St. Joseph Health
St. Jude Medical Center

Policy/Procedure

# Sentinel Event/Adverse Event Reporting And Analysis

Clinical Excellence 11040 **Official** (Rev: 3)

## Affected Departments:

- All Departments

# I. PURPOSE:

A. To describe St. Jude Medical Center's mechanism for identifying, responding to, and reporting of Sentinel Events and/or Adverse Events that occur in the organization.
B. To establish a process for reporting and analyzing, a sentinel event, adverse event, or "near miss" as part of the medical error reduction strategy.
C. To establish a process for implementing corrective action and monitoring process and outcomes.

# II. POINTS TO EMPHASIZE:

St. Jude Medical Center is committed to providing quality health care to patients. An integral part of a Risk Management Program is the establishment of a sentinel event plan. An event is called "sentinel" because it sends a signal or sounds a warning that requires immediate attention. Accordingly, the policy is designed to ensure maximum risk-prevention and loss-reduction activities on the part of the organization in response to a sentinel event. Appropriate response includes a thorough and credible root cause analysis, implementation of improvement strategies to reduce risk, and monitoring of the effectiveness of those improvements. The outcomes of this approach will help increase the general knowledge about sentinel events, their causes and prevention strategies, and maintain public confidence in St. Jude Medical Center, and have a positive impact on improving patient care.

A. **SCOPE:**
All departments of St. Jude Medical Center

1. **DEFINITIONS:**

| Term | Definition |
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| **Patient Safety Event** | **An event, incident, or condition that could have resulted or did result in harm to a patient. A patient safety event can be, but is not necessarily, the result of a defective system or process design, or system breakdown, equipment failure, or human error. Patient safety events also include adverse events, no harm events, near misss, and hazardous condition.** |
| **Adverse Event** | **A patient safety event that resulted in harm to a patient.** |
| **No-harm Event** | **A patient safety event that reaches the patient but does not cause harm.** |
| **Near Miss** | **A patient safety event that did not reach the patient.** |
| **Hazardous Condition** | **A circumstance (other than a patient's own disease process or condition) that increases the probability of an adverse event.** |
| **Sentinel Events** | **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, permanent harm and severe temporary harm.** |

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| Severe Temporary Harm | Is 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 life-threatening condition, or additional major surgery, procedure, or treatment to resolve the condition. |
| Complication | A detrimental patient condition that arises during the process of providing health care, regardless of the setting in which the care is provided, e.g. perforation, hemorrhage, bacteremia. A complication may prolong an inpatient's length of stay or lead to another undesirable outcome. |
| Error of Commission | An error which occurs as a result of an action taken, e.g. a drug is administered at the wrong time, in the wrong dosage, surgery performed on the wrong side of the body. (Source: TJC) |
| Unusual Occurrence | An occurrence such as an epidemic outbreak, poisoning, fire, major accident, disaster, other catastrophe or unusual occurrence which threatens the welfare, safety, or health of patients, personnel or visitors, that must be reported, as soon as reasonably practicable, by telephone to the local health officer and to the state California Department of Public Health Services. An adverse event that causes the death or serious disability of a patient, personnel, or visitor. (Source: Title XXII, California Code of Regulations; California Senate Bill 1301). |
| Severe maternal morbidity | Defined by the American College of Obstetrics and Gynecology, the US Centers for Disease Control and Prevention, and the Society of Maternal and Fetal Medicine, as a patient safety event that occurs intrapartum through the immediate postpartum period (24 hours), that requires the transfusion of 4 or more units of blood products (fresh frozen plasma, packed red blood cells, whole blood, platelets) and/or admission to the intensive care unit (ICU). Admission to the ICU is defined as admission to a unit that provides 24 hour medical supervision and is able to provide mechanical ventilation or continuous vasoactive drug support. |
| Serious Disability | A condition characterized by substantial limitation of one or more of the major life activities; the loss of bodily function or impairment that lasts more than seven days - or is still present at the time of discharge; or the loss of a body part (California SB 1301). |
| Incident Reporting System (IRS) | Computerized method for reporting incidents related to patient and visitor related unusual occurrences, near misses, hazardous conditions, or patient complaints. |
| Intensive Assessment | An Intensive Assessment is a structured interdisciplinary process consisting of the staff most closely involved with the adverse event, members of the Medical Staff if applicable, and staff from the Risk |

