

XXXXXX Nuclear Laboratory

Adverse Drug Results Policy

- I. PURPOSE: To establish a mechanism to ensure that adverse drug reactions are systematically reported and reviewed.
- II. POLICY: All staff has the responsibility of reporting, documenting, and monitoring adverse drug reactions that occur within the facility's population.

III. DEFINITIONS:

- a. Adverse drug reaction (ADR) is any noxious, unintended, undesirable, or unexpected response to a drug that occurs at doses used in humans for prophylaxis, diagnosis, therapy of disease, or for modification of psychological function. This definition is understood to exclude predictable, dose related side effects due to drugs which result in little or no change in patient management, and in particular, mild extrapyramidal side effects due to neuroleptic drug therapy.
- b. Indications of an ADR include anaphylaxis, arrhythmia, convulsions, hallucinations, shortness of breath, rashes, itching, hypotension, dystonia, leukopenia, urinary retention, symptoms associated with neuroleptic malignant syndrome, initial report of tardive dyskinesia, EPS related to nonantipsychotic drugs and also includes true allergic (hypersensitivity) reactions and idiosyncratic reactions.

A significant adverse drug reaction is one that: Requires discontinuing the drug; Requires large, (greater than 50%) dosage decrease; Necessitates admission to an acute care hospital; Delays anticipated discharge/placement; Necessitates supportive treatment; Significantly complicates diagnosis; Negatively affects prognosis; Results in temporary or permanent harm, disability, or death.

IV. RESPONSIBILITIES:

- a. Direct Care Staff: Observe and report suspected adverse drug reactions.
- b. Licensed Nurses: Observe, report, document and begin ADR report.
- c. Physician: Observe, assess, prescribe, document and complete ADR report.
- d. Medical Director: Evaluate and submit significant ADR reports to FDA and manufacturer if required.

V. PROCEDURE:

- a. Reporting:
 - i. Any staff who witnesses a suspected adverse drug reaction will notify the nurse.
 - ii. Nurse will immediately contact the physician to report the possibility of an adverse drug reaction.
 - iii. The nurse will complete the nursing section of the Adverse Drug Reaction Report (Attachment A).
 - iv. The physician will examine the individual, order necessary intervention, if needed, and will complete the medical section of the Adverse Drug Reaction Report.
 - v. The physician will also note the presence of an ADR on the patients report.
- b. Documentation:
 - i. The nurse will document in the patient's medical record, all the events associated with reporting the suspected ADR to include, but not limited to:
 - 1. Signs and symptoms which prompted the ADR reporting procedure; and
 - 2. Date and time the physician was notified of the suspected ADR.
 - ii. The physician will document in the patient's medical record, the adverse drug reaction along with the interventions, if any were necessary.

Written: _____	Date: _____
Revised: _____	Date: _____
Reviewed: _____	Date: _____
	Date: _____

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Adverse Drug Result Form

PART I (To be completed by Nurse):

Patient's Name: _____

DOB# _____

Date of ADR: _____

Description of Reaction: (Also document in Patient Chart)

Current & Recent Medications (include dose & frequency)

- 1.
- 2.
- 3.
- 4.
- 5.
- 6.
- 7.
- 8.
- 9.
- 10.

Signature of Nurse

Date

PART II (To be completed by physician):

Summary of Clinical conclusions (Include relevant medical and lab data)

Specify implicated suspected drug: _____

Recommendations/Actions taken (also document response in Patient Chart)

Signature of Physician

Date