



HEALTH RESEARCH ASSOCIATION

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

POLICY & PROCEDURE

Subject:		Issued By:	
RECORD KEEPING REQUIREMENTS		IDS PHARMACY	
		Approved By: Kathleen R. Hurtado R.Ph. HRA’s President & CEO	
Policy #:	Issue Date:	Revised Date:	Effective Date:
2012	May 1, 2007	August 20, 2007	September 30, 2007

Reference: Original Documentation & Record Keeping of Investigational Drugs Policy dated 4-12-2006 and updated as of 11-1-2006 and 5-1-2007 as well as “Instructions for Completing an Application for Waiver to Store Records Offsite” issued by the California Board of Pharmacy; and “A Guide to California Community Pharmacy Law,” Fifth Edition (2005-2007) by Fred G. Weissman, Pharm.D., J.D.

PURPOSE

To clarify the record keeping requirements associated with dangerous drugs, biologics and medical devices along with those governing Clinical Trial Materials (CTMs) and prescriptions for controlled and non-controlled substances.

WAIVER# 225765 – DATED JANUARY 26, 2007

Subject to the IDS Pharmacy’s waiver to permit record storage offsite approved by the California Board of Pharmacy, the following policies, guidelines and procedures apply to the IDS Pharmacy relative to record keeping requirements:

POLICY

1. **COMPLIANCE WITH WAIVER REQUIREMENTS:** The above-referenced waiver allows the offsite storage of records and documentation of the acquisition and distribution of dangerous drugs, biologics and medical devices. Records must always be in a readily retrievable form and must be kept in a secure area to prevent unauthorized access. The IDS Pharmacy must be able to produce all requested records within two business days of any request by the California Board of Pharmacy or any other authorized officer of the law. The Board of Pharmacy may cancel the waiver, without a hearing, if these conditions are not met. The waiver document itself must be stored onsite. A new waiver for offsite record storage is required if IDS records are ever moved from their current offsite storage location;
2. **IDS PHARMACY TO MAINTAIN & RETAIN RECORDS:** The IDS Pharmacy shall maintain and retain all records of dangerous drugs, biologics and medical devices and CTMs, as well as any related physician orders as mandated by federal, state, institutional, and Sponsor policies, procedures and regulations. Principal Investigators (PIs) must provide the IDS Pharmacy with copies of all CTMs upon receipt or upon request or whenever they become aware of newly available CTMs.

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GUIDELINES & PROCEDURES

1. **DANGEROUS DRUG, BIOLOGIC AND MEDICAL DEVICE RECORDS MUST BE KEPT FOR THREE YEARS:** All records of manufacturing, sale, acquisition and/or disposition of dangerous drugs, biologics and medical devices are to be kept by the IDS Pharmacy for a period of at least three years after the date of the last activity in question;
2. **IDS WILL FILE ALL CTMS IN STUDY-SPECIFIC PROTOCOL BINDERS:** The IDS Pharmacy will file all CTMs – including study-specific protocols, amendments (if available), PIs' brochures (if needed), and package inserts (if available) – in study-specific protocol binders;
3. **CTM RECORDS MUST BE KEPT FOR MINIMUM OF TWO YEARS:** All CTMs – which do not involve records of manufacturing, sale, acquisition and/or disposition of dangerous drugs, biologics and medical devices – shall be retained for a period of two years following the date of either any New Drug Application or after the completion of the clinical trial. Such records may be stored onsite or offsite. All study drug records will be maintained in a readily retrievable form;
4. **THREE-YEAR STORAGE OF PRESCRIPTION RECORDS:** There are a number of factors that determine the length of time that the IDS Pharmacy must retain prescription records: the date of the last activity for a particular study and whether or not the prescription is for a controlled substance. In all cases, prescription records are required to be kept by the IDS Pharmacy for a period of at least three years:
 - a. **PRESCRIPTION RECORDS FOR CONTROLLED SUBSTANCES:** Prescription records for controlled substances must be stored onsite at the IDS Pharmacy for two years after the date of the last activity. After two years from the date of the last activity, these records may be moved to the IDS Pharmacy's offsite storage location according to the terms of the previously-mentioned offsite-storage waiver;
 - b. **PRESCRIPTION RECORDS FOR NON-CONTROLLED SUBSTANCES:** Prescription records for non-controlled substances must be stored onsite at the IDS Pharmacy for one year after the date of the last activity. After that first year, these records may be moved to the IDS Pharmacy's offsite storage location according to the terms of the previously mentioned offsite-storage waiver.



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RESPONSIBILITY

Pharmacist-in-Charge
All IDS Staff