

Subject:		Issued By:	
ADVERSE DRUG REACTION (ADR) REPORTING & REVIEWS		IDS PHARMACY	
		Approved By: Kathleen R. Hurtado R.Ph. HRA's President & CEO	
Policy #:	Issue Date:	Revised Date:	Effective Date:
2021	November 1, 2006	August 20, 2007	September 30, 2007

Reference: Original Adverse Drug Reaction (ADR) Reporting and Reviews policy dated 4-12-2006 and updated as of 11-1-2006.

PURPOSE

To ensure that all IDS Pharmacy Staff Members, Principal Investigators (PIs) and PI Study Teams report adverse drug reactions properly.

USEFUL RESOURCES

Instructions for reporting an internal adverse event are located here:

http://www.usc.edu/admin/provost/oprs/private/docs/hsirb/forms/ae_int_instruc.doc

The form for reporting an internal adverse event is located here:

http://www.usc.edu/admin/provost/oprs/private/docs/hsirb/forms/ae_int.doc

Additional information about adverse events can be found in section 14.4 of the Human Subjects Protection Program (HSPP) Policy Manual located here:

http://www.usc.edu/admin/provost/oprs/private/docs/oprs/pnp/Policies_and_Procedures_101706.pdf

DEFINITION

An adverse drug reaction (ADR) is an event which is noxious and unintended and which occurs at doses normally used for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function.

POLICY

1. **PIs AND PI STUDY TEAMS WILL CLOSELY FOLLOW ALL REPORTING INSTRUCTIONS:** PIs and PI Study Teams will closely follow all adverse event reporting instructions from the documents referenced by the hyperlinks above;



HEALTH RESEARCH ASSOCIATION

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POLICY

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2. **REPORTING REQUIREMENTS FOR PIs, IDS PHARMACY AND THE PHARMACIST-IN-CHARGE:**

The PI will report all adverse events to the IRB using the reporting form available by hyperlink on the previous page. The IDS Pharmacy also will report any known ADRs to the Pharmacy & Therapeutics Committee. Additionally, the Pharmacist-in-Charge will report all known adverse events relating to LA County patients to the Patient Safety Network.

RESPONSIBILITY

Pharmacist-in-Charge
All IDS Staff
PIs and PI Study Teams