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| | **Management or the Quality/Clinical Outcomes Department, who gather to review an adverse outcome. The event has been determined to not meet the definition of a Sentinel Event but the Risk Management or the Quality/Clinical Outcomes Department has determined the event requires investigation and review of causal factors to identify improvement strategies that will prevent the likelihood of a recurrence. The Intensive Assessment mirrors the Root Cause Analysis process and includes, at a minimum, the same scope of analysis for specific types of events (See Attachment B)** |
| **Event Review Team** | **The Administrative and Medical Staff Team, as defined in this policy that initiates the Event Review Team Process. The Event Review Team functions as an ad hoc team of the Medical Staff is afforded the protection provided by Section 1157 of the California Evidence Code.** |
| **Root Cause Analysis** | **A process for identifying the basic or causal factor(s) that underline variation in performance, including the occurrence or possible occurrence of a sentinel event.** |
| **Sexual abuse/assault (including rape)** | **Unconsensual sexual contact involving a patient and another patient, staff member, or other perpetrator while being treated or on the premises of the hospital, including oral, vaginal or anal penetration or fondling of the patient's sex organ(s) by another individual's hand, sex organ, or object.** |

B. Adverse Events
A distinction is made between an adverse outcome that is primarily related to the natural course of the patient's illness or underlying condition (not reviewed as a Sentinel Event) and a death or major permanent loss of function that is associated with the treatment (including the "recognized complications") or lack of treatment of that condition, or otherwise not clearly and primarily related to the natural course of the patient' illness or underlying condition (reviewable).
    1. The phrase, "or the risk thereof', includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome.
    2. Such events are "sentinel" because they signal the need for immediate investigation and response.
    3. The terms "sentinel event" and "medical error" are not synonymous; not all sentinel events occur because of an error and not all errors result in sentinel events.

C. **Reviewable Sentinel Events**:
    1. The following subset of sentinel events that is subject to review by The Joint Commission includes any occurrence that meets any of the following criteria:
        a. The event has resulted in an unanticipated death or major permanent loss of function not related to the natural course of the patient's illness or underlying condition; **OR**
        b. The event is one of the following (even if the outcome was not death or major permanet loss of function not related to the natural course of the patient's illness or underlying condition):
            i. 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 emergency department
            ii. Unanticipated death of a full-term infant
            iii. Discharge of an infant to the wrong family
            iv. Abduction of any patient receiving care, treatment, and services
            v. 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
            vi. Hemolytic transfusion reaction involving administration of blood or blood

products having major blood group incompatibilities (ABO, Rh, other blood groups)

vii. Rape, assault (leading to dealth or permanent harm, or severe temporary harm), or homicide of any patient receiving care, treatment, and services while on site at the hospital
viii. Rape, assault (leading to death or permanent harm, or severe temporary harm), or homicide of a staff member, licensed independent practitioner, visitor, or vendor while on site at the hospital
ix. Invasive procedure, including surgery, on the wrong patient, wrong site, or that is the wrong (unintended) procedure regardless of the type of the procedure or the magnitude of the outcome
x. Unintended retention of a foreign object in a patient after an invasive procedure, including surgery (e.g., 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.
xi. Severe neonatal hyperbilirubinemia (bilirubin >30 milligrams/deciliter)
xii. Prolonged fluoroscopy with cumulative dose >1,500 rads to a single field, or any delivery of radiotherapy to the wrong body region or >25% above the planned radiotherapy dose
xiii. Fire, flame, or unanticipated smoke, heat, or flashes occuring during an episode of patient care
xiv. Any intrapartum (related to the birth process) maternal death or severe maternal morbidity

c. **Examples of Sentinel Events that are NOT reviewable under The Joint Commission's Sentinel Event Policy:**
i. Any close call (near miss)
ii. Full or expected return of limb or bodily function to the same level as prior to the adverse event by discharge or within two weeks of the initial loss of said function, whichever is the longer period
iii. Any sentinel event that has not affected a recipient of care (patient)
iv. Medication errors that do not result in death or major permanent loss of function
v. Suicide other than in an around-the-clock setting or following elopement from such a setting
vi. A death or loss of function following a discharge against medical advice (AMA)
vii. Unsuccessful suicide attempts unless resulting in major permanant loss of function
viii. Minor degrees of hemolysis not caused by a major blood group incompatibility and with no clinical sequalae

D. Senate Bill 1301: The following adverse events need to be reported to the California Department of Public Health (CDPH) no later than five days after the adverse event has been detected, or , if that event is an ongoing or emergent threat to the welfare, health, or safety of patients, personnel, or visitors, not later than 24 hours after the adverse event has been detected. Disclosure of individually identifiable patient information shall be consistent with applicable law. The facility shall inform the patient or the party responsible for the patient of the adverse event by the time the report is made.

