

October 10, 2008

**COLUMBIA UNIVERSITY MEDICAL CENTER
POLICY RELATING TO THE USE AND CONTROL OF
INVESTIGATIONAL DRUGS FOR OUTPATIENTS**

POLICY:

This Columbia University Medical Center (“CUMC”) Policy outlines the standards for the storage, dispensing and administration of, and accountability for, investigational drugs administered to outpatients at CUMC. Where applicable, this Policy is compliant with the New-York Presbyterian Hospital (“NYP”) policy on Use and Control of Investigational Drugs and other NYP policies relating to the storage, dispensing and administration of investigational drugs.

For purposes of this Policy, an “investigational drug” is defined as:

- Any drug not approved by the Food and Drug Administration (“FDA”) which is being studied under an Investigational New Drug Application (21 CFR 312) or a New Drug Application (21 CFR 314); and
- Any drug approved by the FDA which is central to the design of a research study and is being provided by the sponsor of the study or the investigator involved in the study.

This Policy is intended to comply with 21 CFR 312 (Investigational New Drug Application), 21 CFR 314 (Application for FDA Approval to Market a New Drug), New York State regulations, the requirements of the Joint Commission on Accreditation of Healthcare Organizations (the “Joint Commission”) and safe medication practice standards.

For investigational drugs used for inpatients, see the companion Policy “Columbia University Medical Center Policy Relating to the Use and Control of Investigational Drugs for Inpatients at New York-Presbyterian Hospital”.

APPLICABILITY:

This Policy applies to all Columbia University faculty and staff involved in the prescription, storage, dispensing and administration of, and accountability for, investigational drugs used in human subjects research at CUMC.

PROCEDURES:

1. Any use of an investigational drug must be approved by the Columbia University Institutional Review Board or another Institutional Review Board named in the CUMC Federal Wide Assurance (in either case, an “IRB”). All research protocols using investigational drugs must contain the investigational drug information required to be provided in a Columbia University IRB submission. Such information must be reproducible and readily available to all CUMC and NYP staff providing care to patients in a research study. All protocols that include commercially available drugs where NYP supplies will be used must be approved by the NYP Department of Pharmacy .

2. The principal investigator or a co-investigator or his/her IRB-approved designee will inform all

study subjects or their legal representatives that the drug product being used is investigational. Except in exceptional circumstances, as approved by the IRB, informed consent of the subject or his/her legal representative must be obtained prior to the use of an investigational drug.

3. The principal investigator and co-investigators should be identified in the IRB-approved protocol and the FDA Form 1572, if applicable.

4. All professionals involved in the storage, dispensing and administration of investigational drugs must hold active licenses in good standing with New York State, carry adequate personal medical liability insurance and adhere to CUMC credentialing requirements. When Schedule II – IV Controlled Substances are used in a research study, all investigators that prescribe such controlled substances must obtain a “Class 4 Researcher” License issued by the New York State Department of Health. The CUMC Research Pharmacy (the “Research Pharmacy”) will be directed by a licensed pharmacist.

5. As required by federal regulations, the principal investigator is responsible for the handling and use of investigational drugs, provided that the principal investigator may delegate certain of such responsibilities to the Research Pharmacy and to other individuals in accordance with the terms of this Policy.

6. All investigational drugs must be stored either within the Research Pharmacy or in an area controlled by the Research Pharmacy where the investigational drug supplies are secured and stored separately from other drugs and supplies.

7. Only the principal investigator or a co-investigator may write an order for an investigational drug. Prior to dispensing any investigational drug, a complete medication order must be written, signed and entered into the patient’s medical record and the medication profiling system. The prescriber must review the appropriateness of the investigational drug in the context of all other medications being taken by the patient.

8. Investigational drugs may be dispensed once a fully completed order has been received by the Research Pharmacy, and the Research Pharmacy has reviewed the study protocol and the patient’s medication profile and the prescription information has been entered into the medication profiling system.

9. All investigational drugs must be dispensed either directly by the Research Pharmacy or from a Research Pharmacy-controlled automated dispensing cabinet. All dispensing procedures must be approved by the Research Pharmacy before study initiation.

10. Any dispensed investigational drug may be administered to a patient by a physician investigator, a nurse practitioner or a registered nurse in accordance with NYP Policies.

11. Dispensed products must be labeled in accordance with Section 13 of this Policy.

12. In all cases, the principal investigator is responsible for the proper maintenance of all investigational drug records required by the applicable sponsor, the IRB, the FDA, the Joint Commission and federal and state regulations. Product lot numbers and expiration dates must be recorded for each product dispensed, together with patient identifiers for the purpose of possible drug recalls.

13. All dispensed investigational drugs for outpatients must be labeled with, minimally, the

following information:

- A distinctive label that states “For Investigational Use Only”
- Name and address of the institution
- Name of the drug
- Dosage form, strength and quantity.
- Directions for use of the drug
- Patient’s name
- Prescription number
- Date dispensed
- Prescriber’s name
- Patient’s address
- Expiration time or date
- Initials of the individual dispensing the drug

14. As an agent for the principal investigator, the Research Pharmacy will, pursuant to a written agreement, order, store, inventory, dispense and destroy or return to the sponsor all investigational drugs. Accountability records for all drug dispensing will be maintained for appropriate periods of time.

REFERENCES:

1. 21 CFR 312 (Investigational New Drug Application).
2. 21 CFR 314 (Application for FDA Approval to Market a New Drug).
3. Joint Commission on the Accreditation of Health Care Organizations, Accreditation Manual.
4. CFR Title 42, Volume 3, Chapter IV, Part 482.25, Conditions of Participation: Pharmaceutical Services.