



HEALTH RESEARCH ASSOCIATION

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

POLICY & PROCEDURE

Subject: HANDLING DRUG RECALLS	Issued By: IDS PHARMACY
	Approved By: Kathleen R. Hurtado R.Ph. HRA’s President & CEO

Policy #: 2016	Issue Date: April 12, 2006	Revised Date: November 1, 2006	Effective Date: November 1, 2006
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Reference: Original Drug Recall policy dated 4-12-2006.

PURPOSE

To ensure that IDS Pharmacy Staff handle drug recalls consistently.

POLICY

1. **MEDICATION MUST BE OF THE HIGHEST QUALITY:** Only medication of highest quality may be dispensed from the IDS Pharmacy. Any drug of compromised or questionable quality shall be immediately removed from inventory with proper documentation, and the Panacea Rx software will be updated to reflect such removal.

GUIDELINES & PROCEDURES

1. **DRUG RECALL NOTIFICATIONS:** IDS will obtain notification of drug recalls from a variety of sources including: trial sponsors, pharmaceutical manufacturers and pharmaceutical distributors. Sometimes, internally observed problems may lead the Pharmacist in Charge to determine that a certain drug dose has been contaminated, or possibly contaminated, and should be removed from inventory;
2. **EXTERNAL NOTIFICATIONS BUT NO EXISTING INVENTORY:** Whenever an external recall notification is received by IDS, Staff will determine if the product was ever received as well as the quantity on hand, if any. If the product was never received, or if inventory has been depleted, the recall procedure is complete;
3. **EXTERNAL NOTIFICATIONS WITH EXISTING INVENTORY:** If the recalled product was received, and if any inventory remains at IDS, it will be quarantined and documented on the IDS Drug Accountability Log Sheet and/or the Sponsor’s Drug Accountability Log. The quarantined inventory shall be segregated from the rest of the stock until the entity making the recall notification advises IDS to return or destroy the quarantined product;
4. **IF NECESSARY, REFER TO MEDICATION ERRORS POLICY:** If drug has been destroyed or compromised by IDS Staff, please refer to the separate IDS policy entitled “Medication Errors;”



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5. **DOCUMENTATION:** All documentation pertaining to drug recalls, including notifications, return slips, and/or destruction records must be kept in the respective protocol-specific study file folder.

RESPONSIBILITY

Pharmacist in Charge
All IDS Staff