E. Surgical Events:
1. Surgery performed on the wrong body part that is inconsistent with the documented informed consent for that patient.
a. Surgery performed on the wrong patient
b. The wrong surgical procedure performed on a patient, which is a surgical procedure performed on a patient that is inconsistent with the documented informed consent for that patient.
c. Retention of a foreign object in a patient after surgery or other procedure, excluding objects intentionally implanted as part of a planned intervention and objects present prior to surgery that are intentionally retained.
d. Death during or up to 24 hours after induction of anesthesia after surgery of a normal, healthy patient who has no organic, physiologic, biochemical or psychiatric

disturbance, and for whom the pathologic processes for which the operation to be performed are localized and do not entail a systemic disturbance.

2. Product or Device Events – Patient Death or Serious Disability Associated With:
    a. The use of a contaminated drug, device, or biologic provided by the health facility when the contamination is the result of generally detectable contaminants in the drug, device, or biologic, regardless of the source of the contamination of the product.
    b. The use or function of a device in patient care in which the device is used or functions other than as intended. "Device" includes, but is not limited to, a catheter, drain, or other specialized tube, infusion pump, or ventilator.
    c. Intravascular air embolism that occurs while being cared for in a facility, excluding deaths associated with neurosurgical procedures known to represent a high risk of intravascular air embolism.
3. Patient Protection Events:
    a. An infant discharged to the wrong person.
    b. A patient death or serious disability associated with patient disappearance for more than four hours, excluding events involving adults who have competency or decision making capacity.
    c. A patient suicide or attempted suicide resulting in serious disability while being cared for in a health facility due to patient actions after admission to the health facility, excluding deaths resulting from self-inflicted injuries that were the reason for the admission.
4. Care Management Events:
    a. A patient death or serious disability associated with a medication error, including, but not limited to, an error involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or the wrong route of administration, excluding reasonable differences in clinical judgment on drug selection and dose.
    b. A patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products.
    c. Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a facility, including events that occur within 42 days post-delivery and excluding deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy, or cardiomyopathy.
    d. A patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is in the facility.
    e. Death or serious disability, including kernicterus, associated with failure to identify and treat hyperbilirubinemia in neonates during the first 28 days of life. "Hyperbilirubinemia" means bilirubin levels greater than 30 milligrams per deciliter.
    f. Stage 3 or 4 pressure ulcer, acquired after admission to the facility, excluding progression from Stage 2 to Stage 3 if Stage 2 was recognized upon admission.
    g. patient death or serious disability due to spinal manipulative therapy performed at the facility.
5. Environment Events:
    a. A patient death or serious disability associated with an electric shock while being cared for in a facility, excluding events involving planned treatments, such as electric countershock.
    b. Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by a toxic substance.
    c. A patient death or serous disability associated with a burn incurred from any source while being cared for in a health facility.
    d. A patient death associated with a fall while being cared for in a health facility.
    e. A patient death or serious disability associated with the use of restrains or bedrails while being cared for in a health facility.
6. Criminal Events:
    a. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider.
    b. The abduction of a patient of any age.
    c. The sexual assault on a patient within or on the grounds of the facility.

   d. The death or significant injury of a patient or staff member resulting from a physical assault that occurs within or on the grounds of a facility.
7. An adverse event or series of adverse events that cause the death or serious disability of a patient, personnel or visitor.

# III. POLICY:

A. St. Jude Medical Center is committed to providing quality health care to our patients. An integral part of any risk/quality management program is the establishment of a sentinel event plan.
B. An event is called "sentinel" because it sends a signal or sounds a warning that requires immediate attention. Accordingly, this policy is designed to ensure maximum risk-prevention and loss reduction activities on the part of the organization in response to a sentinel event.
C. Appropriate response includes a thorough and credible root cause analysis, implementation of improvements to reduce risk, and the monitoring of the effectiveness of those improvements. The results of this approach will help maintain the confidence of hte public in our organization, and have a positive impact on improving patient care.

