

UTMB HANDBOOK OF OPERATING PROCEDURES

Section 6 Subject 6.1	Compliance Policies General Compliance	05/13/13 - Originated - Reviewed w/changes - Reviewed w/o changes 05/13/13 - Effective Compliance Office - Author
Policy 6.1.4	Significant Events Reporting	

Significant Events Reporting

Definitions

Significant Events – matters including, but not limited to, reports of death or serious injury occurring on campus or involving a member of the university community; allegations of fraud or fiscal loss of \$100,000 or more; allegations involving impropriety or failure to follow law or policy by the Chancellor, a System Executive Vice Chancellor or Vice Chancellor, the General Counsel to the Board, or the System Chief Audit Executive; or an institutional president or vice president; allegations of sexual misconduct; allegations related to the care or safety of minors; material concerns expressed by federal and state oversight agencies; security breaches involving confidential records; potential media reports that may impact the reputation of the university; or matters that reflect a systemic threat to patient safety.

Policy

This policy is designed to implement a reporting process by which UTMB will ensure that significant events are reported to U.T. Systems in a timely manner in accordance with UTS178 Required Reporting of Significant Events.

UTMB leadership from all areas of the Institution shall be responsible for reporting significant events, reviews, investigations, and reports of noncompliance with federal or state statutes and regulations, or U.T. System policies to the Office of Institutional Compliance. The Office of Institutional Compliance shall serve as the institutional point of contact and is responsible for notifying the U.T. System wide Compliance Office of significant events related to UTMB. U.T. Systems will then notify the Board of Regents of significant events it determines necessary.

This reporting is supplemental to already existing communication strategies and any existing communication processes to UT System should continue.

Failure to comply with this policy may result in disciplinary action up to and including termination.

What Should Be Reported

Executive officers should report **significant allegations, reviews, investigations, and reports of noncompliance with federal or state statutes or regulations, or UT System or UTMB policies.** These significant events may include, but are not limited to:

1. reports of death or serious injury occurring on campus or involving a member of the university community (Please note:

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What Should Be Reported, continued

Generally this will exclude patient deaths unless there are extenuating circumstances.);

2. allegations of fraud or fiscal loss of \$100,000 or more;
3. allegations involving impropriety or failure to follow law or policy by the Chancellor, a System Executive Vice Chancellor or Vice Chancellor, the General Counsel to the Board, or the System Chief Audit Executive; or an institutional president or vice president;
4. allegations of sexual misconduct;
5. allegations related to the care or safety of minors;
6. material concerns expressed by federal and state oversight agencies;
7. security breaches involving confidential records;
8. potential media reports that may impact the reputation of the university; or
9. matters that reflect a systemic threat to patient safety.

Reporting Procedure

I. Initial Reports

- a. *Designated Employees.* UTMB executive officers who oversee such functions as business affairs, compliance, audit, legal affairs, information security and safety, public relations, police operations, and patient safety shall designate one or more employees to be responsible for reporting significant events to the Office of Institutional Compliance.
 - i. Designated employees shall serve as the point of contact for reports of significant events for their area and department.
 - ii. Initial reports of significant events or allegations will be provided to the designated employees.
- b. *Executive Officers.* Executive officers are responsible for:
 - i. informing their staff, students, contractors etc. of the need to report incidents promptly;
 - ii. ensuring that designated employees comply with this procedure for incidents reported to them.
- c. *Individual Employees.* UTMB employees may report significant events directly to the Office of Institutional Compliance.

II. Prompt Reporting of Significant Events

- a. Employees are responsible for promptly reporting significant events to the Office of Institutional Compliance or to a Designated Employee for their area and department.
 - b. Reports received by Designated Employees should be promptly communicated to the Office of Institutional Compliance. Within 24 hours of *initial discovery* of a
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Reporting Procedure, continued

- significant event, the Designated Employee should make a report to the Office of Institutional Compliance.
- c. Initial discovery means that the significant event has been brought to the attention of a Designated Employee. Significant events should be reported regardless of whether an investigation has been completed.
 - d. It is important that the Office of Institutional Compliance is made aware of significant events so that U.T. Systems may be promptly notified as required by UTS 178.

Reporting Methods

- Reports may be submitted through one of the following methods:
1. Calling the Office of Institutional Compliance at 409.747.8700;
 2. Calling the Fraud, Abuse and Privacy Hotline at 1.800.898.7679; or,
 3. Online at: <https://www.reportlineweb.com/UTMB>

Required Information

- The report should include the following information:
1. The date of the significant event or allegations;
 2. When and how it was reported to UTMB;
 3. A description of the event or allegation;
 4. The status or resolution of the event or allegation; and,
 5. The name and information of a contact person having knowledge of the facts regarding the significant event.

Significant Event Follow Up Reporting

- The Office of Institutional Compliance will contact the employee or Designated Employee for updates on each significant event. The Office of Institutional Compliance shall:
1. Request a follow-up report within 7 days of the date of the initial report; and,
 2. Request follow-up reports on a monthly schedule, until follow-up reports are no longer necessary.

Effective Date

- Reports should be made effective immediately. Significant allegations or events that have occurred prior to Monday, December 17, 2012 do not need to be reported unless they may result in:
1. Additional actions by federal or state authorities;
 2. Additional actions by UT System or UTMB officials; or
 3. Media reports that may impact the reputation of UTMB.

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References

The University of Texas System, System wide Policy, UTS 178
Required Reporting of Significant Events
IHOP 6.1.10, *Self-Reporting Overpayments Policy*
IHOP 6.2.39, *Privacy Incident Response and Breach Notification*
IHOP 8.2.2, *Campus Security Reporting*
IHOP 9.13.13, *Unusual Event Reporting*
IHOP 9.13.14, *Adverse Drug Events*
IHOP 9.13.16, *Sentinel Events*
IHOP 9.13.18, *Communication of Unanticipated Outcomes*
IHOP 9.13.21, *Reports of Devices/Supplies Involved in Patient Injury, Illness or Death*