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TITLE: REGISTRY OF ADVERSE REACTIONS TO TRANSFUSIONS

PURPOSE: A registry of all reported cases of adverse reactions to transfusions will be maintained at CBB. These include transfusion-transmitted hepatitis B, hepatitis C, HTLV-I/II infection, HIV-1 or HIV-2 infection, sepsis, Chagas, ZIKA Virus infection or TRALI (Transfusion Related Acute Lung Injury) due to blood transfusion.

MATERIALS: Report of Transfusion Transmitted Disease Implicated Donor Report
External Laboratory Test Requisition

Contact Information:

ACL: Associated Clinical Laboratory

BCW: Blood Center of Wisconsin: <http://www.bcw.edu/bcw/index.htm>

IBC: Indiana Blood Center

PROCEDURE: When a case of suspected adverse reaction to transfusion is reported to CBB (Community Blood Bank), the following procedure is to be followed:

A. Transfusion Service:

1. Notify CBB via telephone of a potential transfusion transmitted disease report. Include all product types and unit numbers involved.
 - a. Complete a Transfusion Transmitted Disease Form and send it to the CBB Medical Director, QA Director and/or Technical Director via mail, email or fax.
 - b. Include on the report:
 - i. Unit number (entire ISBT# W0456.....)
 - ii. Product code (ISBT #)
 - iii. Date Transfused
 - iv. Clinical testing performed on recipient/patient that supports diagnosis
 - v. Additional pages may be attached with this information
2. Return any remaining blood product to CBB.

NOTE: Recipient testing will not be performed by or paid for by CBB.

B. CBB

1. Laboratory/designee
 - a. Perform a lookback on each unit number. (=LA, DL)
 - b. Quarantine in-date products from each implicated donor until investigation is complete.
2. QA/designee
 - a. Send a donor recall letter to each involved donor asking him/her to report for follow-up testing.
 - b. Complete Implicated Donor Report, include:
 - i. Date report initiated
 - ii. Hospital involved
 - iii. Patient name and suspected TTD
 - iv. Donor SafeTrace ID #
 - v. Donor Name
 - vi. Implicated Unit # and date of donation
 - vii. Date donor recall letter sent

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- c. Assign a case number to the documents: date report initiated + hospital + TTD +disease (e.g.: 6.2.00.SV.TTD.HCV)
- d. SafeTrace documentation: each involved donor
 - i. Defer donor(s)-P40: pending results of the follow-up testing.
 - a. Under deferral (=DN, DE) document case number
 - b. Under Memo (=DN, MS), document P40 and case number
- e. Complete and distribute instructions for laboratory, donor collections and front desk, to include:
 - i. Donor name, SafeTrace ID # and last donation location
 - ii. Front desk instructions: Notify Collections Management or donor collections staff member that tubes need to be drawn
 - iii. Donor Collections staff instructions:
 - a. what needs to be completed on requisition,
 - b. what tubes to be drawn,
 - c. use of ISBT number,
 - d. Send/Give tubes and requisition to laboratory
 - e. Donor instructions: CBB will contact them by mail of test results and their eligibility as a donor. Until they are contacted, they are deferred from donation. Further questions may be directed to QA, Technical Director and/or Collections Management
 - iv. Lab instructions
 - a. Specimen requirements
 - b. Shipping requirements
 - c. Copies of requisition to:
 - i. Accounting
 - ii. Data Entry/QA
 - d. Freeze additional specimen

C. Donor testing:

Donor testing to be performed will be determined by the CBB Medical Director, but may include the following (but not limited to):

	TEST	PERFORMED BY		TEST	PERFORMED BY
Hepatitis	HBsAg	IBC	Bacteremia	Culture with Gram Stain	ACL
	Anti-HBc	IBC	West Nile Virus	WNV NAT	IBC
	HBV NAT	IBC	TRALI	Anti-HLA antibodies	BCW
	Anti-HCV	IBC		Anti-Granulocyte Antibodies	BCW
	Anti-HCV (2 nd Mfg)	IBC			
	HCV NAT	IBC	Chagas	Anti-Chagas	IBC
HIV	Anti-HIV 1/2	IBC	HTLV I/II	Anti HTLV I/II	IBC
	HIV 1 IFA (WB)	IBC		Anti-HTLV I/II (2 nd Mfg)	IBC
	HIV NAT	IBC	Zika	Zika Virus Test	IBC
	Anti-HIV 2	IBC			
	HIV 2 IFA (WB)	IBC			

