Issuing Department: Human Subjects Protection Program
Policy Number: 2011-022.0
Policy Title: Study Drug - General

Purpose

The purpose of this policy is to set forth requirements for labeling, dispensing storing and maintaining inventory control research drugs.

Definitions

See policy 2011-007.0 for definition of the following terms:

Dispense	Investigational New Drug

Policy

Labeling: All study drug labels must indicate:

- the name, address and phone number of the dispensing area;
- the subject's name or identifying number;
- the name of the prescribing physician;
- the date of issue;
- the drug name and strength or study acronym; and
- directions for use.
- Labels for investigational drugs must also incorporate the following statements: "Caution: New Drug – Limited by Federal law to investigational use."

Dispensing and transfer of drug: There must be an order from the physician (a standing order would be acceptable) if someone other than the physician is delivering study drugs to subjects. Per CT Law only pharmacists and those with prescribing authority may dispense drugs other than over-the-counter drugs. Qualified study staff may then deliver (i.e. hand over) the prescribed and dispensed drug to the subject. The Director of Pharmacy may delegate the ability to approve of dispensing plans to other pharmacy staff.

Storage and Inventory: Investigational new drugs for inpatient use must be stored in the John Dempsey Hospital Pharmacy. Investigational new drugs for outpatient use may be stored in the pharmacy or by the investigator. The Director of Pharmacy must approve of the plans for storage and inventory control of research drug not stored within the Pharmacy. The Director of Pharmacy may delegate the ability to approve of storage and inventory plans to other pharmacy staff.

Procedure

The PI must disclose within the IRB submission the plans for dispensing of research drug and approval from Pharmacy for such plans must be provided.

The PI must disclose within the IRB application the plans for storage and inventory of research drugs and approval from Pharmacy must be provided.

As part of the sign-off statement within the IRIS system the Principal Investigator acknowledges his/her responsibility be confirming that s/he has read the Responsibility of Investigators Regarding Control and Use of Investigational Drug information.

Drug labeling and storage and physicians orders will be verified as part of the Research Compliance Monitoring Program.

Related Policies

2009-005.0 - Monitoring IRB Approved Studies
2011-007.0 – Definitions Applied to Policies

Basis

21 CFR 312
CT Statute – Chapter 400j Pharmacy

Document Attributes

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Reviewed and Approved By:

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