



HEALTH RESEARCH ASSOCIATION

1640 Marengo Street – 7th Floor
Los Angeles, CA 90033

POLICY & PROCEDURE

Page 1 of 6

Subject: PHARMACY DEPT. P&P MANUAL	Issued By: HRA ADMINISTRATION
	Approved By: Kathleen R. Hurtado R.Ph. President & CEO

Policy #: 250	Issue Date: December 1, 2004	Revised Date: November 1, 2006	Effective Date: November 1, 2006
------------------	---------------------------------	-----------------------------------	-------------------------------------

Reference:
P&P #250 with effective date of 12/01/2004.

PURPOSE

To establish the requirements and procedures for conducting clinical (human) drug research, within the LAC+USC Healthcare Network Facilities although primarily at the LAC+USC Medical Center.

POLICY

- TO SUPPORT CLINICAL RESEARCH:** Research is an integral part of the LAC+USC Healthcare Network activities. The Pharmacy Department, through the Investigation Drug Service (IDS), supports Institutional Review Board (IRB) approved clinical drug research for health care practitioners and patients;
- TO ENSURE THAT INFORMED CONSENT PROCEDURES WERE FOLLOWED:** All patients who participate in investigational drug studies must provide Informed Consent in writing. A Signed Informed Consent Form must be obtained from EVERY patient – or the patient’s legally authorized representatives – before ANY treatment is received. It is the responsibility of the Principal Investigator (PI) to obtain Informed Consent. It is the responsibility of the IDS Pharmacist in Charge to ensure that a faxed copy of the Informed Consent Form signature page is obtained FROM EACH PATIENT prior to dispensing;
- INSTITUTIONAL REVIEW BOARDS (IRBs):** The USC Institutional Review Boards review, approve, and provide continuing review for all research in accordance with the Institution’s assurance to the Office for Human Research Protections (OHRP), National Institutes of Health (NIH), and in the event of research involving drugs, the Food and Drug Administration (FDA). The IRB office is located at the entrance of the LAC+USC Medical Center: 2020 Zonal Ave., Room 425, Los Angeles, CA 90033, Telephone: (323) 223-2340;
- USC IRB POLICIES & PROCEDURES:** For all IRB-related policies & procedures, follow this link: <http://www.usc.edu/admin/provost/oprs/policies>.

Subject: PHARMACY DEPT. P&P MANUAL		Issued By: HRA ADMINISTRATION	
		Approved By: Kathleen R. Hurtado R.Ph. President & CEO	
Policy #: 250	Issue Date: December 1, 2004	Revised Date: November 1, 2006	Effective Date: November 1, 2006

GUIDELINES & PROCEDURES

1. **IRB APPLICATION SUBMISSION:** The following instructions are provided to guide researchers in submitting human subject research protocols to the HSIRB for review:
 - a. NCI CIRB website: <http://www.ncicirb.org> - general information and access to downloadable protocol versions and consent forms;
 - b. HSIRB website: <http://www.usc.edu/admin/provost/oprs/hsirb/> - links to the HSIRB website, instructions and sample informed consent template language, and other HSIRB forms are available.
 - c. iStar website: <https://istar-chla.usc.edu> – IRB electronic submission application. Investigators are required to submit CIRB-approved protocols through iStar;

Note: Review & approval by the LAC+USC Healthcare Network departments and committees must be obtained prior to initiation of the protocol.

2. **IRB APPROVAL:** Upon final approval (all stipulations satisfied, if any), the IRB office will provide a final approval letter and an approval stamped informed consent.
3. **WHEN IDS SERVICES ARE REQUIRED:** When Investigational Drug Services (IDS) are required in support of a clinical drug trial, the PI must submit the following documents to the IDS:
 - a. Protocol (all available versions);
 - b. IRB final approval letter;
 - c. IRB-Approved Informed Consent Document(s);
 - d. Clinical Investigators Brochure (if provided by the sponsor);
 - e. Pharmacy Binder (if applicable).

Note: Minutes from the IRB meetings shall automatically be forwarded to the Pharmacy and Therapeutics Committee as well as to IDS.

