(A) Policy Statement

The University of Toledo Medical Center ("UTMC") strives to perfect the quality and safety of patient care through the evaluation of events to determine the presence of Adverse or Sentinel Events and to take appropriate steps to continuously improve quality and safety.

(B) Purpose of Policy

This policy provides a process that allows for early identification, immediate investigation, expeditious response and determination of whether the incident is a Sentinel Event resulting in the need for a Root Cause Analysis.

(C) Procedure

1. Any employee, resident, student, physician, administrator or persons performing work for UTMC who is aware of an incident that may be an Adverse Event or a Sentinel Event is responsible for contacting the House Supervisor and for entering an Incident Report into the Patient Safety Net in accordance with the Patient Safety Event Reporting Policy, 3364-100-50-39. An Incident Report will also be entered into the Patient Safety Net for an incident that is considered a Near Miss.

   a. The Administrator On-Call and the COCO will notify the individuals as outlined in the attached Communication Flow Chart and determine, within 24 hours of notification of the incident, whether the incident is a Sentinel Event. If applicable, the I’m Sorry protocol will be initiated as per the I’m Sorry policy 3364-100-60-10. The COCO may convene a Committee to assist in his or her analysis in determining whether the incident is a Sentinel Event which may include the Chief Administrative Officer, Quality and Patient Safety, hospital administrator, Chief of Staff, legal counsel or others as may be helpful. Physicians who were involved in the patient care of a potential Sentinel Event will not be involved in the final determination of whether an event is a Sentinel Event, but they may provide input.

   b. If the COCO is not physically present for determination of whether an incident is a Sentinel Event, the next physician on the list for call rotation will step in to make the determination.

   c. Medical Staff physicians may ask the Chief Administrative Officer, Quality and Patient Safety to review whether certain events should be considered Sentinel Events.

2. The House Supervisor will immediately compare the events reported against the Sentinel Event criteria. If the incident has the potential to meet the established Sentinel Event criteria, then the House Supervisor will notify the Administrator On-Call and the Chief Operating and Clinical Officer (COCO), or person in lieu of COCO if COCO is not available.

   a. The Administrator On-Call and the COCO will notify the individuals as outlined in the attached Communication Flow Chart and determine, within 24 hours of notification of the incident, whether the incident is a Sentinel Event. If applicable, the I’m Sorry protocol will be initiated as per the I’m Sorry policy 3364-100-60-10. The COCO may convene a Committee to assist in his or her analysis in determining whether the incident is a Sentinel Event which may include the Chief Administrative Officer, Quality and Patient Safety, hospital administrator, Chief of Staff, legal counsel or others as may be helpful. Physicians who were involved in the patient care of a potential Sentinel Event will not be involved in the final determination of whether an event is a Sentinel Event, but they may provide input.

3. Once it is determined that a Sentinel Event is present, a comprehensive systematic analysis will be completed no more than 45 days after the incident, or after the incident was discovered.

   a. A Comprehensive Systematic Analysis is used for identifying the causal and contributory factors that underlie variation in systems and processes and may have contributed to the event. A Root Cause Analysis is the most commonly used form of a comprehensive systematic analysis used to identify the
factors that underlie a Sentinel Event. A Root Cause Analysis focuses on systems and processes, not individual performance.

b. An Intense Analysis, is a performance improvement process that may be applied to Near Misses or an Adverse Event, and which trends and analyzes data and focuses primarily on systems and processes.

c. In accordance with the I’m Sorry Protocol, the COCO may meet with the patient, or the patient’s family if appropriate, after discussing with the attending physician to answer any questions that the patient or family may have.

4. The Chief Administrative Officer, Quality and Patient Safety, or designee, will begin the investigation immediately. The investigation will include at a minimum the following:

   a. Review of medical record;
   b. Review of relevant policies, procedures and standards of care;
   c. Interview applicable personnel, including but not limited to medical staff members, outside employees and hospital employees, who witnessed or have any knowledge or information regarding the Sentinel Event;
      1) Inspect or review all relevant material, equipment and devices and secure the same;
      2) Meet with and interview the patient or family of the affected patient, as appropriate
      3) Document findings, conclusions, actions.

5. The Chief Administrative Officer, Quality and Patient Safety, or designee, will convene a team to conduct a Comprehensive Systematic Analysis in the form of a Root Cause Analysis. This team may be comprised of a person from the Quality Department, Hospital Administration, Office of Legal Affairs, pertinent staff members, and physicians as necessary.

   a. Within 45 days of the event or of becoming aware of the event, the team will develop an action plan. The action plan will identify strategies that will be taken to reduce the risk of similar events occurring in the future. The action plan will include recommendations for assigning responsibility for the implementation of these actions, ongoing monitoring and specific time frames. In addition, strategies for measuring effectiveness and sustaining the change will be included. Ongoing compliance for implementation of the action plan will be tracked by the Chief Administrative Officer, Quality and Patient Safety.

6. The Chief Administrative Officer, Quality and Patient Safety, or designee, will present the findings and recommendations to the Peer Review Committee. The Peer Review Committee will either accept or decline the findings and action plan.

   a. If accepted, it must be implemented and the Peer Review Committee will assist with action plan compliance.
   b. If declined, the Root Cause Analysis Team will reconvene and gather more information or modify the action plan as requested by the Peer Review Committee.

   The Peer Review Committee will be periodically updated and will help facilitate compliance as necessary.