1. Collect donor specimen per instruction and requirements

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- 2. Process and ship specimens per instructions and requirements.
 - a. Consult Surround Web Interface: Accessioning SOP for additional specimen/shipping information
- 3. When results completed/received give results to QA.
- 4. QA or designee will perform the following:
 - a. Entry or documentation of test results in SafeTrace: =DN, DE, & MS
 - b. Documentation of Test Results on Implicated Donor report
 - c. Deactivation of deferral (if indicated).
 - d. Letter to donor
 - e. Additional Lookback if required
 - f. Letter to Transfusion Service upon completion of all donors
 - g. Notification to appropriate department of health if required
 - h. Notification to appropriate other agencies if required (FDA, CDC, etc)
- 5. Medical Director:
 - a. Review of implicated donor report to determine donor eligibility
 - b. Review of transfusion service report(s)

D. If a donor is the only source of transfusion for a patient with transfusion-transmitted hepatitis, that donor will be permanently deferred. Permanent deferral also occurs if a donor is implicated in two cases of transfusion-transmitted hepatitis where multiple donors are involved.

REPORTING & INTERPRETING RESULTS:

- 1. Complete: a. Report of Transfusion Transmitted Disease – Hospital Transfusion Service
 - b. Implicated Donor Report
- 2. The Medical Director will review completed reports and determine donor eligibility.

References:

21 CFR, 606.170

AABB Standards for Blood Banks and Transfusion Services, current edition, STD: 7.5.2, 7.5.4, 7.5.5

Surround Web Interface: Accessioning SOP

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Original Effective Date	Revised by	Revision	Supersedes Revision #
9.12.1991	D. Pirschel	REMOVED UNYTS	1.001
	D. Pirschel	Remove BRD Union Square address	1.002
	D. Pirschel	Added:testing laboratory information Added: additional information on entry into SafeTrace and responsibilities by department	1.003
	J. Vieyra	Added: Anti-HCV (2 nd mfg) and Anti-HTLV I/II (2 nd mfg)	1.004
	D. Pirschel	Deleted: GCRBC: Gulf Coast Regional Blood Center: http://yourlab.giveblood.org Chagas RIPA Added: IBC: Indiana Blood Center	1.005
	D. Pirschel	Deleted: Director, Donor Operation Added: GCRBC: Gulf Coast Regional Blood Center Collections Management Zika Per IND protocol GCRBC/Roche	1.006
	T. Collier	Deleted: GCRBC: Gulf Coast Regional Blood Center GCRBC/Roche "Specimen Shipment To External Testing Laboratory" SOP and/or References: Specimen Shipment To External Testing Laboratory" SOP Added: IBC/Roche	1.007
	D. Pirschel	Deleted: Roche Per IND protocol Added: Zika Virus Test	1.008

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REVIEWED BY:			
Department Head	Name	Signature	Date
QA Auditor	Deborah McAndrew	<i>Deborah A. McAndrew</i>	10-17-17
Technical Director	Tracy Collier	<i>Tracy Collier</i>	10-17-17
APPROVED BY:			
Position	Name	Signature	Date
QA Director	Diane Pirschel	<i>Diane Pirschel</i>	10-23-17
Medical Director	Jeffrey A. Richmond MD	<i>J. Richmond</i>	10-18-17
IMPLEMENTATION DATE: NOV 06 2017			

REVIEW			
MEDICAL DIRECTOR	DATE	MEDICAL DIRECTOR	DATE

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RETIRED SOP

SOP RETIRED BY	TITLE	INITIALS	DATE RETIRED	COPIES RECEIVED
				LAB