POLICY

It is the policy of the UCLA Hospital System to thoroughly review potential and actual adverse events in order to understand the causes that underlie these occurrences in order to facilitate improvements in patient care. The Event Reporting System shall be used to report any occurrence that is not consistent with routine operations that may potentially or actually result in injury, harm, or loss to any patient or visitor at UCLA Hospital System and outpatient clinics. Significant injuries should be immediately reported to a supervisor and to the Quality Management and Risk Management Departments (See Events Report Procedure below). Events may also be identified through any of the organization’s quality or peer review processes.

Reported events will be screened by the Quality Management and Risk Management Departments. If the determination is made that further investigation of the event is warranted (see Tables A, B, and C, below), initial details of the case will be investigated by the Quality Management and /or Risk Management Departments, who will conduct appropriate interviews and medical record reviews. Medical Center leadership, including but not limited to, the Chief Quality Officer, Chief Medical Officer, Chief Operating Officer, Associate Director of Patient Care Services, Quality Executive, Quality Director, Director of Nursing, and Risk Manager will determine what further action is required. A Root Cause Analysis is required in response to all Sentinel Events (See Attachments III & IV). The Quality Management Department will facilitate investigation of those cases in which a Root Cause Analysis or Event Investigation/Causal Analysis meeting is required.

All significant events will be reported to the Incident Review Committee, Clinical Excellence Committee, Medical Executive Committee, and governing body. Reportable adverse events, as defined by the California Department of Public Health (CDPH)(CA Health and Safety Code 1279.1) and Medi-Cal (DHCS Form 7107), shall be reported to CDPH and/or Medi-Cal within 5 days of discovery, unless the event is an ongoing urgent or emergent threat to the welfare, safety, or health of patients, personnel, or visitors, in which case, these events shall be reported to CDPH within 24 hours of discovery (See Attachment I for a list of Reportable Adverse Events). For Sentinel Events, the Associate Vice Chancellor and CEO, UCLA Hospital System, or designee, in consultation with other appropriate personnel, is responsible for determining whether to report the event to any external agencies Disclosure of the adverse event to the patient and/or family will follow the process outlined in Policy HS 1340 – Unanticipated Adverse Outcomes – Disclosure of.
DEFINITIONS

"Root Cause Analysis": A process for identifying the basic or causal factor(s) that underlie variation in performance, including the occurrence or possible occurrence of a sentinel event. Analysis focuses on processes and systems, not individuals.

"Reportable Adverse Event": as defined by CDPH (CA Health and Safety Code 1279.1) or Medi-Cal (DHCS Form 7107), events that cause the death or serious disability of patients, personnel or visitors. These events shall be reported to CDPH and/or Medi-Cal within 5 days of discovery, unless the event is an ongoing urgent or emergent threat to the welfare, safety, or health of patients, personnel, or visitors, in which case these events shall be reported to the CDPH within 24 hours of discovery. See Attachment I for a list of Reportable Adverse Events.

"Adverse Event" or "Event": Any occurrence that is not consistent with the routine operation of UCLA Hospital System or that potentially may, or resulted in injury, harm, or loss to any patient, employee, or visitor at UCLA Hospital System facilities, including outpatient clinics. An event may also include a major violation of established procedure or a disturbance or unfavorable situation that could disrupt hospital functions.

"Event Report": For the purposes of this policy, an "Event Report" refers to the completion of an Event Report either through the electronic Event Reporting System (EVR), or as part of the downtime procedures, by completing a "Confidential Report of Incident Form."

"Medical Device": An instrument, apparatus, implement, machine, implant, reagent, or other similar article (other than drugs), including any component part, accessory or associated equipment that are intended for use in the diagnosis, treatment or prevention of disease.

"Sentinel Event": As defined by the Joint Commission an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase, "or the risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. See Attachment II for examples of Sentinel Events always requiring a Root Cause Analysis and Attachment III for examples of Sentinel events not always requiring a Root Cause Analysis.

PROCEDURES

Event Reporting Procedure

I. Completing the Report

A. The Event Reporting System shall be used to report any potential or actual adverse events. Should the Event Reporting System be unavailable, the reporter will be automatically directed to the electronic downtime forms. If the computer system is down, then the reporter should complete the appropriate downtime form.

