Commission (TJC) that the pharmacy must control the storage, dispensing, labeling and distribution of investigational agents

III. Policy/Procedure

A. Policy

1. The Investigational Drug Services Pharmacy provides mechanisms for the acquisition, storage, preparation, distribution, and control of clinical trials materials (CTM) for clinical trials with human subjects conducted at the University of North Carolina Healthcare System. These mechanisms are in accordance with the policies and procedures established for the IV Admixture Service, the Ambulatory Care Service, the Central Inpatient Service, and for specific clinical trials and study medications as deemed appropriate by an Investigational Drug Service (IDS) pharmacist.
2. A clinical trial is defined as any experiment that involves the use of a test article and one or more human subjects. An experiment is a procedure done in order to discover or demonstrate some fact or general truth. The use of a Compassionate plea medication at UNC Healthcare shall be considered a clinical trial. However, the following ARE NOT considered to be clinic trials unless a research protocol is being followed:
 - a. The use of FDA-approved drug products, biological products, and medical devices for unapproved indications.
 - b. The use of extemporaneously prepared formulations of FDA-approved drug products.
3. A test article may be any of the following:
 - a. A drug product, approved or unapproved by the FDA.
 - b. A biological product, approved or unapproved by the FDA.
 - c. A medical device, approved or unapproved by the FDA.
4. Per TJC, the pharmacy must control the storage, dispensing, labeling and distribution of all investigational medications.
5. In emergency situations, approval by the Institutional Review Board may not be a prerequisite for pharmacy services. The attending physician writes a note in the patient's medical record documenting the emergency nature of the situation. Study medications are dispensed to patients upon the request of an authorized prescriber who has previously

obtained informed consent from involved patients or patient representative. In emergency situations, dispensing of a test article may not be dependent on obtaining informed consent. However, a "Waiver of Consent" procedure must be followed in accordance with guidelines from the FDA and the Institutional Review Board.

6. Maintain records of the receipt and disposition of study medications in such a way that the Investigational Drug Service can account for the distribution of each unit of medication that it supplies.
7. Investigational agents may be received by the Investigational Drug Services and redistributed to other pharmacy areas of the hospital for preparation and dispensing.
 - a. A satellite is defined as a pharmacy area other than the Investigational Drug Services Pharmacy (e.g., Cancer Hospital Inpatient/Infusion Pharmacy [CHIP], Sterile Products Area [SPA]) being responsible for the preparation and dispensing of an investigational agent.
 - b. The Investigational Drug Services will be responsible for supplying the pharmacy area with information required to prepare and dispense the agents appropriately.
 - c. Inventories of agents may or may not be split between the Investigational Drug Services Pharmacy and the satellite area. This will be dependent upon the protocol.
 - d. Investigational Drug Services Pharmacy is ultimately responsible for all investigational agents received.
 - e. Satellite dispensing areas must follow all protocol specific drug accountability, preparation and dispensing procedures as outlined in the Protocol Information Sheet for the protocol found in the study notebook.

IV. Original Policy Date and Revisions

Jan 1999, Feb 2007, Jan 2011, January 2014