

<p>PROCEDURE FOR: Medication Administration: Investigational Drugs: Inpatient Utilization of</p>
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- POLICY:
1. All investigational drugs shall be registered and stored in the hospital pharmacy.
 2. All investigational drugs must have Institutional Review Board (IRB) or compassionate use approval before they are administered to patients.
 3. When study design permits, the distribution of investigational drugs shall be in concert with the Pharmacy Department's unit dose distribution system.
 4. Documentation of informed consent shall be obtained prior to administration of an investigational drug.
 5. Adequate information about investigational drugs shall be provided to nurses who administer investigational drugs.
 6. Investigational drugs are study and/or patient-specific and are not to be diverted for other use.
 7. An implementation plan must be prepared for studies using investigational drugs when it is anticipated that two or more patients will be enrolled.

- PROCEDURE:
1. The attending physician with authority to use an investigational drug for hospitalized patients shall:
 - a. transfer the drug supply to the hospital pharmacy for registration and storage
 - b. provide hospital pharmacy personnel with:
 - 1) investigational protocol
 - 2) proof of IRB or compassionate approval
 - 3) relevant information about the clinical use of the drug
 - 4) a copy of the patient's signed consent form
 2. The hospital pharmacy personnel will:
 - a. maintain a separate storage and perpetual inventory for each investigational drug.
 - 1) All investigational drugs shall be labeled as such and stored separately from other pharmaceuticals.
 - 2) An inventory log will be maintained for each dosage form and strength of each drug used. A periodic inventory is taken to ensure that diversion is not occurring.
 - b. ensure that the IRB or compassionate use approval has been obtained. Documentation of this approval will be made on the inventory record of the pharmacy.
 - c. supply the investigational drug in unit-dose packaging, if appropriate, and label the product as an investigational drug. To ensure study integrity, pre-randomized, pre-packaged patient-specific drugs are not to be repackaged.
 3. RN or LPN shall not administer the first dose of an investigational drug without assurance from the pharmacy that IRB or compassionate use approval has been obtained.
 4. RN or LPN shall administer investigational drugs only after:
 - a. determining that informed consent has been obtained and is

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available in the Pharmacy Department and/or in the medical record.

- b. being provided with complete and concise clinical information about the drug. This information shall be provided by the Pharmacy Department and shall be maintained with the nursing treatment plan.
5. A single notebook will be assembled for each study containing:
- a. a summary sheet explaining the study purpose and dispensing procedures
 - b. a drug information sheet (non-FDA approved drugs)
 - c. drug inventory log(s)
 - d. randomization list, when applicable
 - e. patient profile, if needed
 - f. study protocol
 - g. all invoices, documentation of study drug return, all written communications and any other documents pertaining to the study.

APPROVAL: Nursing Standards Committee
Department of Pharmacy

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