LAC+USC MEDICAL CENTER
DEPARTMENT OF NURSING SERVICES POLICY

Subject: **RESEARCH AND INVESTIGATIONAL DRUGS**	Original Issue Date: 08-91	Policy # **912**
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Departments Consulted:	Reviewed & Approved by:	Approved by:
Pharmacy	Professional Practice Committee Pharmacy & Therapeutics Committee Nurse Executive Council Attending Staff Association Executive Committee	(signature on file) Nancy Blake Chief Nursing Officer

PURPOSE

To describe guidelines for the Registered nurse (RN) upon the administration of research and investigational drugs.

POLICY

Research is a recognized part of the LAC+ USC Medical Center activities. The Nursing department supports Institutional Review Board (IRB) approved clinical drug research for health care practitioners.
An RN can administer research and investigational drugs provided:

- Nursing is consulted during planning phase, if nursing time is needed.
- The Institutional Review Board has approved protocol.
- A copy of the protocol is on the unit where the research is being conducted.
- Nursing staff has received orientation to the specific drug.
- The patient and/or patient's authorized representative has signed the Institutional Review Board Informed Consent Form and it has been placed in the medical record.
- Drugs are distributed through Pharmacy.
- Investigators/research nurse present when the first group of patients are entered into the study.

PROCEDURE

IRB approval is required to conduct research at LAC+ USC (Inpatient Tower, Clinic Tower, Outpatient Building, Rand Schrader and Augustus Hawkins). The LAC+ USC Medical Center Research Approval Form must be completed, and signatures obtained from the County Clinical Team (Administrator, Nursing and Clinical).

- Nursing staff may confirm IRB approval of a research study via the SharePoint Research site (under Departments- Other Services – Research).
- Verify the patient has a signed informed consent. A copy of the informed consent shall be available in the medical chart. The nurse shall contact the principal investigator or the study coordinator if a consent form cannot be found in the chart.
- Review of drug information regarding the pharmacology, proper administration and disposal, toxicities and monitoring guidelines for the investigational drug.
- All investigational drug use must be initiated with a provider's order.

DOCUMENTATION

- Document in accordance with documentation standards.
- After administration of the medication document drug, dose, route, and time medication given on the medication administration record.
- Document and report any adverse reactions and any relevant patient responses to the investigational agent in the Safety Intelligence: Event Report.
- Return any unused drug to Investigational Drug Service Pharmacy (IDS)

The nurse may contact IDS at 323-865- 3538, Monday –Friday 8am- 430pm.
for any questions regarding the use of an investigational drug.

- During off hours, the nurse will contact the prescribing provider.

REFERENCES

Pharmacy Department Policy and Procedure Manual

REVISION DATES

92, 93, 94, 95, 96, 98, 2000, 12/01, 03/02, 08/03, 12/03, 06/04, 02/08, 02/14, 12/21