

Subject: STUDY SITE CLOSE-OUT		Issued By: IDS PHARMACY	
		Approved By: Kathleen R. Hurtado R.Ph. HRA's President & CEO	
Policy #: 2024	Issue Date: March 15, 2007	Revised Date: August 20, 2007	Effective Date: September 30, 2007

Reference: Original Study Site Close-Out Policy dated 4-12-2006 and updated as of 3-15-2007.

PURPOSE

To ensure that IDS Pharmacy Staff efficiently close out terminated studies according to the study contract – or according to other superseding instructions received from a study Sponsor – with proper documentation.

DEFINITION

Study Site Close-Out is the termination of an active study at IDS Pharmacy.

POLICY

1. **PROCEDURES TO BE FOLLOWED:** All IDS and HRA Staff will comply with the procedures described below. All clinical trial materials and documents will be stored in accordance with 21 CFR 312.62 located at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=312.62>.

PROCEDURE

1. **NOTIFICATION OF PENDING CLOSURE TO THE IDS PHARMACY:** Both the Principal Investigator (PI) and the Site Auditor/Monitor and/or Contract Research Administrator will inform the Pharmacist-in-Charge of a pending study closure near to the conclusion of the study. Notification may be made via e-mail (to: vludan@health-research.org), fax (323) 222-9925 or telephone (323) 222-8933;
2. **IDS STAFF WILL FOLLOW STUDY-SPECIFIC CLOSE-OUT PROCEDURES:** The Site Auditor/Monitor and/or Sponsor will notify the IDS Pharmacy in writing about the contract-specific pharmacy site Close-Out procedures (e.g. Close-Out letter with instructions on drug destruction and drug accountability or a formal Close-Out visit) related to their study;
3. **FINAL DRUG ACCOUNTABILITY:** The Sponsor's representative and IDS Staff will conduct a final drug accountability audit according to either contract-specific procedures or notification of alternate procedures from the study's Sponsor related to pharmacy Close-Out. For additional information on drug accountability, please refer to the IDS Pharmacy Policy & Procedure entitled "Inventory Control & Drug Accountability" located here: <http://www.health-research.org/files/pharmacy/Control.pdf>;



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POLICY & PROCEDURE

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- DRUG RETURNS OR FINAL DISPOSITION:** The IDS Study Close-Out Drug Accountability Log will be signed by the Site Auditor/Monitor or the Contract Research Administrator, IDS Staff, and/or the PI in order to account for all remaining study drug inventory. Relative to any final drug disposition (e.g. shipping unused drug back to the Sponsor or destroying the unused drug on-site), IDS Staff will follow the procedures outlined in either the study’s contract or the Close-Out notification documents received from the study’s Sponsor. If no such documents and/or procedures exist, IDS Staff will follow the instructions in the IDS Pharmacy Policy & Procedure entitled “Drug Returns & Destruction” located here: <http://www.health-research.org/files/pharmacy/DrugReturns.pdf>;
- PHARMACIST-IN-CHARGE NOTIFIES HRA’S ACCOUNTING DEPARTMENT OF CLOSE-OUT VISITS:** The Pharmacist-in-Charge will notify HRA’s Accounting Department of all Study Site Close-Out Auditor/Monitor visits.

RESPONSIBILITY

- PI
- Auditor/Monitor
- Sponsor or Sponsor’s representative (Contract Research Administrator)
- IDS Staff
- HRA’s Accounts Receivable Manager