



HEALTH RESEARCH ASSOCIATION

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

POLICY & PROCEDURE

Subject:		Issued By:	
INVESTIGATIONAL DRUG STORAGE & DISTRIBUTION		IDS PHARMACY	
		Approved By: Kathleen R. Hurtado R.Ph. HRA's President & CEO	
Policy #:	Issue Date:	Revised Date:	Effective Date:
2001	September 1, 2007	April 16, 2008	April 20, 2008

Reference: Original Investigational Drug Storage & Distribution policy dated 4-12-2006 and further revised as of 9-1-2007.

PURPOSE

To ensure that all investigational drugs are stored and distributed in accordance with institutional policies and procedures, as well as state and federal laws.

STORAGE TEMPERATURE DEFINITIONS

1. **ROOM TEMPERATURE RANGE:** 15 degrees C to 30 degrees C;
2. **REFRIGERATOR TEMPERATURE RANGE:** 2 degrees C to 8 degrees C;
3. **FREEZER TEMPERATURE RANGE:** minus 20 degrees C to minus 40 degrees C.

POLICY

1. **IDS PHARMACY=CENTRAL DISTRIBUTION POINT:** Investigational drugs for all HRA-administered human subjects' research studies at the LAC+USC Healthcare Network must be shipped to and received by the IDS Pharmacy at the following address:

Investigational Drug Service
Health Research Association Pharmacy
1200 North State St. Trailer 25A
Los Angeles, CA 90033
Attn: Pharmacist-in-Charge
Phone: (323) 222-8933
Fax: (323) 222-9925

Any investigational drugs to be returned to project Sponsors also must be handled by the IDS Pharmacy;

2. **TRANSFERS:** Any transfer of medication between Pharmacy Department units must be conducted by the appropriate Pharmacy Department (inpatient, outpatient clinics, comprehensive health centers, Norris Hospital pharmacy, etc...);



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3. **STORAGE ACCORDING TO PROTOCOL:** All investigational drugs must be stored in accordance with the instructions listed in the study’s IRB-approved protocol.

GUIDELINES & PROCEDURES

1. **TEMPERATURE LOGS:** A log of temperatures for the refrigerator, freezer and ultra-low freezer – as well as the room temperature in the IV “clean” room, the stock room and the main room – must be maintained by IDS Staff on a daily basis. The log must indicate the date, temperature, location and the initials of person recording the temperature;
2. **REPORT ALL TEMPERATURE DEVIATIONS TO PHARMACIST-IN-CHARGE:** Any deviation from the temperature definitions described on the previous page of this policy must be immediately reported to the Pharmacist-in-Charge;
3. **IF TEMPERATURE DEVIATION OCCURS, DRUGS MUST BE QUARANTINED:** In the event that any stored drugs are subjected to temperatures outside of the temperature ranges described on the previous page, all such drugs must be immediately quarantined. Any such event must be documented and notices must be sent to Sponsors, Principal Investigators (PIs) and to HRA’s administrative offices. All such drugs shall remain quarantined until other instructions are received by study Sponsors in writing;
4. **TEMPERATURE RECORDS MUST BE READILY AVAILABLE TO MONITORS/AUDITORS:** It is the responsibility of the Pharmacist-in-Charge to keep temperature logs readily available for study site monitors/auditors to review;
5. **SEGREGATE DRUGS BY PROTOCOL:** The Pharmacy Staff will segregate investigational drugs by study protocol;
6. **QUARTERLY REPORTS TO THE P&T COMMITTEE:** The Pharmacist-in-Charge also is responsible for quarterly Pharmacy Quality Assurance reporting to the LAC+USC Healthcare Network Pharmacy and Therapeutics (P&T) Committee;



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7. **UNUSED INVESTIGATIONAL DRUGS MUST BE RETURNED TO IDS:** Any previously dispensed but unused investigational drugs must be returned to the IDS Pharmacy. Only the IDS Pharmacy may return unused investigational drugs to Sponsors.

RESPONSIBILITY

All IDS Staff
PIs
The PI's Study Team