B. Event Reports are utilized to track patient safety related data for the purpose of determining when system improvements are needed. Event reports also serve to identify specific events that may result in litigation against the University and/or its staff. This information is used by the Risk Management Department, formalized medical staff committees responsible for the evaluation and improvement of patient care and safety practices, and the Executive Environment of Care Committees.

C. All information requested within the Event Report should be provided. The reporter should report only "known facts" and not speculate or place blame. The Event Report should be completed using the
D. All events shall be reported to the employee's supervisor. The completion of any internal departmental notification form concerning an event does not substitute for the completion of an Event Report.

E. The Event Reporting System ("EVR") shall not be used to address or document disciplinary/personnel actions, to document interdepartmental or interpersonal disputes that may be resolved in a more direct and constructive manner, nor shall it be placed within a staff member's personnel file.

II. Examples of Events to Report

A. Reportable events/occurrences include, but are not limited to, the following major categories:

   1. Unexpected variations or complication in medical treatment
   2. Unexpected variation or complication in surgical procedure
   3. Retained foreign objects including those resulting from broken or fractured medical equipment but excluding those intentionally retained
   4. Perinatal complication
   5. Equipment/device issue
   6. Medication error or Adverse Drug Reaction
   7. Falls
   8. Pressure Ulcers
   9. Diagnostic or testing issue
   10. Patient flow related issues
   11. Fire and environmental hazards
   12. Unprofessional behavior that compromises or has the potential to compromise patient care
   13. IV transfusion complications (including blood and blood products)
   14. Injury other than fall
   15. Attempted suicide

B. Should an employee have a question as to whether or not to report an event/occurrence, they first should contact their supervisor or call the Quality Management or Risk Management Department.

C. If the event involves a slip or fall, the person completing the report should also contact UCLA Health System Security Department and request an investigation that may include a Floor Test at the site of the fall. All spills and wet floors should be reported to Health System Facilities.

   UCLA Medical Center / Resnick Neuropsychiatric Hospital: Loose tiles, debris and other potential hazards must be immediately reported to the Trouble Desk.

   Santa Monica-UCLA Medical Center and Orthopaedic Hospital: Loose tiles, debris and other potential hazards must be immediately reported to the Engineering Department.

D. If the event involves harm, injury, or loss to a student, volunteer or employee, occurring as they serve in that capacity and not as a patient of the facility, the event should be reported to the department/unit supervisor.
E. Equipment-Related Events – (See also Policy HS 0331 – Reporting Of Incidents Related to Medical Equipment and Devices (Event Reports)) The federal Safe Medical Device Act ("SMDA") of 1990 requires that a report be filed with the Food and Drug Administration ("FDA") when a device causes or contributes to a patient death, serious illness, or serious injury. The Event Report will be the source document for evaluation for possible SMDA reporting. It is essential that the Event Report be made within 24 hours, as the law requires that reports be filed within 10 working days of first notice. The Event Report must include the following information for identification:

1. product name;
2. model number;
3. serial number (if applicable);
4. lot number (if applicable);
5. Manufacturer's name; and
6. Brief description of the event.

III. Procedure/Responsibility

A. Filing Event Reports

1. An Event Report shall be completed and submitted when an employee observes or becomes aware of a reportable occurrence or hazardous condition.

2. Event Reports are confidential communications protected by sections 1156 and 1157 of the California Evidence Code. They are not subject to release to the patient or other persons, even in response to a subpoena.

3. The Event Report must be completed entirely in the Event Reporting System and the user must log out after the event is submitted. If a paper version is used, the "Confidential Report of Incident" form must never be placed in the patient's medical record, kept at the nurses' station, left on the unit, or left on the supervisor's desk where unauthorized persons can gain access.

4. NO COPIES OF THE REPORT CAN BE MADE FOR ANY PURPOSE. IN ADDITION, NO REFERENCE TO THE REPORT IS TO BE MADE IN THE MEDICAL RECORD, NOR SHALL ANY REFERENCE BE MADE THAT ONE HAS BEEN OR WILL BE COMPLETED OR SUBMITTED.

