Name of Policy:	**Incident/ Error/ Accident Review**
Policy Number:	3364-108-106
Department:	Pathology/Laboratory – Blood Bank
Approving Officer:	Chief Operating Officer - UTMC Director, Blood Transfusion Service
Responsible Agent:	Blood Transfusion Service Supervisor Administrative Director, Lab
Scope:	Pathology/Laboratory – Blood Bank

THE UNIVERSITY OF TOLEDO MEDICAL CENTER

Effective Date: **03/20/2023**
Initial Effective Date: 6/1996

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

(A) Policy Statement

The Blood Transfusion Service has a process to capture, assess, investigate and monitor events that deviate from UTMC policy or procedure or other applicable regulations and requirements.

(B) Purpose of Policy

To capture and classify variant events; investigate and identify problems; implement corrective action and evaluate effectiveness of corrective action.

(C) Procedure

All errors (unplanned deviations) or variances from procedure detected in previously described reviews are documented on a Lab Occurrence Report. Document all pertinent information including unit numbers, patient identification and detailed description of the problem. In addition, UTMC Occurrence Reports should be initiated using the Datix Patient Safety report online for all serious errors that affect patient safety. Deviations from policy or procedure with prior approval from BTS-Medical Director or designee (planned deviations) must also be documented. All variances are reviewed by the BTS supervisor and referred to the BTS Medical Director or designee if warranted. Appropriate corrective actions and follow-up are recorded on Variance Report. Recurrent variances by Blood Transfusion Service personnel are corrected by retraining. Repeated negligence or breach of policy or procedure will result in disciplinary action. Variance reports are referred as follows:

⇒ Hospital departments, Risk Management; variances involving personnel outside of Department of Pathology
⇒ Laboratory CQI Coordinator; variances involving specimen collection, delays, laboratory personnel
⇒ Lab Utilization Review Committee, Risk Management; serious variances requiring interdisciplinary approach for resolution; irregular blood ordering practices or blood usage for peer review. Incidents considered "Sentinel Events" will be investigated and reported to The Joint Commission by Risk Management.
⇒ American Red Cross; variances involving blood or component unit quality or availability; severe adverse effects of transfusion.
⇒ Product/ Equipment Vendors or Manufacturers; variances involving reagents, equipment or products.
⇒ Federal Drug Administration; biological product deviations (BPD) that occur while products are under UTMC control that affect the safety, purity, or potency of a blood product. See guidance documents and forms attached or to report electronically within 45 days, see CBER web site at www.fda.gov/cber/biodev/biodev.htm); fatal transfusion reactions.

Communication of Concerns

Personnel with concerns about quality or safety are encouraged to communicate those concerns to Lab Administration or Hospital Executive Management. Anonymous communication of quality or safety concerns may also be made to CAP or Joint Commission. Contact information is located in the Policy manual and posted in the laboratory.

Approved by:		**Review/Revision Date:**
/s/	03/21/2023	6/96 3/22/2011 1/98 3/01/2013 3/99 3/2/2015 4/00 3/1/2017 7/01 3/1/2019 1/05 3/1/2021 1/2008 3/20/2023 6/9/2008
Lauren Stanoszek, M.D. Assistant Professor Director, Blood Transfusion Service	Date	
/s/	03/21/2023	
Christine Stesney-Ridenour Chief Operating Officer - UTMC		
Review/Revision Completed By: Danielle Weilnau, MLS(ASCP)^{CM}		**Next Review Date:** 3/1/2025
Policies Superseded by This Policy:		

References:

AABB Standards for Blood Banks and Transfusion Services, current edition.