# IV. PROCEDURE:

A. **Notification of a Suspected Sentinel or Significant Adverse Event**
   1. All St. Jude Medical Center and Medical Staff personnel are responsible for reporting any suspected Sentinel Event or significant adverse event **immediately** to the Clinical Excellence Department and complete an electronic Incident Reporting System (IRS) form. These event of a serious or critical nature require a verbal or telephone communication to the Clinical Excellence Department by calling anyone of the people below as soon as possible
      a. Vice President of Clinical Excellence - X5156
      b. Manager, Risk Management Services - X6551
      c. Manager Regulatory Compliance - X3609
      d. Patient Safety Officer - X2236
      e. Risk Management Supervisor - X2235
   2. During normal business hours, in addition to notifying the Clinical Excellence Department, St. Jude Medical Center staff will immediately notify their respective Clinical Coordinator/Supervisor, who will notify the Unit/Department Director. The Unit/Department Director will notify their respective Vice President.
   3. The Clinical Excellence Department will notify the Chief Executive Officer (CEO), the Chief Operating Officer (COO), the Chief Nursing Officer (CNO), and, if appropriate, the Director of Medical Staff Services.
   4. After business hours, or on weekends or holidays, St. Jude Medical Center staff will immediately notify their respective immediate Clinical Coordinator/Supervisor and complete an Incident Reporting System (IRS) Form. The Clinical Coordinator/Supervisor will notify their department Management Team Member and the Administrative Resource Nurse (ARN). The Department Management Team member will notify their respective Vice President. The ARN will notify the Administrator on Call.
   5. The Clinical Excellence Department will also screen for potential Sentinel Events via the Incident Reporting System and the quality monitoring processes of the organization.
   6. On an annual basis, staff will be educated regarding their role in the event reporting process as well as their role in promoting patient safety.
B. **Determination of Sentinel Event and Initial Response**
   1. The Clinical Excellence Department, in collaboration with appropriate supervisors and staff, shall conduct the initial investigation into a potential Sentinel Event. They shall, in concert with the COO/CNO and the Vice President of Clinical Excellence, identify those incidents that need further analysis in accordance with this policy.
   2. When considering next steps, the Clinical Excellence Department will use available information to assess if the occurrence meets any of the criteria for a potential Sentinel Event as known at that time.
   3. An Event Review Team (ERT) will be convened to determine if the event meets the criteria for a Sentinel Event.
      a. The ERT will be composed of the CEO, the COO, the CNO, the Medical Staff Chief of

Staff or designee (as appropriate), the Medical Staff Chair of the Patient Safety/Performance Improvement Committee or his designee (as required), the Chair of the appropriate Medical Staff Department or his designee (as appropriate), the Director of Medical Staff Services (as appropriate), the Vice President of Clinical Excellence, appropriate staff from Clinical Excellence Department, and/or others as representative of the event.

b. Quorum Requirement: a minimum of three of the organizational leadership team will constitute a quorum.

4. The ERT shall be convened as soon as possible and within ***72 hours*** of initial notification or discovery of the event to:
    a. Review the initial findings.
    b. Determine if the event meets the definition of a sentinel event.
    c. Determine if the event meets the definition of a Senate Bill 1301 Reportable Adverse Event to the California Department of Public Health (CDPH).
    d. The ERT may determine on occasion that it needs more information to make the determination if an event meets sentinel event criteria, (e.g. pending autopsy results and peer review findings), in which case the ERT will extend the timeline and re-convene upon the availability of such information to make the determination decision.
5. The ERT will make recommendations for any initial sentinel event or adverse event intervention plan for immediate follow-up care and services, risk reduction and any appropriate reporting requirements. Immediate response may include:
    a. Ensuring everything possible is being done to provide follow-up care and services to ensure the best possible outcomes for any involved patient(s) or parties.
    b. Ensuring all parties receive appropriate information. If necessary, the ERT will appoint a hospital spokesperson.
    c. Following any immediate regulatory reporting requirements. If the event meets the SB 1301 definition of a reportable adverse event, then it must be reported within five days to the CDPH, or within 24 hours, if determined to constitute "an ongoing or emergent threat to the welfare, health, or safety of patients, personnel, or visitors".
    d. Obtaining, sequestering or preserving any appropriate evidence and/or medical equipment related to the event.
    e. Reminding all staff of the confidentiality surrounding the event and the patient.

