

# SUNY DOWNSTATE MEDICAL CENTER

## UNIVERSITY HOSPITAL OF BROOKLYN POLICY AND PROCEDURE

**Subject:** INVESTIGATIONAL DRUG/  
DISPENSING AND UTILIZATION

**Prepared by:** Nicholas Galeota, MS, R.Ph

**Reviewed by:** William Gerdes

**Committee** Pharmacy & Therapeutics Committee

**Approved:** Medical Executive Committee

**Approved by:** Nicholas Galeota, MS, RPh

Margaret Jackson, MA, RN

Sage Wiener, MD

Mathew Foley, MD

Michael Lucchesi, M.D

Patricia Winston, MS, RN

William P. Walsh, MBA, MSW

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**TJC Standards:** MM.06.01.05: The hospital safely manages investigational medications  
MM.05.01.11: The hospital safely dispenses medications.

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### I. PURPOSE

To ensure safe use of investigational drugs that have been approved for use by SUNY Downstate Medical Center's IRB in human subjects enrolled in Clinical Drug Trials.

To provide safe handling of investigational drugs dispensed by the Investigational Drug Lab.

### II. POLICY

Dispensing investigational drugs is under the direct control of the Principal Investigator and the Investigational Drug Lab. Dispensing and utilization of investigational drugs must be approved by the Institutional Review Board (IRB).

Investigational drug studies must undergo an ancillary review by the Research Pharmacist or designee. Research Pharmacist review may take place in parallel with the

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IRB review process. However, the IRB cannot issue a final approval letter until approval is granted by the Research Pharmacist.

Investigational drugs used for ALL patients shall be managed, prepared, and dispensed by the Research Pharmacist.

Investigational drugs may only be administered as part of a protocol approved by the IRB and to patients who have signed an approved Informed Consent.

To defray the costs of providing storage, preparation, dispensing and administrative services arising from the use of investigational drugs, the Research Pharmacist and/or Director of Pharmacy may negotiate with principal investigators on the transfer of appropriate fees and compensation to the Investigational Drug Lab and/or Pharmacy.

### III. DEFINITION(S)

Investigational and/or research study drugs are drugs or pharmaceuticals which:

- A. are in Phase I, II, or III clinical trials or have an Investigational New Drug number or are under investigation, and have not been released by the FDA for general distribution and use. These drugs usually bear the following statement on their labels: "Caution – New Drug – Limited by Federal Law to Investigational use".
- B. have FDA approval, but are being investigated for a non-FDA approved indication, use, or a dosage that had not previously been approved by FDA.
- C. have FDA approval for the intended use, are not on the hospital formulary, and are being supplied to the Principal Investigator for comparison to the new study drug.

### IV. RESPONSIBILITIES

#### A. The Institutional Review Board (IRB)

The IRB approves clinical research protocols involving investigational drugs and provides guidance to investigators about conducting studies in the hospital.

#### B. The Principal Investigator

The principal investigators of approved protocols are the individuals who bear the legal responsibility for the accountability of investigational drugs. Only they, or other professional individuals-including other physicians, nurses or health professionals-designated by the principal investigators can dispense investigational drugs or authorize the Pharmacy to dispense such drugs.

In addition to the foregoing, investigators are responsible for the following:

- a) Submitting clear and complete orders regarding dispensing investigational drugs for admitted patients.
- b) Anticipating costs of drugs not provided by a sponsor and appropriately informing patients or other payers.
- c) Sending signed informed consent forms to the Pharmacy for those patients whose investigational drugs are dispensed by the pharmacy.
- d) Retaining all study documents for 5 years after completion of research protocols using investigational drugs.
- e) Contacting nursing personnel who are responsible for administering the investigational drug and arranging instruction on in-service about the

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research protocol for nurses who complete the in-service process should be listed within the Study Binder, and only they are authorized to administer study drugs.

Nurses handling study drugs must be educated about the protocol and how to administer the study drug before they are called upon to do so.

- f) Directing the supplier of the investigational drug to send the trial material to the investigator or designated Pharmacy storage area. The drug is the property of the investigator; the Pharmacy serves only as the storage and distribution center.
- g) Upon notification by the Pharmacy that the predetermined minimum inventory level has been reached, the principal investigator shall collaborate with the study coordinator to ensure adequate inventory of study drug.

### **C. The Pharmacy**

The Investigational Drug Lab is responsible for the storage, dispensing, preparation and record keeping for the investigational drugs that have been placed in their care.

The Investigational Drug Lab will maintain a Study Book containing the protocol and related documents for each approved protocol for studies in which the Investigational Drug Lab dispenses investigational drugs, and use this to file copies of the protocol informed consent and details of drug dispensed either to investigators (who, in turn, would administer or dispense the drug to patients), or directly to patients.

