



HEALTH RESEARCH ASSOCIATION

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

POLICY & PROCEDURE

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Subject: PROCEDURAL DEVIATION REPORTING		Issued By: IDS PHARMACY	
		Approved By: Kathleen R. Hurtado R.Ph. HRA's President & CEO	
Policy #: 2013	Issue Date: April 12, 2006	Revised Date: November 1, 2006	Effective Date: November 1, 2006

Reference: Original Memo-to-File policy dated 4-12-2006.

PURPOSE

To ensure that HRA's Executive Management is informed whenever IDS Pharmacy Staff have deviated from standard policies and procedures.

POLICY

1. **IMMEDIATE E-MAIL NOTIFICATION OF HRA'S PRESIDENT & CEO:** The IDS Pharmacist in Charge is responsible for e-mailing HRA's President & CEO to immediately report ANY deviation from IDS Pharmacy Policies & Procedures, no matter how insignificant the deviation.

GUIDELINES & PROCEDURES

1. **E-MAIL NOTIFICATION SHOULD INCLUDE ALL OF THE FOLLOWING:**
 - a. Date and time of procedural deviation;
 - b. Study protocol number;
 - c. Site number;
 - d. Name of PI;
 - e. Detailed documentation of deviation being reported;
 - f. Name of person sending the e-mail notification;
2. **COPY E-MAIL TO PROTOCOL-SPECIFIC FILE FOLDER:** A copy of the e-mail should be printed out and included in the protocol-specific file folder.

RESPONSIBILITY

Pharmacist in Charge
All IDS Staff