I. Title

Medical Device Recall, Alert, Safety Hazard Notification, and Response

II. Policy

UTMB is committed to patient safety and responds accordingly to medical device recall notices as required by the FDA.

UTMB departments shall comply with the recommendations included in any recall, alert, or safety hazard notice provided by the FDA and/or product manufacturer. Compliance efforts, or an explanation of any differences between the manufacturer’s recommendations and UTMB activities, shall be communicated via the ECRI Alerts Tracker system or routed to Quality & Healthcare Management.

III. Notification Process

A. Medical Device recalls and safety hazard notifications are received by and distributed to the appropriate department director (or designee) by Quality & Healthcare Management using the ECRI Alerts Tracker system. Recipients of ECRI alerts shall review the information provided, determine applicability, complete corrective action recommended by the manufacturer or the FDA, and document such efforts via the ECRI Alerts Tracker system in a timely manner.

B. Medical device recalls and safety hazard notices are also received by Quality & Healthcare Management via letter or e-mail delivery and are distributed electronically to the appropriate department director (or designee) for processing as described above.

C. Medical device recalls and safety hazard notices received by a department other than Quality & Healthcare Management shall be forwarded to Quality & Healthcare Management for processing.

D. A record of all recalls and safety hazard responses received will be maintained by Quality & Healthcare Management.

IV. Patient Contact

Physicians should be considered the primary liaison in concert with Quality & Healthcare Management when circumstances require that a patient be contacted.

V. Dates Approved or Amended

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VI. Contact Information
Quality & Healthcare Management
(409) 772-8509