



**Institutional Handbook of Operating Procedures  
Policy 09.13.16**

Section: Clinical Policies	Responsible Vice President: EVP and CEO Health System
Subject: General Procedures	Responsible Entity: Health System

**I. Title**

*Sentinel Events*

**II. Policy**

UTMB is committed to patient safety. Any employee who has knowledge of a [sentinel event](#), or a [near miss](#) that could lead to a sentinel event, involving a UTMB patient, must notify his/her supervisor or administrator as soon as possible. The supervisor or the administrator must notify Patient Safety or Risk Management immediately. **All unusual events should be reported by using the designated event reporting system.**

**Pursuant to Texas Health and Safety Code Chapter 161, and Texas Occupations Code Chapter 160, all findings from an investigation is confidential and privileged and shall be maintained by Patient Safety for the use of UTMB Health’s Safety Culture Committee reporting structure and process(es).**

In addition, for patients who are also subjects in a research protocol, other reporting may be required per Institutional Review Board ([IRB](#)) [policy](#).

Sentinel event: A patient safety event (not primarily related to the natural course of the patient’s illness or underlying condition) that reaches a patient and results in death, severe harm (regardless of duration of harm), or permanent harm (regardless of severity or harm).

Severe harm: An event or condition that reaches the individual, resulting in life-threatening bodily injury (including pain or disfigurement) that interferes with or results in loss of functional ability or quality of life that requires continuous physiological monitoring or a surgery, invasive procedure, or treatment to resolve the condition.

Permanent harm: An event or condition that reaches the individual, resulting in any level of harm that permanently alters others and/or affects an individual’s baseline.

A formal [root cause analysis \(RCA\)](#) will be conducted under the auspices of the UTMB Quality & Healthcare Safety Department for events that meet the definition of sentinel event including:

Defining Events That Are Sentinel:

1. Suicide of any patient receiving care, treatment, and services in a staffed, around-the-clock care setting or within 72 hours of discharge, including from the hospital’s emergency department (ED);
2. Unanticipated death of a full-term infant;
3. Abduction of any patient receiving care, treatment, or services;
4. Discharge of an infant to the wrong family;

5. [Rape](#), assault (leading to death or permanent loss of function), or homicide of any patient receiving care, treatment or services while on site at the hospital;
6. Rape, assault (leading to death or permanent loss of function), or homicide of a staff member, licensed independent practitioner, visitor, or vendor while on site;
7. Any elopement (that is, unauthorized departure) of a patient from a staffed around the-clock care setting (including the ED), leading to death, permanent harm, or severe temporary harm to the patient;
8. Administration of blood or blood products having unintended ABO and non-ABO (Rh, Duffy, Kell, Lewis, and other clinically important blood groups) incompatibilities, hemolytic transfusion reactions, or transfusions resulting in severe temporary harm, permanent harm, or death;
9. Surgery or other invasive procedure performed at the wrong site, on the wrong patient, or that is the wrong (unintended) procedure for a patient regardless of the type of procedure or the magnitude of the outcome;
10. Unintended retention of a foreign object in a patient after an invasive procedure, including surgery;  
    “After surgery” is defined as any time after the completion of final skin closure, even if the patient is still in the procedural area or in the operating room under anesthesia. This definition is based on the premise that a failure to identify and correct an unintended retention of a foreign object prior to that point in the procedure represents a system failure, which requires analysis and redesign. It also places the patient at additional risk by extending the surgical procedure and time under anesthesia. If a foreign object (for example, a needle tip or screw) is left in the patient because of a clinical determination that the relative risk to the patient of searching for and removing the object exceeds the benefit of removal, this would not be considered a sentinel event to be reviewed. However, in such cases, the organization shall (1) disclose to the patient the unintended retention, and (2) keep a record of the retentions to identify trends and patterns (for example, by type of procedure, by type of retained item, by manufacturer, by practitioner) that may identify opportunities for improvement.
11. Severe neonatal hyperbilirubinemia (bilirubin > than 30 milligrams/deciliter);
12. Fluoroscopy resulting in permanent tissue injury when clinical and technical optimization were not implemented and/or recognized practice parameters were not followed;
13. Any delivery of radiotherapy to wrong patient, wrong body region, unintended procedure or > 25% above the planned radiotherapy dose;
14. Fire, flame, or unanticipated smoke, heat, or flashes occurring during direct patient care caused by equipment operated and used by the hospital. To be considered sentinel event, equipment must be in use at the time of the event; staff do not need to be present;
15. Any intrapartum (related to the birth process) maternal death;
16. Severe maternal morbidity.
17. Fall in a staffed-around-the-clock setting or fall in a care setting not staffed around the clock during a time when staff are present resulting in any of the following: any fracture; surgery, casting, or traction; required consult/management or comfort care for a neurological (for example, skull fracture, subdural or intracranial hemorrhage) or internal (for example, rib fracture, small liver laceration) injury; or a patient with coagulopathy who receives blood products as a result of fall; death or permanent harm as a result of injuries sustained from the fall (not from physiologic events causing the fall)
18. Preventable Adverse Events (PAE) are required for mandatory state reporting. A root cause analysis will be conducted for each reportable event and maintained at the facility. Health Facilities are required to report designated preventable adverse event (PAE) data as written in the Texas Administrative Code Title 25, Part 1, Chapter 200, Subchapter A, Rule 200.2; Texas Administrative Code Title 25, Part 1, Chapter 133, Subchapter A, Rule 133.49; and Texas Administrative Code Title 25, Part 1, Chapter 135, Subchapter A, Rule 135.26. See Title 25, Part 1, Chapter 200, Subchapter A at [http://texreg.sos.state.tx.us/public/readtac\\$ext.viewwtac](http://texreg.sos.state.tx.us/public/readtac$ext.viewwtac).

