(A) Policy Statement

Known or suspected instances of infection of donor tissue or organs will be investigated and appropriate actions taken for notification of recipients and prevention of further implantation.

(B) Purpose of Policy

To prevent the spread of infection, ensure timely notification for those who may have received contaminated tissue or organs, and provide appropriate resources for screening and/or treatment.

(C) Procedure

(1) Healthcare personnel who become aware of adverse events or infections of recipients of tissue or organ transplant will notify Infection Prevention, who will notify the Risk Manager and the Surgical Administrator.

(2) The Surgical Administrator or his designee will:

(a) Immediately report identified patients to the tissue source facility, or appropriate Organ Procurement Organization that coordinated the receipt of the tissues/organ.

(b) Sequester any remaining tissues/organs from the same donor.

(c) Report to the Institutional Review Board (IRB) Chairperson within 24 hours, if patient is/was involved in clinical trials. The IRB chairperson will ensure that an adverse event document is prepared and forwarded to the Risk Manager.

(d) Findings will be analyzed and presented to the Risk Management department.

(e) Affected patients will be notified through their physician of record, their primary care physician and by certified mail or as otherwise appropriate to the situation.

(f) The Risk Manager will call together a committee to examine the possibility of risk to the facility.
(i) This committee will consist of the Risk Manager, Infection Preventionist, Operating Room Manager, the patient’s physician, Quality Management, Legal Department and others as needed.

(ii) The Infection Preventionist will assist the Risk Manager in the investigation of the case and the possibility of other cases related to the same incident.

(3) A plan will be developed to respond to this event and will include:

(a) Rapid notification of patients who may have been recipients from the same donor, through their physicians of record, their primary care physicians or other means of tracking, if available.

(b) Education of the recipient through the patients’ physicians regarding signs and symptoms of infection, and the relative risk of developing infection.

(c) Recommendations to the recipients’ physicians for laboratory testing as determined by the situation.

(d) The facility will report voluntarily to the FDA Safety Information and Adverse Event Reporting program Form: FDA 3500 (rev. 10/15).

Records will be maintained in the Risk Management/Legal Affairs Department or Infection Prevention and Control department as appropriate.

References
