



HEALTH RESEARCH ASSOCIATION

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

POLICY & PROCEDURE

Subject: DISPENSING & LABELING OF INVESTIGATIONAL DRUGS		Issued By: IDS PHARMACY	
		Approved By: Kathleen R. Hurtado R.Ph. HRA's President & CEO	
Policy #: 2010	Issue Date: May 1, 2007	Revised Date: August 13, 2007	Effective Date: September 1, 2007

Reference: Original Dispensing of Investigational Drugs Policy and Labeling of Investigational Drug Policy dated 4-12-2006 and updated as of 11-1-2006. See also, State of California Business and Professions Code section 4076 (a) (11) (A).

PURPOSE

To clarify the policies and procedures involving the dispensing and labeling of study drugs.

POLICY

1. **DISPENSED ACCORDING TO IRB-APPROVED STUDY-SPECIFIC PROTOCOL:** The IDS Pharmacy will dispense all study drugs according to the individual study's IRB-approved study-specific protocol. In doing so, the Pharmacist-in-Charge is responsible for ensuring that IDS Staff follow all institutional policies and procedures as well as all applicable federal and state regulations;
2. **MUST HAVE A WRITTEN ORDER FROM A LICENSED PHYSICIAN:** The IDS Pharmacy must receive a written order from a licensed physician listed on FDA Form 1572 in order to dispense a study drug to patients;
3. **STUDY MUST BE IRB-APPROVED WITH A FULLY-EXECUTED CONTRACT:** In order to dispense a study drug, the study-specific protocol must be IRB-approved and the contract with the study's Sponsor must be fully executed. Fully executed, signed contracts are kept on file at HRA's administrative offices.

GUIDELINES & PROCEDURES

1. **ORDERS MAY BE FAXED OR DELIVERED:** Written study drug orders may be faxed to the IDS Pharmacy at (323) 222-9925 or physically delivered to the IDS Pharmacy at 1200 North State St., Trailer 25A, Los Angeles, CA 90033;
2. **ONLY AUTHORIZED PRESCRIBERS:** Only those individuals authorized to prescribe investigational and/or study drugs under California Pharmacy Law section 4170 (c) may submit a written order to the IDS Pharmacy. According to the 2007 California Board of Pharmacy Lawbook, an authorized prescriber is described in the following manner:



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"Prescriber," as used in this section, means a person, who holds a physician's and surgeon's certificate, a license to practice optometry, a license to practice naturopathic medicine, a license to practice dentistry, a license to practice veterinary medicine, or a certificate to practice podiatry, and who is duly registered by the Medical Board of California, the State Board of Optometry, the Bureau of Naturopathic Medicine, the Dental Board of California, the Veterinary Medical Board, or the Board of Osteopathic Examiners of this state.

3. **PRESCRIBER'S NAME MUST BE LISTED ON FDA FORM 1572:** In addition to the other restrictions and requirements listed in this policy, a valid prescriber for a particular study-specific protocol must be listed on either FDA Form 1572 or an addendum to the FDA Form 1572. For more information about FDA Form 1572 go to: <http://www.fda.gov/cder/forms/1571-1572-help.html>;
4. **ENTER ORDER IN TWO COMPUTER SYSTEMS:** All investigational and/or study drug orders must be entered into two different computer systems:
 - a. **PANACEARX** – In order to properly dispense and label the drug, the order must be entered into the PanaceaRx pharmacy software database;
 - b. **LAC+USC SYSTEM** – In addition to the above data entry, the order also must be entered into the LAC+USC Healthcare Network Pharmacy Computer System to record the dosing to one of their patients if admitted into the hospital;
5. **FAX OF INFORMED CONSENT SIGNATURE PAGE REQUIRED:** It is the responsibility of the Pharmacist-in-Charge to ensure that the IDS Pharmacy has proof of a signed Informed Consent Document prior to dispensing drugs. It is the responsibility of the Principal Investigator (PI) or the PI's Study Team to ensure that the IDS Pharmacy receives a copy of the full Informed Consent (IC) Document. At a bare minimum, the Pharmacist-in-Charge must receive the first page of the IC Document containing the name of the study, as well as the signed signature page of each patient-specific IC Document. If this document is not already in the study-specific protocol binder, the Study Coordinator should be telephoned to request that a copy be faxed to the IDS Pharmacy at (323) 222-9925;

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6. **LABELING:** The final product must be labeled and the labeling must be verified by a licensed pharmacist. All labels must be created using the PanaceaRx software system and must contain ALL of the following information:

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| a. Patient name; | i. Prescription number; |
| b. Drug name; | j. Directions for use; |
| c. Physician name; | k. Study-specific protocol number; |
| d. Pharmacist initials; | l. Expiration date; |
| e. Pharmacy name and address; | m. Expiration time (IVs); |
| f. Concentration of drug; | n. Storage requirements; |
| g. Amount of drug; | o. Cytotoxic label, if required; and |
| h. Date prepared; | p. # of refills, if required. |

7. **AFFIX A PHYSICAL DESCRIPTION OF TABLETS OR CAPSULES TO MEDICATION CONTAINER:** For all commercially available oral, solid medications, a physical description of the drug must be affixed to the container. This description must contain the dosage form, color, shape and any ID codes that may appear on the tablets or capsules;

8. **COPY ORDER TO STUDY-SPECIFIC PROTOCOL BINDER:** All written orders received by the IDS Pharmacy must be copied and included in the study-specific protocol binder;

9. **UPDATE PANACEARX & DRUG ACCOUNTABILITY LOG SHEET AFTER DISPENSING:** Upon dispensing, the pharmacist should check to ensure that the PanaceaRx inventory record shows that drug was dispensed. In addition, the following information must be included on the Drug Accountability Log Sheet:

- a. Log date;
- b. Patient name/initials;
- c. Dose and quantity dispensed;
- d. Arithmetic and physical balance;
- e. Initials of licensed pharmacist and Staff-Member preparing log, if required; and
- f. Lot # and expiration date.



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10. **DELIVERY & SIGNATURE:** Upon delivery of the study drug to the designated clinic or ward, IDS Staff must obtain a signature from the person receiving the drug on the IDS Receipt Log confirming receipt of the drug;

RESPONSIBILITY

Pharmacist-in-Charge
IDS Staff
Authorized Prescribers