4. **IDS ADDRESS:** All of the above, plus any investigational drugs, must be shipped to: 1200 N. State St., Trailer 25-A, Los Angeles, CA 90033. Phone (323) 222-8933; Fax (323) 222-9925.



HEALTH RESEARCH ASSOCIATION

1640 Marengo Street – 7th Floor
Los Angeles, CA 90033

POLICY & PROCEDURE

Page 3	of 6
--------	------

Subject: PHARMACY DEPT. P&P MANUAL		Issued By: HRA ADMINISTRATION	
		Approved By: Kathleen R. Hurtado R.Ph. President & CEO	
Policy #: 250	Issue Date: December 1, 2004	Revised Date: November 1, 2006	Effective Date: November 1, 2006

5. **COMPASSIONATE USE PROTOCOLS:** When a practitioner determines that a patient may clinically benefit from an investigational drug, the following must be obtained prior to administration of such therapy:
 - a. **IRB APPROVAL** by calling (323) 223-2340. Or, call the IDS at (323) 222-8933 for assistance;
 - b. **WHEN IRB IS CLOSED** If the IRB office is closed and the Secretary of the IRB cannot be reached via pager, the PI may request authorization from either the Chair of the Pharmacy and Therapeutics Committee or the Medical Officer on Duty (MOD). Ask the medical center operator for the MOD;
 - c. **NOTIFICATION OF EMERGENCY USE** Notification of such emergency use must be submitted to the IRB Office within 5 days of compassionate use drug administration.

6. **NON-INSTITUTION PROTOCOLS:** When a patient is admitted to this institution on an investigational drug protocol that has not been reviewed and approved by our local IRB, the physician must:
 - a. **USE CLINICAL JUDGMENT** For example, do not interrupt investigational continuous intravenous therapy for serious diseases such as primary pulmonary hypertension and congestive heart failure;
 - b. **OBTAIN ORIGINAL IRB APPROVAL & INFORMED CONSENT DOCUMENTATION** Determine who the PI is and contact the research staff for drug information, protocol, their IRB approval documents and a signed Informed Consent Document for that patient;
 - c. **OBTAIN LOCAL IRB APPROVAL** by calling (323) 223-2340. Or, call the IDS at (323) 222-8933 for assistance. If the IRB office is closed and the Secretary of the IRB cannot be reached via pager, the investigator may request authorization from the Chair of the Pharmacy and Therapeutics Committee pending subsequent approval from the IRB. The local IRB must be contacted for review on the next business day for further instructions.



HEALTH RESEARCH ASSOCIATION

1640 Marengo Street – 7th Floor
Los Angeles, CA 90033

POLICY & PROCEDURE

Page 4	of 6
--------	------

Subject: PHARMACY DEPT. P&P MANUAL		Issued By: HRA ADMINISTRATION	
		Approved By: Kathleen R. Hurtado R.Ph. President & CEO	
Policy #: 250	Issue Date: December 1, 2004	Revised Date: November 1, 2006	Effective Date: November 1, 2006

7. STORAGE, CONTROL & DISTRIBUTION OF INVESTIGATIONAL DRUGS:

- a. **SHIP TO ADDRESS** All clinical trial materials (CTM) should be shipped to the Investigational Drug Service (IDS), Health Research Association Pharmacy: 1200 N. State St., Trailer 25-A, Los Angeles, CA 90033. Phone (323) 222-8933;
- b. **LABELED “FOR INVESTIGATIONAL USE ONLY”** Prescription labels will be distinguished from other drug labels by a message “For Investigational Use Only;”
- c. **INFORMED CONSENT** The IDS staff must perform verification of a signed, informed consent before the initial dose of an investigational drug is dispensed;
- d. **DRUG INVENTORY COUNTS** Inventory of CTM will be performed on an as needed basis – but no less than quarterly – as determined by the level of activity. Inventory counts must be taken upon the receipt of all new CTM shipments and at study close-out. CTM accountability records must be retained according to ICH guidelines for Good Clinical Practice (<http://www.ich.org/LOB/media/MEDIA482.pdf>);