7. The COCO, or designee, will report on Sentinel Event activities to the Clinical Affairs Committee of the Board of Trustees.

8. Sentinel Events will be reported by UTMC administration to external agencies to the extent required in accordance with applicable laws, regulations and the rules of accrediting agencies. (For example: Events related to renal transplants will be reported to OPTN and ESRD Network as applicable, Reports to IRB if related to human subject research; Report to FDA if related to a medical device; Report to CDC if related to transmission of a communicable disease; Report to OPO if related to an infectious disease present in a recovered organ from a deceased donor that could be transmitted to other recipients.)

9. All documents generated as a result of a Sentinel Event, an Adverse Event or a Near Miss, including but not limited to the initial report, the findings and the Root Cause Analysis forms will be maintained in a strictly
confidential manner by all parties who receive the documentation. These documents are considered to be confidential reports and are part of the peer review and quality assessment process of the Hospitals. They are protected from disclosure pursuant to the provisions of ORC 2305.25 and ORC 2305.25.3. Unauthorized disclosure or duplication is absolutely prohibited.

(D) Definitions

An Adverse Event is a serious, undesirable and usually unanticipated patient safety event that resulted in harm to the patient but does not rise to the level of being sentinel.

A No Harm event is a patient safety event that reaches the patient but does not cause harm.

A Close Call or Near Miss is a patient safety event that had no impact on a patient but could have had an impact if it was not aborted, discovered or if intervention occurred prior to it reaching the patient.

A Hazardous or Unsafe Condition is a circumstance (other than the patient’s own disease process, or condition) that increases the probability of an Adverse or Sentinel Event.

A Sentinel Event is an event that primarily related to the natural course of the patient’s illness or underlying condition) that reaches a patient and results in death, permanent harm, or severe temporary harm. Severe temporary harm is defined as a critical, potentially life-threatening harm lasting for a limited time with no permanent residual, but requires transfer to a higher level of care/monitoring for a prolonged period of time, transfer to a higher level of care for a life-threatening condition, or additional major surgery, procedure, or treatment to resolve the condition. These events are called “sentinel” because they signal the need for immediate full investigation and response. Events subject to review include any events that meet the following criteria:

- The event is one of the following (even if the outcome was not death or major permanent loss of function unrelated to the natural course of the patient’s illness or underlying condition):
  - Suicide of any individual receiving care, treatment or services in a staffed around-the-clock care setting or within 72 hours of discharge, including from the hospital Emergency Department.
  - Unanticipated death of a full-term infant.
  - Discharge of an infant to the wrong family.
  - Abduction of any individual receiving care, treatment or services.
  - Any elopement (that is, unauthorized departure) of a patient from a staffed around the clock care setting (including the Emergency Department), leading to death, permanent harm, or severe temporary harm to the patient.
  - Rape/assault (leading to death, permanent harm, or severe temporary harm) or homicide of any patient receiving care, treatment or services while on site at UTMC.
  - Rape, assault (leading to death, permanent harm, or severe temporary harm), or homicide of a staff member, licensed independent practitioner, visitor or vendor while on site at UTMC.
  - Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities, (i.e. ABO, Rh, other blood groups).
  - Invasive procedure, including surgery on the wrong patient, wrong site or wrong (unintended) procedure.
  - Unintended retention of a foreign object in a patient after an invasive procedures, including surgery.
  - Prolonged fluoroscopy with cumulative dose >1500 rads to a single field or any delivery of radiotherapy to the wrong body region, or >25% above the planned radiotherapy dose.
  - Fire, flame, or unanticipated smoke, heat, or flashes during an episode of patient care.
  - Any intrapartum (related to the birth process) maternal death or severe maternal morbidity.
  - Severe neonatal hyperbilirubinemia (bilirubin >30 milligrams/dl)

Signature block to follow.
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Sentinel Events, Adverse Events
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Approved by:

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Policies Superseded by This Policy: 7-50-38 Sentinel Events/Adverse Events
Adverse/Sentinel Event Flow Process

Incident Report or receipt of information related to a potential Sentinel Event

Does the event meet TJC Sentinel Event Screening Tool Requirements?

Chief Operating and Clinical Officer determines whether Sentinel Event

Should a Root Cause Analysis still be completed?

NO

COCO may convene a group to help with assessment

YES

Chief Administrative Officer, Quality & Patient Safety or Designee begins investigation

Root Cause Analysis process followed

Findings reported to Peer Review Committee accepted?

NO

Event is entered into Quality and Safety tracking system

Implement and monitor actions

Reported to Medical Staff and Board

YES

NO
Communication Flow Chart

Any Nurse, Physician, Medical Student, Resident, UTMC Employee MUST NOTIFY for a(n) Sentinel or Adverse Event (defined as an event that is a serious adverse event with an unanticipated outcome resulting in death, or severe or permanent harm)

Enter into Patient Safety Net

House Supervisor

Chief Operating Officer (or person in lieu of COCO if COCO is not available) notifies the following within 24 hours:

Administrator On-Call

Chief Administrative Officer, Quality and Patient Safety for quality review or RCA if Adverse Event Under Sentinel Event Policy

Medical Staff Office (Chief of Staff COCO) for medical staff action with respect to peer review or privileges

Legal/Risk Dept for Claim Reporting, I'm Sorry Protocol and SOCC/RCA review

Hospital Administration (CEO who will contact EVP/President, with contact to Public Relations if necessary)