For investigational studies that require dispensing and administering medications to admitted patients, the Research Pharmacist shall coordinate and oversee any changes in technologic and/or electronic systems to order, label, or administer the investigational drugs.

Pharmacists shall dispense investigational medications only upon receipt of a prescription or copy of the physician's original order signed by an authorized investigator or his designee.

The institutional policy and procedure for the handling of investigational drugs should be reviewed by the pharmacist before undertaking a new investigational drug study.

The dispensing pharmacist is responsible for entering all required data on the Drug Accountability Record.

The dispensing pharmacist shall confirm that the inventory is accurate and balanced and notify the principal investigator when the previously determined minimum inventory level is reached, if applicable.

Maintain accurate records (e.g., drug accountability records) for the perpetual inventory of an investigational stock, name of patients receiving the drug, data, quantity of each issue, patient's location, and physician's name, as per study sponsor's requirements.

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Store the drug according to the manufacturer's specifications.

Provide suitable containers for storage and dispensing.

Ensure appropriate labeling of storage areas and dispensed drug product.

Ensure a copy of the informed consent form is available in the Pharmacy prior to filling the first medication order/prescription for an individual study participant.

### V. PROCEDURES/GUIDELINES

1. Upon receipt of a prescription for an in-patient or an out-patient for an investigational drug, the following elements of the prescription must be present:
  - a) Name of the hospital
  - b) Study name or number
  - c) Patient name or patient initials assigned during study enrollment
  - d) Medical record number/financial number for patient (if applicable) or patient study ID
  - e) Location of the patient for inpatient studies
  - f) Date
  - g) Name of the drug
  - h) Dosage
  - i) Frequency
  - j) Duration, if applicable
  - k) Quantity to be dispensed
  - l) Principal investigator's signature or his designee
  - m) Printed name of prescriber
2. A copy of the patient's informed consent shall be provided to the Research Pharmacist prior to filling the first order/prescription of study drug for the participant. If the copy of informed consent is not available, the pharmacist shall contact the study coordinator.
3. The dispensing pharmacist shall ensure that drug labeling for any dispensed products include the cautionary statement, "Investigational drug limited by law to investigational use only."
4. When dispensing, the pharmacist processes the medication order as per the policies Verification and Review of Medication Orders and Patient Medication Orders. The dispensing pharmacist records the date of dispensing, quantity dispensed lot (or kit), number of the drug and dispense of the labeled drug to the principal investigator or his designee. Such information shall be recorded on drug accountability forms/logs each time study drug is dispensed.
5. If a patient is admitted to SUNY Downstate Medical Center and is participating in a study that involves investigational study drugs from another pharmacy, it is up to the attending physician to determine whether the study drugs shall be continued during the admission. The attending physician may order continuation of the investigational agent as a non-formulary medication brought into the hospital by the patient or patient's designee. The attending

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physician must obtain a copy of the study protocol and patient consent form for the investigational study and provide such documentation to the Investigational Drug Lab prior to non-formulary approval and medication administration.

6. Investigational drugs can also be dispensed to principal investigators or their designees. The same patient information and other details as required for investigational drugs dispensed directly to patients, as described above, are required. However, the investigator may request drug supplies that are anticipated for patients expected to be seen for clinical trial visits during the following one-week period (this period can be extended for up to two weeks if holidays or other interruptions to the normal daily Investigational Drug Lab service are predicted.) It is the responsibility of the investigator or the investigator's designees to return any indisposed medicine containers to the Investigational Drug Lab, as well as unused medications that are returned by patients.
7. Investigational drugs dispensed for outpatient use must be dispensed and labeled according to legal requirements for dispensing,

### VI. ATTACHMENTS

None

### VII. REFERENCES

NYSDOH regulations on the use of investigational drugs in human subjects.  
 FDA regulations on the use of investigational drugs in Phase III Clinical Drug Trials.

Date Reviewed	Revision Required (Circle One)		Responsible Staff Name and Title
	Yes	No	
8/01 (New)	<b>Yes</b>	<b>No</b>	Nicholas Galeota, Director of Pharmacy
8/03	<b>Yes</b>	<b>No</b>	Pharmacy & Therapeutics Committee
10/05	<b>Yes</b>	<b>No</b>	Nicholas Galeota, Director of Pharmacy
10/07	<b>(Yes)</b>	<b>No</b>	Executive Committee
10/07	<b>Yes</b>	<b>No</b>	Pharmacy and Therapeutics Committee
7/12	<b>(Yes)</b>		LilyAnn Jeu, PharmD, Medication Safety Pharmacist Motria Mishko, PharmD, Investigational Drug Pharmacist
1/2016	<b>Yes</b>	<b>(No)</b>	LilyAnn Jeu, Medication Safety Pharmacist
2/2017	<b>(Yes)</b>	<b>No</b>	Nicholas Galeota, Director of Pharmacy