

Subject:		Issued By:	
DISCONTINUATION OF THERAPY		IDS PHARMACY	
		Approved By: Kathleen R. Hurtado R.Ph. HRA's President & CEO	
Policy #:	Issue Date:	Revised Date:	Effective Date:
2015	April 12, 2006	November 1, 2006	November 1, 2006

Reference: Original Discontinuation of Investigational Drug Therapy policy dated 4-12-2006.

PURPOSE

To ensure that proper procedures are followed whenever a clinical trial participant is discontinued from investigational drug therapy.

POLICY

1. **DISCONTINUATION MUST BE ON WRITTEN PHYSICIAN'S ORDER:** Any discontinuation of investigational drug therapy must be written on a Physician's Order with a copy sent to the IDS Pharmacy. The copy of the discontinuation order must be included in the protocol-specific study file folder.

GUIDELINES & PROCEDURES

1. **WHO MAY AUTHORIZE THE DISCONTINUATION OF INVESTIGATIONAL DRUG THERAPY:** Only those individuals authorized to prescribe investigational drugs under California Pharmacy Law section 4170 (c) (http://info.sen.ca.gov/pub/03-04/bill/sen/sb_0151-0200/sb_175_bill_20030902_chaptered.html), may submit a written discontinuation order to the IDS Pharmacy. The Physician's Order must be signed by an individual listed on FDA Form 1572 or listed on an addendum to the FDA 1572. For more information about FDA Form 1572 look here: <http://www.fda.gov/cder/forms/1571-1572-help.html>;
2. **WHAT MUST BE INCLUDED IN DISCONTINUATION ORDER:** All discontinuation orders must include the following information:
 - a. Patient Name;
 - b. Study Name and Protocol Number;
 - c. Name of Study Drug;
 - d. Time and Date of Discontinuation.
3. **TWO COPIES OF DISCONTINUATION ORDER:** One copy of the discontinuation order must be kept in the patient's chart, with another copy in the protocol-specific study file folder;



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POLICY & PROCEDURE

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4. **UPDATE LAC+USC PHARMACY COMPUTER SYSTEM:** The Pharmacist in Charge is responsible for ensuring that any open drug orders in the LAC+USC Pharmacy Computer System are cancelled whenever therapy is discontinued by a Physician's Order.

RESPONSIBILITY

Pharmacist in Charge
All IDS Staff