Name of Policy: Documentation/Recordkeeping/ Record Review Policy Number: 3364-108-105 Approving Officer: Senior Hospital Administrator Director, Blood Transfusion Service Responsible Agent: Blood Transfusion Service Supervisor Administrative Director, Lab Scope: Pathology/Laboratory – Blood Bank	UTOLEDO HEALTH Effective date: ~~03/01/2025~~ Original effective date: 06/1996
Key words: Document, Retention, Recordkeeping, Review, Procedures	

☐	New policy proposal	☒	Minor/technical revision of existing policy
☐	Major revision of existing policy	☐	Reaffirmation of existing policy

(A) ~~(A)~~ Policy Statement

The Blood Transfusion Service provides, in a uniform format, documentation relating to transfusion of patients at UTMC in the form of records, procedures, and policies and retains these records for the time specified by FDA, CAP and AABB standards.

(B) ~~(B)~~ Purpose of Policy

To describe a system of generation, implementation, revision, review, ~~retention~~retention, and retrieval of all records pertinent to the transfusion of patients at UTMC.

(C) ~~(C)~~ Procedure

~~1.~~(1) All pertinent documents such as forms, policies, ~~procedures~~procedures, and records shall bear the "University of Toledo" name or "University of Toledo Medical Center, Toledo, Ohio" name and location.

~~2.~~(2) Format and revisions of forms or records that will be part of the patient's permanent medical record must be reviewed and approved by the UTMC Forms Committee. These forms must be submitted for review to the Medical Records department and bear a Medical Record form number. All forms in use in the Blood Transfusion Service are listed on the Forms Inventory (Attachment #1).

~~3.~~(3) The following records are retained for a minimum of five years: Request for Blood Transfusion, Telephone Request logs, Transfusion Records, Blood release forms, hard copy ARC Shipping Records /Issue and Transfer Records. The following records are retained a minimum of ten years: Patient Test/Transfusion Records and Patient Transfusion History Records (prior to 9/1/99), Records of unit receipt and final disposition, Special Studies, and Investigation of Adverse Reaction to Blood

Transfusion (Clinical Report and Laboratory Investigation~~.~~). ~~-~~Long-term storage for records is arranged through Materials Management. Storage boxes are obtained through General Stores and must be labeled appropriately prior to relocation. Listings of Stored Records are maintained in the BTS.

~~4.~~(4) Results obtained in testing are entered into the BBIS immediately. All results are reviewed for accuracy and completeness before release and acceptance. Results including compatibility testing results, released for transfusion, issued and transfused units are available through the electronic Medical Record.

~~5.~~(5) Test records not entered into the computer may include antibody identification studies, transfusion reaction investigations and tests sent to the ARC Reference Laboratory. Separate written reports are generated, reviewed by the Medical Director of Blood Transfusion Service or designee and charted for these tests.

~~6.~~(6) A report of issued and transfused units is generated daily for comparison to Blood Release forms to ensure units are in appropriate status in BBIS and appropriate transfusion according to indications criteria. The BTS supervisor or designee must be notified when discrepancies on the log are detected.

~~7.~~(7) Draw a single line through the errors along with tech initials and date to correct recorded results. Record the correct information above or nearby. Overwritten information is not acceptable. The use of "White-out" or other means of obliteration is likewise unacceptable. Incorrect results entered into the computer must be invalidated by the BTS supervisor or designee. The correct results are then reported.

(8)~~8.~~ The Blood Transfusion Service Supervisor or Core Lab Manager is designated to review the following:

- (a) Exception reports from BBIS are reviewed daily at the conclusion of investigation and resolution of problems.
- (b) Daily Billing report.
- (c) Blood release forms are reviewed for transfusion orders and indications. Correct unit status is ensured by review of Issued and Transfused Units log.
- (d) Special studies, including antibody identification and elution studies.
- (e) Transfusion reaction investigations.
- (f) Monthly results of reagent quality control, instrument function checks and equipment temperature monitoring.
- (g) Orphan Unit Cross Check Report, when applicable.

~~9.~~(9) The Blood Transfusion Service Medical Director, Laboratory Medical Director or physician designee reviews the following:

- (a) Special Studies, including antibody identifications and elution studies. Written reports, if necessary, are signed before release.

(b) Transfusion reaction investigations. Results are interpreted, ~~reported~~reported, and signed by the Medical Director or physician designee.

(D) References

(1) AABB Standards for Blood Banks and Transfusion Services, current edition.
(2) Guidance for Industry, Current Good Manufacturing Practice for Blood and Blood Components, U.S. Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research (CBER), September 1998.

Approved by:	Policies Superseded by This Policy:
	• *None*
	Initial effective date: 06/1996
Lauren Stanoszek, M.D. Assistant Professor Director, Blood Transfusion Service	All Review/Revision Dates: 6/96 1/98 3/99 11/99 10/00 1/05 1/2008 6/9/2008 03/22/2011 3/01/2013 3/2/2015 03/01/2017 03/01/2019 03/01/2021 03/20/2023 ~~03/01/2025~~
Date	
Russell Smith Pharm D, MBA, BCPS, CPEL, FACHE Senior Hospital Administrator	
Date	
Review/Revision Completed by: Danielle Weilnau MLS(ASCP)^{CM}	Next review date: ~~03/01/2027~~

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~~Approved by:~~	~~Review/Revision Date:~~
	~~6/96~~ ~~1/98~~ ~~3/99~~ ~~11/99~~ ~~10/00~~ ~~1/05~~ ~~1/2008~~ ~~6/9/2008~~ ~~03/22/2011~~ ~~3/01/2013~~ ~~3/2/2015~~ ~~03/01/2017~~ ~~03/01/2019~~ ~~03/01/2021~~ ~~03/20/2023~~
~~Lauren Stanoszek, M.D.~~ ~~Assistant Professor~~ ~~Director, Blood Transfusion Service~~ ~~Date~~	

Christine Stesney-Ridenour Chief Operating Officer - UTMC Review/Revision Completed By: Danielle Weilnau, MLS(ASCP)CM	Date	Next Review Date: 3/1/2025
Policies Superseded by This Policy:		

References:

AABB Standards for Blood Banks and Transfusion Services, current edition.
Guidance for Industry, Current Good Manufacturing Practice for Blood and Blood Components, U.S. Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research (CBER), September 1998.