Name of Policy:	**Investigation of Tissue Recipient/Donor Infections**
Policy Number:	**3364-109-DIS-209**
Department:	Infection Control University Health Services Hospital Administration
Approving Officer:	Chair, Infection Control Committee Chief of Staff Chief Medical Officer
Responsible Agent:	Infection Preventionist
Scope:	The University of Toledo Medical Center and its Medical Staff

THE UNIVERSITY OF TOLEDO MEDICAL CENTER

Effective Date: 09/01/2023

Initial Effective Date: 2/28/2011

_____ New policy proposal	_____ Minor/technical revision of existing policy
_____ Major revision of existing policy	__X__ Reaffirmation of existing policy

(A) Policy Statement

Known or suspected instances of infection or disease transmission of donor tissue or organs will be investigated, and appropriate actions taken for notification of recipients and prevention of further implantation from affected donor(s).

(B) Purpose of Policy

To prevent the unintended transmission of infectious disease to a recipient and to ensure timely notification for those who may have received infected or 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 report the event through Safety Net reporting system or notify Infection Prevention and Control and the Administrator for Surgical Services as soon as possible but no more than 24 hours after learning of the event.

(2) Infection Prevention and Control and the Administrator for Surgical Services will review presented information and promptly notify the Risk Management Department as necessary.

(3) The Administrator for Surgical Services or designee will:

(a) Notify the Transplant Administrator according to policy 3364-140-45 Transplant Adverse Events if the infection or issue with contaminated tissue or organ is related to a kidney transplant donor or recipient.

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

(c) Sequester any remaining tissues/organs from the same donor within the organization as applicable.

(d) 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.

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

(f) 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 regarding the risk for infection or subsequent infection found.

(g) The Risk Manager will call together a committee to examine the possibility of risk to the facility.

(i) This committee will consist of at a minimum representation from: Risk Manager, Infection Preventionist and Control, Operating Room, the patient's physician, Quality Management, and Legal.

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

(4) 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. 02/20).

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

References

U.S. Food and Drug Administration. MedWatch Forms for FDA Reporting. Retrieved from https://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm

The Joint Commission Tissue Implants Standards. Retrieved from https://www.jointcommission.org/standards/standard-faqs/ambulatory/transplant-safety-ts/000001800/

Approved by: /s/ 08/28/2023 Michael Ellis, MD — Date Chair, Infection Control Committee /s/ 08/30/2023 Asif Mahmood, MD — Date Chief of Staff /s/ 08/28/2023 Michael Ellis, MD — Date Chief Medical Officer *Review/Revision Completed By:* *Infection Control Committee*	**Review/Revision Date:** 07/16/2014 06/30/2017 08/10/2020 08/22/2023 **Next Review Date:** 08/2026
Policies Superseded by This Policy: 3364-109-DIS-209	