

Subject:		Issued By:	
INTERNAL QUALITY ASSURANCE (AUDITS)		IDS PHARMACY	
		Approved By: Kathleen R. Hurtado R.Ph. HRA's President & CEO	
Policy #:	Issue Date:	Revised Date:	Effective Date:
2028	March 15, 2007	August 20, 2007	September 30, 2007

Reference: Original Internal Quality Assurance (Audits) Policy and Procedure dated 4-12-2006 and updated as of 3-15-2007. See also, California Board of Pharmacy Lawbook located at http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf.

PURPOSE

To closely monitor drug inventory in order to control losses and ensure compliance with applicable federal, state and local laws and regulations, including institutional policies and procedures, JCAHO and HIPAA.

POLICY

- REGULAR AUDITING OF MEDICATION PREPARATION, USAGE, STORAGE AND RECORD KEEPING:** The IDS Pharmacist-in-Charge will monitor current operations regularly to identify areas of inconsistency and to provide a mechanism for continuously improving the quality of services provided by the IDS Pharmacy. Related topics include: "Medication Error Reporting" Policy & Procedure (<http://www.health-research.org/files/pharmacy/Errors.pdf>) and "Adverse Drug Reaction (ADR) Reporting & Reviews" Policy & Procedure (<http://www.health-research.org/files/pharmacy/ADR.pdf>). All IDS Pharmacy Policies & Procedures are located at: <http://www.health-research.org/pp.htm>.
- FULFILLING STATE OF CALIFORNIA LAW REQUIREMENT:** Per the California State Board of Pharmacy Lawbook, all pharmacies in California must establish a quality assurance program.

PROCEDURES

- STUDY-SPECIFIC PROTOCOL BINDERS:** For each study-specific protocol in which the IDS Pharmacy is involved, a study-specific protocol binder must be prepared and contain the following:
 - A copy of the most updated study-specific protocol version as well as previous versions;
 - A copy of the Investigational Drug Brochure;
 - A copy of the Summary Dispensing Instructions;
 - The Institutional Review Board (IRB) Approval Letter;
 - Office of Contact Administration Approval with Executed Contract;
 - FDA Form 1572 located at: <http://www.fda.gov/opacom/morechoices/fdaforms/FDA-1572.pdf>;
 - Physician Orders;
 - Signed Informed Consent Form for each patient;



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POLICY & PROCEDURE

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- i. Drug receipts;
 - j. Drug returns or destructions;
 - k. Any correspondence from the Sponsor, the Principal Investigator, or the Study Coordinator regarding a specific study; and
 - l. Twenty-four hour contact information (telephone numbers) for study personnel;
2. **DRUG INVENTORY AUDIT:** After each prescription is filled, physical inventory and Panacea Rx inventory need to be reconciled. Then, if the physical inventory does not match the study logs and/or the Panacea Rx database, an internal audit will be performed on the product in question. The procedures documented below must be followed precisely:
- a. Check log arithmetic;
 - b. Check prescription orders against the logs;
 - c. Check drug storage area to see if drug was inadvertently misplaced;
 - d. Check Panacea Rx software system's inventory count; and
 - e. Record all findings in the log, and then place a memo to file in the study-specific protocol binder. Record all findings and/or adjustments into the Panacea Rx software database.

RESPONSIBILITY

Pharmacist-in-Charge
All IDS Staff
Office of Contract Administration

Quality Assurance Report

Date: _____

Location: _____

Participants in the Quality Assurance Review:

_____	_____
_____	_____
_____	_____
_____	_____

Pertinent data and other information relating to the medication error(s) reviewed and documentation of any patient contact:

Findings and Determinations generated by the Quality Assurance Review:

Recommended changes to IDS Pharmacy policy, procedures, systems, or processes, if any:
