

LOS ANGELES GENERAL MEDICAL CENTER POLICY

Subject: CONTROL OF INVESTIGATIONAL DRUGS		Original Issue Date: 4/16/02	Policy # 901
		Supersedes: 7/20/20	Effective Date: 05/08/23
Policy Owner(s): Director of Pharmacy Services Executive Sponsor(s): Chief Medical Officer			
Departments Consulted: Pharmacy & Therapeutics Committee Nursing Services	Reviewed & Approved by: Attending Staff Association Executive Committee Senior Executive Officer	Approved by: Chief Medical Officer	
		Chief Executive Officer	

PURPOSE

To ensure that policies and procedures support the proper storage, distribution, and control of investigational medications. To ensure compliance with all applicable rules and regulations that govern the use of investigational drugs within the Medical Center.

POLICY

Investigational drugs will be integrated into the pharmaceutical care plan of each individual patient. Appropriate health care professionals will be knowledgeable about all pharmaceutical agents that are ordered for a specific patient. The Attending Staff Association Committee that oversees medication use, Pharmacy and Therapeutics Committee, will be knowledgeable regarding all active investigational drug studies that are conducted within the institution.

PROCEDURE

The following steps shall be followed for all investigational drug use for patients at the Los Angeles General Medical Center:

- All investigational drugs will be shipped to and received by the appropriate pharmacy department unit (inpatient, outpatient clinics, comprehensive health centers, Investigational Drug Service, Norris, etc). For studies that are conducted at more than one facility, i.e., cancer research at the Medical Center and USC\Kenneth Norris, Jr. Cancer Hospital, the investigational drugs can be sent to either Pharmacy Department. The transfer of medication between facilities will be conducted through the respective Pharmacy Departments.
- All investigational drugs will be returned to the sponsor through the appropriate pharmacy department operation.
- Since the Medical Center Pharmacy Department is responsible for ensuring that all medication is properly stored and distributed, regular audits will be conducted on all investigational storage locations outside of the Pharmacy Department.

		Page 2	Of 2
Subject: CONTROL OF INVESTIGATIONAL DRUGS	Effective Date: 05/08/23	Policy # 901	

- The Medical Center Pharmacy Department will provide a regular report to the Pharmacy and Therapeutics Committee of the Attending Staff Association regarding all investigational drug studies that are "active within the Medical Center. "Active" is defined as studies that are currently enrolling patients within the Medical Center.
- All investigational drugs must be ordered on a physician order form by an appropriately credentialed clinician and sent to the Pharmacy Department.
- The Pharmacy Department must enter the investigational drug into the patient's medication record.
- Nursing must ensure that the investigational drug is listed on the Medication Administration Record and that the administration is properly documented.

RESPONSIBILITY

Pharmacy Department
Attending Staff
Pharmacy and Therapeutics Committee
Nursing Staff

REFERENCES

California Code of Regulations, Title 22, 70263
Joint Commission Standards (Care of Patients)

REVISION DATE

March 28, 2005; October 1, 2008; December 10, 2013, March 14, 2017; July 20, 2020,
May 8, 2023