**III. Procedures**

Quality Management and Patient Safety and/or another appropriately designated UTMB department, will initiate an investigation of a reported sentinel event, severe harm event, permanent harm event, [adverse event](#), or near miss, if applicable, immediately after notification and will work with Health System leadership to determine if an RCA should be conducted. A formal RCA may be conducted for adverse events or near misses at the discretion of Health System leadership.

All RCAs will involve UTMB staff whose departments are associated with the event. The Quality & Healthcare Safety department will work with the applicable departments to determine participants in the RCA meeting.

Refer to the [UTMB Health System RCA Process](#).

Refer to the Texas preventable Adverse Event Reporting 3 Tier Phase-In Implementation.

**IV. Relevant Federal and State Statutes**

[45-CFR-46.103](#)

[21 CFR 312.32\), 21CFR312.62, 21 CFR 50.27 \(a\) Expedited Safety Reporting Requirements for Human Drug and Biological Products – Final Rule \(21 CFR Parts 20, 310, 312, 314, and 600\) \[Docket No. 93N-0181\] Vol. 62, No. 194, pg. 52237 - 52253](#)

[Joint Commission Sentinel Events \(SE\) Accreditation Process information found within the Comprehensive Accreditation Manual \(CAMH\) for hospitals](#)

**V. Related UTMB Policies and Procedures**

[IHOP – 03.02.04 – Sexual Misconduct](#)

[IHOP - 06.01.04 - Significant Matters Reporting](#)

[IHOP - 09.13.13 - Unusual Event Reporting](#)

[IHOP - 09.13.14 - Adverse Drug Events](#)

[IHOP - 09.13.18 - Disclosure of Unanticipated Outcomes](#)

**VI. Additional References**

[UTMB Health System RCA Process](#)

[PAE Categories and Tiers](#)

[The Joint Commission](#)

**VII. Dates Approved or Amended**

<i>Originated: 07/26/1999</i>	
<i>Reviewed with Changes</i>	<i>Reviewed without Changes</i>
08/01/2013	01/03/2018
11/01/2016	
03/22/2017	
07/01/2021	

**VIII. Contact Information**

Health System Administration

(409) 266-9915