5. Electronically completed Event Reports will be automatically forwarded to all appropriate persons (unit manager, category manager or sub-category manager) once they are completed in the Event Reporting System. In addition, the Quality/ Risk Management Departments will be notified automatically of events where patient harm is indicated. In situations where patient harm occurs, a call should be made immediately to the Quality Management or Risk Management Department in addition to completing the electronic report. Unit and/or category managers should investigate the occurrence reported and enter appropriate follow-up into the Event Reporting System in a timely manner along with providing the event with a severity score ranking.

The following is a guide on ranking the event's severity based on harm type and level of harm. Harm Types:

a. **Hazardous Condition**: Set of circumstances not related to the disease process that increases the likelihood of a serious adverse event. For example: wet floor, broken
b. **Error**: Unintended act, either of omission or commission, that results in an event that is not related to the actual course of the patient's illness or underlying condition. Any deviation from policy or procedure.

c. **Non-error**: Event reported not related to an error that could not have been reasonably prevented. For example: unexpected patient deterioration, adverse drug reactions, unpreventable skin breakdown, unpreventable falls, IV device disconnection, phlebitis, disruptive family members.

d. **Prior event**: Event occurred prior to admission or entry into the system.

e. **Non-incident**: Event reported for tracking or analysis only. May include reports inappropriate for the Event Reporting System. No level of harm is applied to this type of event.

**Level of Harm:**

a. **No Harm (1)**: Near miss. Did not reach patient

b. **No Harm (2)**: Reached patient. Monitoring may be required.

c. **Minimal Harm (3)**: Minor treatment applied. Inconvenience or delay resulted.

d. **Moderate Harm (4)**: Initial or prolonged hospitalization, or minor procedural intervention resulted. Higher level of care required.

e. **Serious Harm (5)**: A life threatening event. Examples include: unplanned surgical procedure, intubation, anesthesia or moderate sedation.

f. **Patient Death (6)**

g. **Unable to Determine (7)**: Due to discharge or other unusual circumstances, patient outcome cannot be determined. This also applies to events in which the relationship between the event and a patient outcome cannot be determined.

6. The Quality Management and Risk Management Departments will retain access to all the original reports.

7. The Quality Management and Risk Management Departments monitor Event Reports to identify medical device related incidents; when appropriate, these events are reported to the FDA, as required by law. In addition, the manufacturer is notified in order to ensure corrective action(s).

8. Clinical Engineering will include a review of all equipment-related events in a quarterly report to the Environment of Care Committees.

9. Monitoring shall be performed to identify trends and patient care improvement opportunities. Results will be presented to Incident Review and Clinical Excellence Committees and to the Westwood and Santa Monica Environment of Care Committees. When it is determined that a corrective action is required, the effectiveness of the action taken will be monitored and reported by the Incident Review Committee.

B. Notification of Patient and/or Family Member of Adverse Event – See Policy HS 1340 Unanticipated Outcomes – Disclosure of

C. Notifying Quality/Risk Management
Any event that results or may result in significant harm or injury to a patient or visitor shall be reported immediately to the Quality Management or Risk Management Departments. A Risk Management representative may be contacted after hours, on weekends and holidays by calling the page operator and asking for the risk manager on-call.

D. Notification of the California Department of Public Health and/or Medi-Cal

The UCLA Hospital System is required to report Adverse Events, as defined by the California Department of Public Health (CDPH) (CA Health and Safety Code 1279.1) (Attachment I) and Medi-Cal (DHCS Form 7107)

CDPH reporting is the responsibility of the Office of Licensing, Accreditation and Policy (See: Policy HS 9010, Mandatory Reporting). The Quality/ Risk Management Departments shall confer with the Office of Licensing, Accreditation and Policy, as appropriate, to ensure that the Medical Center meets its CDPH reporting obligations. Medi-Cal reporting is the responsibility of the Quality Management Department in collaboration with the Office of Licensing and Accreditation.

Sentinel/Non-Sentinel Event Procedures

Determination of Level of Investigation Required

The following tables define the criteria to be used as a guideline for assessing the event severity and required level of needed follow-up action.