8. **IDS TO DISTRIBUTE INVESTIGATIONAL DRUGS:** The IDS Pharmacy will inventory all investigational study drugs used at the LAC+USC Medical Center and will coordinate the distribution of investigational medications throughout the Medical Center. All inpatient and outpatient distribution of investigational Study Medication will be dispensed through the IDS Pharmacy;

9. **REQUIRED DOCUMENTATION & CLOSE OUT PROCEDURE:** At the conclusion of a study, the PI must notify the IDS Pharmacist in Charge. All returns to the study sponsor must be processed through the IDS Pharmacy. Records will be created listing the name of the study, PI, name of the drug, date and quantity that arrived into the Medical Center and the date and quantity of investigational drug destroyed or leaving the Medical Center;

10. **IN-PATIENT DISPENSING – PHYSICIANS’ ORDERS REQUIRED:** Inpatient investigational medications must be written on an inpatient Physicians’ Orders. The medications must be entered into the Pharmacy Information System by research pharmacists. All doses must contain appropriate labeling and patient information. Administration of the investigational medication must be recorded in the Medication Administration Record (MAR).



HEALTH RESEARCH ASSOCIATION

1640 Marengo Street – 7th Floor
Los Angeles, CA 90033

POLICY & PROCEDURE

Subject: PHARMACY DEPT. P&P MANUAL		Issued By: HRA ADMINISTRATION	
		Approved By: Kathleen R. Hurtado R.Ph. President & CEO	
Policy #: 250	Issue Date: December 1, 2004	Revised Date: November 1, 2006	Effective Date: November 1, 2006

- 11. **OUT-PATIENT DISPENSING:** Outpatient investigational drug dispensing, must contain appropriate prescription labeling and patient information. The doses dispensed must be in the patient’s medical record. Drug orders for investigational study drugs are entered into the LAC+USC Medical Center Pharmacy Information System;
- 12. **QUARTERLY REPORTS FROM IDS TO P&T COMMITTEE:** IDS will submit a quarterly status report to the P&T Committee;
- 13. **INVESTIGATIONAL DRUG ADMINISTRATION:** Only Registered Nurses, properly in-serviced by the PI or the research team, may administer investigational drugs.

PRIOR TO ADMINISTRATION of an investigational drug, the nurse shall:

- a. **VERIFY INFORMED CONSENT** The nurse must verify the patient has a signed an informed consent document. A copy of the informed consent shall be available in the medical chart. The nurse shall contact the PI or the study coordinator if a consent form cannot be found in the chart;
- b. **REVIEW DRUG INFORMATION** The nurse must conduct a review of drug information regarding the pharmacology, proper administration and disposal, toxicities and monitoring guidelines for the investigational drug.
Note: It is the responsibility of the principal investigator to provide staff with adequate information regarding the investigational drug. The nurse may contact the IDS @ 222-8933 for information or assistance.
- c. **VERIFY DOSING & DIRECTIONS** The nurse must verify the investigational drug’s appropriate dosing and directions for use.

AFTER ADMINISTRATION of an investigational drug, the nurse shall:

- a. **DOCUMENT MAR** The nurse must document on the medication administration record (MAR) the drug, dose, route and time that the drug was given;
- b. **REPORT SIDE EFFECTS** The nurse must inform the PI or study coordinator of any side effects or unexpected patient responses to the drug;
- c. **DOCUMENT NURSING NOTES** The nurse must document in Nursing notes, any adverse events and any relevant patient response(s) to the investigational agent;
- d. **RETURN UNUSED DRUGS** The nurse must return any unused drug to IDS.



HEALTH RESEARCH ASSOCIATION

1640 Marengo Street – 7th Floor
Los Angeles, CA 90033

POLICY & PROCEDURE

Page 6	of 6
--------	------

Subject: PHARMACY DEPT. P&P MANUAL		Issued By: HRA ADMINISTRATION	
		Approved By: Kathleen R. Hurtado R.Ph. President & CEO	
Policy #: 250	Issue Date: December 1, 2004	Revised Date: November 1, 2006	Effective Date: November 1, 2006

RESPONSIBILITY

- PIs
- Study Coordinators
- Patient Caregivers
- IDS Pharmacists and Pharmacy Technicians
- HRA's President & CEO