Institutional Handbook of Operating Procedures Policy 09.13.14	
Section: Clinical	Responsible Vice President: Executive Vice President Health System
Subject: General Clinical Procedures and Care	Responsible Entity: Pharmacy

I. Title

Adverse Drug Events

II. Policy

Adverse drug events such as potential medication errors, medication errors, medication incompatibilities, and adverse drug reactions shall be reported by the healthcare professional(s) involved in, witnessing, or first discovering the adverse drug event. ***This includes all adverse drug events, which should be addressed with a positive, proactive, and educational approach geared towards information gathering with appropriate follow-up to facilitate improvement in all aspects of the medication use process.***

This policy applies to non-research related contexts only. If UTMB patients are involved in clinical research studies, UTMB's Institutional Review Board is the appropriate authority to receive reports of adverse events that occur in the research context.

III. Reporting Adverse Drug Events (ADE's)

A. All actual ADE's will be communicated to the treating provider. The treating provider is responsible for notifying the attending physician. Any ADE that results in temporary or permanent harm, or that requires additional monitoring or treatment to prevent harm, must be communicated to the attending physician immediately.

B. Reporting of the incident of an adverse drug event is private and confidential, and must not be:
   1. shared with personnel other than those specified by the procedure below;
   2. referenced in a patient's medical record or an employee's file; or
   3. printed or copied.

IV. ADE Subcommittee Responsibilities

A. The Adverse Drug Event Subcommittee is a subcommittee of the Pharmacy and Therapeutics (P&T) Committee, which reports to the OPS (Operations) Council. ADE is a multidisciplinary committee established to provide oversight of the creation of safe systems within the medication use process. The subcommittee functions to analyze potential and actual ADE's, as well as create and/or recommend policy changes, and initiate appropriate staff training/education to prevent the recurrence of future ADE's.

B. All ADE's will be reported to the pharmacy for data compilation purposes. The ADE subcommittee will compile, assess and make recommendations based on data analysis.

V. Documentation Guideline

A. Actual or suspected adverse drug reactions must be documented in the patient's medical record.
B. All actual and potential adverse drug event occurrences subject to this policy should be reported using the hospital's incident reporting software. This report must be completed with specific,

factual, and objective information so that the true magnitude and nature of circumstances can be studied.

VI. Relevant Federal and State Statutes

Health Care Quality Improvement Act (HCQIA). 42 U.S.C. §§ 11101-11152

VII. Related UTMB Policies and Procedures

IHOP - 09.11.05 - *Physician Orders*
IHOP - 09.13.13 - *Unusual Event Reporting*

VIII. Additional References

American Society of Health-System Pharmacists. *ASHP Guidelines on Preventing Medication Errors in Hospitals*; Am J Hosp Pharm. 1993; 50:305-14.

IV. Dates Approved or Amended

Originated: 7/20/1998	
Reviewed with Changes	*Reviewed without Changes*
03/23/2017	7/22/2016