<table>
<thead>
<tr>
<th>Likelihood of Event Recurrence Value</th>
<th>Potential Consequence of Event</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>5 Insignificant</td>
</tr>
<tr>
<td>1 – Certain</td>
<td></td>
</tr>
<tr>
<td>2 – Likely</td>
<td></td>
</tr>
<tr>
<td>3 – Possible</td>
<td></td>
</tr>
<tr>
<td>4 – Unlikely</td>
<td></td>
</tr>
<tr>
<td>5 – Rare</td>
<td></td>
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</table>

Table A

Table B

<table>
<thead>
<tr>
<th>Likelihood of Event Recurrence Value (#)</th>
<th>Probability Categories of Event Recurring</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Frequent or Certain</td>
<td>Expectation that the event will recur immediately or within weeks or months</td>
</tr>
<tr>
<td>2</td>
<td>Likely</td>
<td>Will probably recur more than once within 12 months</td>
</tr>
<tr>
<td>3</td>
<td>Possible</td>
<td>May recur every 1 to 2 years</td>
</tr>
<tr>
<td>4</td>
<td>Unlikely</td>
<td>Possibly recur every 2 to 5 years</td>
</tr>
<tr>
<td>5</td>
<td>Rare</td>
<td>Possibly recur every 5 to 30 years</td>
</tr>
</tbody>
</table>

4 - Low Risk 3 - Moderate Risk 2 - High Risk 1 – Sentinel/Adverse Event
### Conducting a Root Cause Analysis

A Root Cause Analysis will be conducted for all Sentinel Events as defined in Appendix II, and other events as deemed appropriate by Leadership. Investigation shall be initiated within twenty-four (24) hours of notification or discovery of the occurrence and the meeting held within 3 working days. The Root Cause Analysis will consist of an investigation to understand the underlying process issues and a follow-up Action Plan to be fully developed within forty-five (45) days of the notification of the event or discovery of the event.

### Roles and Responsibilities

Once the determination has been made that a Sentinel Event has occurred, the following steps will be taken.

1. A multidisciplinary team will be identified including applicable Hospital System leadership and staff members closely involved in the systems and processes surrounding the event.
2. Prior to the team meeting, interviews with individuals associated with the event will be conducted and appropriate documentation will be reviewed as possible.
3. The multidisciplinary Root Cause Analysis team will meet to discuss the event focusing on the processes and systems involved in the event. The analysis will be consistent with the Joint Commission’s "Minimum Scope of Root Cause Analysis for Specific Types of Sentinel Event."
4. Once the root cause has been determined, an Action Plan will be developed to include changes in processes and systems that would reduce risks of the similar event occurring in the future. The Action Plan will include the name of the person responsible for the Action Plan, the date of implementation, and how monitoring will occur.
5. If appropriate, a process improvement team will be convened whose members may or may not be the same as those on the Root Cause Analysis team.
6. Results of Root Cause Analysis and follow-up Action Plan will be reported to leadership. The responsibility for follow-up action will be identified in the Action Plan.

### Conducting an Event Investigation/Causal Analysis

The following steps will be taken when Leadership has determined the event does not require full Root Cause Analysis methodology, but does warrant further analysis.

**Investigation/Causal Analysis**

1. A multidisciplinary team, including applicable leadership and staff members will meet to discuss the event focusing on the processes and systems involved in the event, not the individuals.
2. Appropriate information will be available at the meeting to thoroughly review the event factors.

3. The factors contributing to the event will be determined, and their applicability to other organizational processes will be assessed.

4. An Action Plan will be developed to include changes in processes and systems that would reduce risks of the similar event occurring in the future. The Action Plan will include the name of the person responsible for the Action Plan, the date of implementation, and how monitoring will occur.

5. If appropriate, a process improvement team will be convened whose members may or may not be the same as those on the original multidisciplinary team.

6. Results of the investigation and follow-up Action Plan will be reported to leadership.

Confidentiality

A. Event Reports of Incidents/Occurrences are confidential communications protected by the attorney-client privilege. They are not subject to release to the patient or other persons, even in response to a subpoena. All such reports shall be kept under the auspices of the Quality Management Department. The investigation and/or resolution (including remedial or corrective actions) of Sentinel Events are confidential peer review protected activities.