C. **The Root Cause Analysis Team Process**

1. If the event is deemed as a sentinel event, the Clinical Excellence assigned lead investigator staff member will convene a RCA Team as soon as possible.
2. The RCA Team will function as an ad hoc Interdisciplinary Committee of the Patient Safety/Performance Improvement Committee of the Medical Staff that will meet under the auspices of the Medical Staff Peer Review process.
3. The assigned lead Clinical Excellence staff member will prepare a thorough and credible comprehensive systematic analysis and action plan within **45 business days** of the event or of becoming aware of the event.
4. The members of the RCA Team will be representative of the process/services to be examined. The RCA Team may include representation from Medical Staff leadership, Administration, SJMC staff, and others as appropriate to the event.
5. The RCA Team is responsible for following this Policy and Procedure, and for submitting a thorough and credible root cause analysis to the Patient Safety/Performance Improvement Committee, the the Quality Committee of the Board of Trustees,Executive Medical Committee, and other appropriate committees.
6. In rare instances that the RCA Team requires greater than 45 business days to complete its work in order to do a thorough and credible root cause analysis (e.g. multiple, complex processes under investigation), the Team Facilitator from the Clinical Excellence Department will notify the Vice President of Clinical Excellence, the appropriate Vice President, and the Patient Safety/Performance Improvement Committee Team's status, the extension request, and the expected completion date. All efforts will be made to complete the root cause analysis and recommendations in a timely manner.
7. The RCA Team will primarily focus on the systems and processes that were responsible for the event. The Team will complete a root cause analysis using the "Framework for Conducting a Root Cause Analysis" and/or other appropriate tools, e.g. "Cause Mapping".

8. Utilizing the framework, the Team will determine the potential improvements in processes or systems that would tend to decrease the likelihood of such an event occurring in the future.
9. A Root Cause Analysis (RCA) will be considered acceptable if it has the following characteristics:
    a. The analysis focuses primarily on systems and processes, not individual performance.
    b. The analysis progresses from special causes in clinical processes to common causes in organizational processes.
    c. The analysis repeatedly digs deeper by asking "Why?" then, when answered, "Why?" again, and so on.
    d. The analysis identifies changes, which could be made in systems and processes either through redesign or development of new systems or processes that would reduce the risk of such events occurring in the future.
    e. The analysis is thorough and credible.
10. To be **thorough** the RCA must include the following:
    a. A determination of the human and other factors most directly associated with the sentinel event and the process(es) and systems related to its occurrence;
    b. An analysis of the underlying systems and processes through a series of "Why" questions to determine where redesign might reduce risk;
    c. An inquiry into all areas appropriate to the specific type of event as described in Attachment B;
    d. An identification of risk points and their potential contributions to this type of event;
    e. A determination of potential improvement in processes or systems that would tend to decrease the likelihood of such events in the future, or a determination, after analysis, that no such improvement opportunities exist.
11. To be **credible**, the root cause analysis must do the following:
    a. Include consideration of any relevant literature;
    b. Provide an explanation for all the findings of "not applicable" or "no problem";
    c. Be internally consistent (that is, not contradict itself or leaving obvious questions unanswered).
    d. Include participation by the leadership of the organization and by the individuals most closely involved in the processes and systems under review;
    e. Ensure the Minimum Scope of Review areas of the TJC are addressed;
12. An Action Plan is a product of the of the root cause analysis process which identifies the strategies that an organization intends to implement to reduce the risk of similar events occurring in the future. An acceptable action plan must include the following:
    a. Identifies, in situations where improvement actions are planned, who is responsible for implementation, when the action will be implemented (including any pilot testing), and how the effectivenss of the action will be evaluated.
    b. Identifies changes that can be implemented to reduce risk or formulates a rationale for not undertaking such changes;
    c. A summary of the RCA process will be prepared by the Clinical Excellence Department to include a high-level summary of the issue, team membership by discipline, relevant literature searches, and summary of the Action Plan to include Risk Reduction strategies and status;
    d. The RCA Team is responsible for submitting a thorough and credible root cause analysis to the Patient Safety/Performance Improvement Committee, the Executive Medical Committee, the Quality Committee of the Board of Trustees, and other appropriate committees.
13. Approval and Oversight of Action Plan:
    1. Oversight of the RCA intervention plan and the ongoing monitoring of the corrective action is the responsibility of the Clinical Excellence Department and the Department Director where the event occurred.
    2. The Clinical Excellence Department will schedule a 30-day follow-up meeting (60 days and 90 days after the date of the RCA) of the RCA Team to review the results of any ongoing monitoring and ensure the intervention plan has been implemented.
    3. Record will include any and all documentation related to the event, the subsequent root cause analysis, any corrective actions taken in response to identified opportunities for improvement or risk reduction strategies, and documentation that

actions taken have demonstrated effective resolution to concerns identified.

4. Protection from Discovery**:** All activities undertaken by the RCA should be done under the privilege provided by Section 1157 of the California Evidence Code. Other legal protections are to be implemented as determined by legal counsel.

