Institutional Review Board Drug Inventory Form for LAC+USC Healthcare Network

Titl	le of Project:			
Pri	ncipal Investigator:			
1.	Does this study involve the administration of any <u>INPATIENT OR OUTPATIENT INVESTIGATIONAL</u> drugs within the LAC+USC Health Care Network?			
	No Yes (If yes, then proceed to Item 2)			
2. The principle investigator must submit a copy of the protocol, Investigator's Brochurc completed Drug Inventory Form to the following:				
	□ IRB			
	☐ Investigational Drug Service (IDS) (Fax: 323-222-9925)			

3. Review the LAC+USC Healthcare Network Policy #250 on Investigational Drugs.

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 governs the use of investigational drugs within the network.

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 (P&T) 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 drugs used for patients at the LAC+USC Healthcare Network.

- All <u>INPATIENT AND OUTPATIENT</u> Investigational drugs will be shipped to and received by the
 appropriate pharmacy department unit (inpatient, outpatient, 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.
- Network Pharmacy Department is responsible for ensuring that all medication is properly stored and distributed.
- The Network 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 Network".
 "Active" is defined as studies that are currently enrolling patients within the Network
- All <u>INPATIENT</u> investigational drugs must be ordered on a physician order form <u>FROM THE PATIENTS</u>
 <u>CHART</u> by an appropriately credentialed clinician and <u>THE "YELLOWTAIL</u> sent to the Pharmacy Department.
- The Pharmacy Department must enter the investigational drug into the patient's medication record.
- Nursing must ensure that the <u>INPATIENT</u> investigational drug is listed on the Medication Administration Record (MAR) and that the administration is properly documented.

Responsibility: Pharmacy Department, Attending Staff, P&T Committee, Nursing Staff

<u>References:</u> California Code of Regulations, Title 22, 70263, JCAHO Standards MM.7.40, LAC+USC Healthcare Network Policy/Procedure #250

List the study drugs to be administered and check if FDA approved or experimental. Who has financial responsibility for the drug? (study sponsor vs. LAC+USC Medical Center). Prior to entering the LAC+USC Network, who will be supplying the drug (e.g.: commercial, drug company sponsor, IDS Research Pharmacy, Norris Pharmacy etc)?

LIST OF DRUGS AND BIOLOGICS IN THIS IRB STUDY

DRUG (One per line)	FDA APPROVED for any indication	IND SUBSTANCE SEE #1 BELOW	FINANCIAL RESPONSIBLITY (DRUG SPONSOR OR LAC+USC?)	DRUG SUPPLIER BEFORE ENTERING LAC+USC NETWORK	STORAGE AREA
					□HRA Pharmacy (IDS)
					□Norris Pharmacy
					□LAC-USC Medical Center Pharmacy (Location)
					□University Hospital Pharmacy
					□HRA Pharmacy (IDS)
					□Norris Pharmacy
					□LAC-USC Medical Center Pharmacy (Location)
					□University Hospital Pharmacy
					□HRA Pharmacy (IDS)
					□Norris Pharmacy
					□LAC-USC Medical Center Pharmacy (Location)
					□University Hospital Pharmacy
					□HRA Pharmacy (IDS)
					□Norris Pharmacy
					□LAC-USC Medical Center Pharmacy (Location)
					□University Hospital Pharmacy
					□HRA Pharmacy (IDS)
					□Norris Pharmacy
					□LAC-USC Medical Center Pharmacy (Location)
					□University Hospital Pharmacy

With my signature below, I attest that this is an accurate listing of all drugs used in this study and that I will follow the Healthcare Network Policy on Investigational Drugs.

Print Primary Investigators Name	Signature	Date