Name of Policy: **Lookback Protocol** THE UNIVERSITY OF TOLEDO **Policy Number:** 3364-108-503 **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: **Effective Date:** 03/20/2023 Pathology/Laboratory - Blood Bank Initial Effective Date: 10/1986 New policy proposal Minor/technical revision of existing policy Major revision of existing policy Reaffirmation of existing policy

(A) Policy Statement

The Blood Transfusion Service participates in Look-back programs according to AABB and ARC standards.

(B) Purpose of Policy

To prevent infectious disease transmission and identify transfusion recipients that may be candidates for testing and counseling services.

(C) Procedure

The American Red Cross has a policy to notify Blood Transfusion Services of blood units from previous donations when donors' current donation tests positive for anti-HIV-1/HIV-2, anti-HTLV I, anti-HCV, HCV NAT, HIV NAT, HBV DNA NAT or WNV NAT. Recipients of past donations from these donors are considered "at risk" and must be identified and offered testing. If confirmed positive, the recipient is offered counseling for clinical management and to reduce the possibility of spreading infection. Testing and counseling services are also provided by American Red Cross Blood Services, Donor and Client Support Center (ARCDCSC).

- 1. The Lookback procedure is initiated by the ARCDCSC following confirmation of donor's positive tests.
- 2. ARCDCSC will notify the UTMC Blood Transfusion Service (BTS) Medical Director by letter, identifying the implicated blood component units.
- 3. The UTMC BTS Medical Director or designee ascertains the final disposition of the implicated blood units. If the unit was transfused, the recipient's name, hospital identification number and the attending physician are recorded on the ARCDCSC form. The completed ARCDCSC notification form is returned to the ARCDCSC Medical Director.
- 4. The UTMC BTS Medical Director notifies the attending physician in writing and provides the physician with a copy of the completed ARCDCSC notification form. Information concerning resources for testing and counseling services is provided to the physician. The resources include but are not limited to the following:
 - a) HIV Clinical Nurse Specialist (AIDS Resource Team ART)
 - b) HIV Psych Clinical Nurse Specialist
 - c) Infection Control Practitioner
 - d) ARCDCSC
- 5. The UTMC BTS Medical Director notifies the Risk Management department. If the recipient's physician is unwilling or unavailable to contact the recipient, Risk Management (in collaboration with the AIDS Resource Team or the Infection Control Practitioner in the case of HCV and other viral tests) will contact the recipient on the attending physician's behalf. Required written documentation and notification

requirements will be processed according to the Department of Health and Human Services policy 42 CFR Part 482 for HIV notification, or the most current FDA Guidelines on recipient notification related to donor testing for HCV. Current ARC guidelines will be followed for other viral tests.

6. The physician must contact Risk Management to clarify legal issues related to disclosure to any individuals other than the recipient.

Approved by:		Review/Revision Date:
		6/96 3/20/2023
		1/98
/s/	03/21/2023	3/99
Lauren Stanoszek, M.D.	Date	1/05
Assistant Professor		12/07
Director, Blood Transfusion Service		6/9/2008
		3/25/2011
		3/01/2013
/s/	03/21/2023	3/02/2015
Christine Stesney-Ridenour	Date	3/1/2017
Chief Operating Officer - UTMC		3/1/2019
D : /D :: G 1/ 1D		3/1/2021
Review/Revision Completed By: Danielle Weilnau, MLS(ASCP) ^{CM}		
Danielle Welliau, WES(ASCF)		Next Review Date: 3/1/2025

It is the responsibility of the reader to verify with the responsible agent that this is the most current version of the policy.

Reference:

- 1. AABB Standards for Blood Banks and Transfusion Services, Current edition.
- 2. Centers for Disease Control and Prevention. Recommendations for Prevention and Control of Hepatitis C (HCV) infections and HCV-related Chronic Disease. MMWR 1998;47(No. RR-19)
- 3. Current Good Manufacturing Practice for Blood And Blood Components. Supplemental testing, and Donors Notification of Consignees and Blood Recipients of Recipients of Donor Test Results for anti-HCV. Docket number 98D-0143 USDHSS, FDA CBER September 1998.
- 4. 21 CFR 610.46-48 and 42 CFR 482.27(c)
- 5. FDA Guidance for Industry, August 24, 2007, "Lookback for Hepatitis C Virus (HCV): Product Quarantine, Consignee Notification, Further Testing, Product Disposition, and Notification of Transfusion Recipients Based on Donor Test Results Indicating Infection with HCV".