



## CLINICAL POLICY

### Reporting Adverse Medical Device Incidents

**A. EFFECTIVE DATE :**

June 30, 2021

**B. PURPOSE :**

In compliance with the Safe Medical Devices Act of 1990 (Act) it is the policy of John Dempsey Hospital to report to the Food and Drug Administration (FDA) or the device manufacturer, if known, any medical device incident that, after preliminary investigation, is believed to have caused or contributed to a patient's death, serious illness, or serious injury.

**C. POLICY :**

It is the policy of JDH to understand and embrace a non-punitive culture of safety in regards to medical error reporting. A primary goal of this system is to learn about adverse events and gain new knowledge about the causes of errors in order to prevent future errors.

JDH seeks to obtain information about adverse medical device incidents that leads to improvement in a non-punitive environment encouraging trust and respect between those who report errors and those who receive and analyze them. In order to accomplish this, it is imperative that front-line practitioners, who have necessary and insightful information about any complication or event that causes complication, feel comfortable reporting significant complications or serious/fatal events whether or not caused by potential errors, "near misses," and hazardous situations. The JDH system of reporting encourages unrestricted practitioner reporting, is non-punitive with respect to those who report, and provides a mechanism for confidential reports.

The following are options available to anyone reporting any medical complication with or without suspected error:

- A Safety Intelligence (S-I) report may be completed on line.
- Personal or phone contact may be made with the Risk Management Office (LM043; ext. 2687)
- The confidential "REPORTLINE" may be used at 888/685 – 2637. This line operates under the UCHC Reporting Compliance Concerns Policy (available on the Compliance Office website).

**D. SCOPE:**

This policy applies to any UConn Health staff member who discovers, witnesses, or is notified of a suspected medical device incident. Included within the scope of this policy are personnel who use or operate a medical device, such as physicians, nurses, technicians, and therapists that reside within JDH and UMG patient care areas.

**E. DEFINITIONS :**

- Serious Illness or Injury - a serious illness or injury as defined by the Act is an illness or injury that is life threatening or that either results in permanent impairment of a bodily function or permanent damage to a

bodily structure or necessitates immediate medical or surgical intervention to preclude permanent impairment of a bodily function or permanent damage to a bodily structure.

- Medical Device - FDA defines a medical device as any instrument, apparatus, or other article that is used to prevent, diagnose, mitigate, or treat a disease or to affect the structure or function of the body, with the exception of drugs. For example, a medical device includes but is not limited to ventilators, monitors, dialyzers, and any other electronic equipment, implants, thermometer, patient restraints, syringes, catheters, in vitro diagnostic test kits and reagents, disposables, components, parts, accessories, and related software.

**F. MATERIAL(S) NEEDED :**

NONE

**G. PROCEDURE :**

1. Any faculty or staff member who discovers, witnesses, or is notified of a medical device incident that he or she suspects may have caused a death, serious illness, or serious injury to a patient under treatment shall immediately notify, either in person or by telephone, the attending physician, complete a Safety Intelligence Report (SI), and notify the Clinical Engineering and Supply Chain Operations Departments.
2. To ensure proper follow-up and investigation of the incident, the faculty or staff member who reports the adverse medical device incident shall provide the following information to the Clinical Engineering and Supply Chain Operations Departments.
  - A. patient's name
  - B. room and bed number
  - C. name of attending physician notified
  - D. product name
  - E. location of the product
  - F. serial number of the product
  - G. model number
  - H. name of the manufacturer, if known
  - I. brief description of the incident
3. The UConn Health staff member who reports the adverse medical device incident shall secure the medical device (complete with all associated disposables and packaging materials) that is involved in a patient injury.
4. After a SI is completed, Clinical Engineering and Supply Chain Operations Departments will coordinate an investigation of the device-related incident.
  - a. Conduct a preliminary investigation of the incident and determine whether the medical device appears to have caused or contributed to the event and why. As needed, UConn Health will request faculty or staff members to assist with this investigation. Reports, records, and written findings will be filed with UConn Health.
  - b. Once the preliminary incident investigation is completed, UConn Health will determine whether the incident is reportable under the Safe Medical Devices Act.

- c. If the device-related incident is deemed reportable under the Act, UConn Health will complete the FDA Mandatory Medwatch Report.
5. UConn Health will send or fax the Medwatch Report to the manufacturer and/or the Food and Drug Association, within 10 working day after it has been determined whether the incident is considered reportable. Any level of serious injury, illness or death requires the report to be sent to BOTH the FDA and the manufacturer.
6. UConn Health will maintain a file of the Medical Device Reports sent to the FDA and to device manufacturers.
7. Any corrective actions impacting the current inventory of medical devices will be conveyed to the medical device users directly and through appropriate communication channels.

**H. ATTACHMENTS :**

NONE

**I. REFERENCES :**

- Equipment Involved in Patient Injury, Policy #11-020
- Tracking of Medical Devices to Provide and Effective Method for Device Recalls and an Efficient Patient Notification Process, Policy #11-036
- Reporting Compliance Concerns, UCHC Policy #2003-33

**J. SEARCH WORDS :**

NONE

**K. ENFORCEMENT:**

Violations of this policy or associated procedures may result in appropriate disciplinary measures in accordance with University By-Laws, General Rules of Conduct for All University Employees, applicable collective bargaining agreements, the University of Connecticut Student Code, other applicable University Policies, or as outlined in any procedures document related to this policy.

**L. STAKEHOLDER APPROVALS :**

On File

**M. COMMITTEE APPROVALS :**

NONE

**N. FINAL APPROVAL :**

- |   |                                   |
|---|-----------------------------------|
| <p>1. <u>Andrew Agwunobi, MD (Signed)</u><br/>Andrew Agwunobi, MD, MBA<br/><b>UConn Health Chief Executive Officer</b></p>  | <p><u>07/21/2021</u><br/>Date</p> |
| <p>2. <u>Anne D. Horbatuck, (Signed)</u><br/>Anne D. Horbatuck, RN, BSN, MBA<br/><b>Clinical Policy Committee Co-Chair</b></p>  | <p><u>07/21/2021</u><br/>Date</p> |
| <p>3. <u>Scott Allen, MD (Signed)</u><br/>Scott Allen, MD<br/><b>Clinical Policy Committee Co-Chair</b></p>   | <p><u>07/19/2021</u><br/>Date</p> |
| <p>4. <u>Caryl Ryan (Signed)</u><br/>Caryl Ryan, MS, BSN, RN<br/><b>Interim Chief Operating Officer, JDH</b><br/><b>VP Quality and Patient Services &amp; Chief Nursing Officer</b></p> | <p><u>07/18/2021</u><br/>Date</p> |

**O. REVISION HISTORY :**

Date Issued: 7/76

Date Revised: 1/86, 11/88, 12/88, 9/91, 8/09, 10/14, 5/18, 6/21

Date Reviewed: 11/94, 5/97, 2/00, 10/03, 05/06, 9/08, 09/12, 04/16