All paper and electronic reports, discussions, and other documents pertaining to sentinel evaluation and/or reporting shall be deemed confidential and not subject to disclosure. (Section 1157 California Evidence Code.) No copies of paper or electronic forms, investigation reports, or other documents are to be made for any reason. All follow-up analysis reports are maintained for performance improvement review purposes and are protected from disclosure. The sole purpose of these reports is for improvement of quality of care. Root Cause Analysis and Action Plan Reports will be filed confidentially in the Quality Management Department.

Sentinel Event Alerts

A. Sentinel Event Alerts are periodic publications dedicated to providing important information relating to the occurrence and management of sentinel events in the Joint Commission-accredited health care organizations.

B. The Sentinel Event Alert describes underlying causes and suggests steps to prevent occurrences in the future.

C. Upon receiving a Sentinel Event Alert an interdisciplinary team is formed, facilitated by the Licensing and Accreditation Department, with the appropriate disciplines relative to the Sentinel Event Alert and the team does the following:

1. Review the Alert and consider relevant information if appropriate to the organization's services.
2. Consider information in the Alert when designing and redesigning processes.
3. Evaluate systems in light of information in the Alert.
4. Consider standard-specific concerns
5. Implement relevant suggestions or reasonable explanation for not implementing relevant changes.

D. The Sentinel Event Alert is routed to the appropriate staff and departments, and Medical Staff with actions taken by the interdisciplinary team.
### REFERENCES

CDPHCA Health and Safety Code 1279.1  
21 U.S.C.A. Sec. 360i  
California Evidence Code Sections 952 and 1156 and 1157  
CA Health and Safety Code 1279.1  
JC, CAMH 2003: LD. 5.1 and PI.4.4  
Title 22 California Code of Regulations §70737  
UCLA Hospital System Policy HS 1340 – Unanticipated Outcomes – Communication of  
UCLAHospital System Policy HS0331

### CONTACT

Director, UCLA Quality Management

### REVISION HISTORY (Pre- PolicyStat)

Replacing UCLA Policy 0328 and 0331– Sentinel Events and Event Reports Policies.

<table>
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### APPROVAL

Johnese Spisso, RN, MPA  
President and CEO  
UCLA Health System  

Christopher Tarnay, M.D.  
Chief of Staff  
Ronald Reagan UCLA Medical Center
Roger M. Lee, M.D.
Chief of Staff
Santa Monica-UCLA Medical Center and Orthopaedic Hospital

Robert Suddath, M.D.
Chief of Staff
Resnick Neuropsychiatric Hospital at UCLA

**Attachments:**

- Downtime SOFI Form.pdf
- I: California Department of Public Health Reportable Adverse Events
- II: Sentinel Events
- III: Sentinel Event Examples

## Approval Signatures

<table>
<thead>
<tr>
<th>Step Description</th>
<th>Approver</th>
<th>Date</th>
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<tbody>
<tr>
<td>Administration Approval</td>
<td>Robert Suddath: Hs Assoc Clin Prof-Hcomp [JM]</td>
<td>03/2017</td>
</tr>
<tr>
<td>Administration Approval</td>
<td>Roger Lee: Hs Clin Prof-Hcomp [MA]</td>
<td>03/2017</td>
</tr>
<tr>
<td>Administration Approval</td>
<td>Christopher Tarnay: Hs Assoc Clin Prof-Hcomp [MA]</td>
<td>03/2017</td>
</tr>
<tr>
<td>Administration Approval</td>
<td>Johnese Spisso: Ceo Med Ctr [MA]</td>
<td>03/2017</td>
</tr>
<tr>
<td>Executive Medical Boards - MSEC, RNPH PSEC, SMEMB</td>
<td>James Morva: Admin Anl Prn 1</td>
<td>03/2017</td>
</tr>
<tr>
<td>Hospital System Policy Committee Chair</td>
<td>Margaret Armbruster: Dir</td>
<td>02/2017</td>
</tr>
<tr>
<td>Hospital System Policy Committee</td>
<td>James Morva: Admin Anl Prn 1</td>
<td>02/2017</td>
</tr>
<tr>
<td></td>
<td>Brenda Clemens: Dir Ast</td>
<td>02/2017</td>
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