D. **The Intensive Assessment (IA) Team Process**

1. If the event is deemed to be non-sentinel, but still presents an opportunity for performance improvement and/or risk reduction, the ERT will recommend convening an Intensive Assessment Team (IAT), and/or decide on specific actions to be implemented.
2. Oversight of the initiation of the Intensive Assessment Team (IAT) is the responsibility of the Clinical Excellence Department.
3. The Intensive Assessment Team will function as an ad hoc Interdisciplinary Committee of the Patient Safety/Performance Improvement Committee of the Medical Staff that will meet under the auspices of the Medical Staff Peer Review process.
4. A member of the Clinical Excellence Department will facilitate the IA Team.
5. The members of the IA Team will be representative of the process/services to be examined. The IA Team may include representation from Medical Staff leadership, Administration, SJMC staff, and others as appropriate to the event.
6. The IA Team will focus on the systems and processes that were responsible for the event. The Team will complete an Intensive Assessment, which will include The Joint Commission's minimum scope of detailed inquiry based on the type of event, as outlined in Attachment B. Using this framework, the Team will determine the potential improvements in processes or systems that would tend to decrease the likelihood of such an event occurring in the future.
7. The IA Team is responsible for submitting a summary of the Intensive Assessment to the Patient Safety/Performance Improvement Committee, the Executive Medical Committee, the Quality Committee of the Board of Trustees and other appropriate committees.
    a. Oversight of the initiation of the Intensive Assessment intervention plan and the ongoing monitoring of the corrective action is the responsibility of the Quality/Clinical Outcomes Department and the Department Director where the event occurred.
    b. The Clinical Excellence Department will schedule a 60-day follow-up meeting (60 days after the date of the IA) of the IA Team to review the results of any ongoing monitoring and ensure the intervention plan has been implemented.
8. Protection from Discovery**:** All activities undertaken by the IA should be done under the privilege provided by Section 1157 of the California Evidence Code. Other legal protections are to be implemented as determined by legal counsel.

E. **Referral for Confidential Peer or Personnel Review**

1. During the RCA or IA process, if the event requires review of the performance of a single identifiable individual; the matters will be referred directly for physician peer review or other appropriate referral such as to Human Resources or Administration.
2. Events involving individual physicians and allied health personnel shall be subject to applicable provisions of the Medical Staff Bylaws.

F. **Reporting of Adverse Events**

1. California Department of Public Health Services (CDPH) shall be notified as soon as reasonably practical, and within five calendar days as defined by California Senate Bill 1301.
2. Any employee death due to a sentinel event will be reported to OSHA.
3. In the event of a medical device-related sentinel event, reporting to the FDA will occur and the Safe Medical Device Act policy will be followed.
4. Other reporting shall be completed as appropriate for the type of event (e.g. notification of law enforcement or Adult Protective Services, etc).
5. The Clinical Excellence Department shall keep a complete and confidential record of the sentinel event.
    a. The record will include any and all documentation related to the event; and the subsequent root cause analysis;
    b. Any corrective actions taken in response to identified opportunities for improvement or risk reduction strategies, and;
    c. Documentation that actions taken have demonstrated effective resolution to concerns identified.

# V. RELATED ITEMS (OTHER POLICIES, ATTACHMENTS):

A. Root Cause Analysis Matrix
B. Critical Event Huddle Standard Work
C. Structure and Communication Flow for Internal Quality Report
D. Incident Reporting System (IRS), Electronic Quality/Risk Management Event Report (Q/RMER) Policy

# VI. REFERENCES:

A. The Joint Commission CAMH, Sentinel Events, Accreditation Manual, January 2015
B. The Joint Commission Sentinel Event Policy and Procedures - January 2015
C. Title XXII California Code of Regulations, Division 5 (General Acute Care Hospital), Section 70737.
D. California Healthcare Association Consent Manual 2014
E. Centers for Medicare and Medicaid Services, Appendix Q.

## Referenced Documents

| Reference Type | Title | Notes |
|---|---|---|
| **Documents referenced by this document** | | |
| Applicable Documents | Structure and Communication Flow for Internal Quality Reporting | |
| **Documents which reference this document** | | |
| Applicable Documents | Incident Reporting System (IRS), Electronic Quality/Risk Management Event Report Q/RMER | |
| Applicable Documents | Root Cause Analysis Matrix | |

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| **Signed by** | ( 01/05/2015 ) Teresa Frey, VP Clinical Excellence | | |
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