

Subject:		Issued By:	
DRUG RETURNS & DESTRUCTION		IDS PHARMACY	
		Approved By: Kathleen R. Hurtado R.Ph. HRA's President & CEO	
Policy #:	Issue Date:	Revised Date:	Effective Date:
2004	September 30, 2007	April 6, 2008	April 15, 2008

Reference: Original Handling of Drug Return and Destruction Policy dated 4-12-2006 and further revised as of 9-30-2007.

PURPOSE

To ensure that unused study drugs are either returned to the study's Sponsor or destroyed.

POLICY & PROCEDURES

1. **REGULATORY & CONTRACTUAL COMPLIANCE:** The IDS Pharmacy will comply with the following when returning or destroying study drugs:
 - a. All federal, state and local regulations;
 - b. Institutional policies and procedures;
 - c. Study Sponsors' study-specific protocols;
2. **SEQUESTRATION:** All investigational agents that are slated for return or destruction will be sequestered away from active study drugs upon notification of study completion. No drugs are to be "re-used" for different studies without prior authorization from the study Sponsor;
3. **UNUSED STUDY DRUGS MUST BE RETURNED TO IDS:** Any unused IDS drugs that were dispensed to a Principal Investigator (PI), or to their Study Team, must be returned to the IDS Pharmacy upon study completion or upon the request of the IDS Pharmacist-in-Charge;
4. **STORAGE FEES:** HRA charges an annual fee of \$1,000.00 for all active studies which covers Auditor/Monitor visits and annual IDS drug storage fees. For the safety of all IDS Pharmacy Staff Members, all used or partially used vials will be discarded/destroyed appropriately as the vials are used. If a Sponsor refuses to take possession of empty, or partially empty, vials – and refuses to allow the IDS Pharmacy to destroy the same – a monthly charge of \$100.00 will apply. *(Note: The assessment of this "storage fee" is optional for non-oncology studies and applied at the discretion of HRA's President & CEO).* All used medications for oncology studies will be discarded/destroyed appropriately to ensure the safety of IDS Staff Members. IDS Pharmacy will also appropriately discard/destroy any expired drugs;
5. **DOCUMENT RETURNS IN STUDY-SPECIFIC PROTOCOL BINDER:** All packing slips and/or bills of lading that are related to returns of study drugs must be kept in the study-specific protocol binder;



HEALTH RESEARCH ASSOCIATION

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

POLICY & PROCEDURE

Subject:		Issued By:	
DRUG RETURNS & DESTRUCTION		IDS PHARMACY	
		Approved By: Kathleen R. Hurtado R.Ph. HRA’s President & CEO	
Policy #:	Issue Date:	Revised Date:	Effective Date:
2004	September 30, 2007	April 6, 2008	April 15, 2008

6. **DESTRUCTION AUTHORIZATION:** The IDS Pharmacy will not destroy unused study drugs without prior authorization from the study Sponsor. However, in the event that a study Sponsor has been provided with a written notice of the IDS Pharmacy’s intention to return or destroy any unused study drug – and the Sponsor has not responded to such notification within 60 days – the IDS Pharmacy will interpret this inaction as a tacit authorization for destruction. The IDS Pharmacy shall notify any such Sponsor that their lack of response to the written request has led to drug destruction. The Pharmacist-in-Charge will record the following for all destroyed drugs: drug name, study-specific protocol number, drug strength, size and quantity, as well as the date of destruction;

7. **UPDATE INVENTORY COUNT IN SOFTWARE AND ON LOGS:** It is the responsibility of the Pharmacist-in-Charge to account for any drug returns and/or drug destruction by adjusting the inventory level within the pharmacy software as well as on all Drug Accountability Log Sheets;

8. **SPECIAL INSTRUCTIONS FOR CYTOTOXIC DRUGS:** All waste associated with chemotherapeutic and/or cytotoxic agents (i.e., syringes, needles, IV tubing, IV bottles, & medication vials) must be disposed of in the yellow chemotherapy “sharps” containers.

RESPONSIBILITY

Pharmacist-in-Charge
IDS Staff
PIs and their Study Teams