CHILDREN'S HOSPITAL LOS ANGELES
DEPARTMENT OF PATHOLOGY & LABORATORY MEDICINE
LABORATORY MEDICINE – BLOOD BANK/BLOOD DONOR CENTER

Nonconforming Event Report (NER) / Unusual Occurrence Report (UOR) - Part 1

CHLA Tracking Number: NER (UOR)_____

Reporter obtains NER (UOR) tracking number from QA and completes page 1. Staff involved in event (occurrence) completes page 2. Attach appropriate supporting documentation and submit to lead staff for review.

Section A – Logistics: *Reporter documents timeline and staff involved in event (occurrence).*

Discovery Date/Time/By: _____ Report Date/By: _____

Event Date/Time: _____ Staff/Location Involved: _____

Section B – Control: *Reporter documents donors/patients and products involved in event.* Date/Time/By: _____

Donor Name/ Patient Name	Donor ID/ Patient MRN	Unit Number	Products											
			ISBT Code	Description	Issued?		Current Disposition							
					No	Yes	Q	A	T	D	E	C		

Description Abbreviations: PLP, RBC, FFP, WB, CRYO, RP, GRN, HPC, MAR, CPA, Cord, IRR, LR, WASH, SPLIT, Low Vol, Vol Red, No Products, No Donation
Disposition Abbreviations: Q = Quarantine/Pending Quarantine, A = Available/Assigned, T = Transfused, D = Red-bagged/Deleted, E = Expired, C = Consigned

Quarantine of Current In-House In-Date Products: ☐ N/A ☐ Yes Date/Time/By: _____

Notification to Quarantine Current Consigned In-Date Products: ☐ N/A ☐ Yes Date/Time/By: _____

Unit Number	ISBT Code	Distribution Date	Expiration Date	Consignee	Contact Name/Title

HemaCare Corporation @ (800) 826-7962; Seraplex, Inc. @ (626) 792-9945; Other _____ @ _____

Section C – Description: *Reporter describes event and how/when/where/why it was discovered*. Date/By: _____

_____

_____

_____

_____

Section D - Immediate Resolution: *Reporter describes immediate corrective actions.* Date/Time/By: _____

_____

_____

Section E – Explanation: *Staff involved describes how/what/when/where/why event occurred.* Date/By: _____

_____

_____

_____

_____

_____

_____

Section F – Source: *Staff involved checks (x) ☐'s of areas and documents SOPs involved in event.* Date/By: _____

Blood Donor Center

Donor Registration	SOP(s)
☐ Duplicate donor/wrong donor/ID	
☐ ISBT unit number	
☐ Retest special process	
☐ Visit type/designated request	
Donor Screening	**SOP(s)**
☐ Demographics	
☐ Physical exam/medical history	
☐ Donor eligibility/deferral	
Other:	

Blood Donor Center

Draw Information	SOP(s)
☐ ISBT unit number/data entry/lot release	
☐ Failure code	
☐ Special process	
Blood Collection	**SOP(s)**
☐ Donor misidentification	
☐ Blood unit labeling	
☐ Sample tube labeling	
☐ Missing samples/unit	
Customer Service	

Component Processing	
Component Creation	**SOP(s)**
☐ Preparation	
☐ Quality control	
☐ Labeling	
☐ SafeTrace®	
Stock Management	**SOP(s)**
☐ Storage	
☐ Shipping/consignments	
Other:	

Donor Testing	
BSL	**SOP(s)**
☐ BSL shipment/BSL results	
SafeTrace®	**SOP(s)**
☐ Results/data entry	
Donation Management	**SOP(s)**
☐ Eligibility/deferrals	
☐ Testing/quarantine/discard	
☐ Notification/retesting/reentry	
Other:	

Transfusion Service

Accessioning	SOP(s)
☐ Duplicate patient	
☐ Special needs	
Routine Testing	**SOP(s)**
☐ Quality control/reagents	
☐ Testing	
☐ Results/data entry	
Component Modification	**SOP(s)**
☐ Preparation	
☐ Labeling	
Customer Service	
Other:	

Transfusion Service

Product Labeling	SOP(s)
☐ Mismatched unit tags/labels	
☐ Labeling	
Product Distribution	**SOP(s)**
☐ Product selection/special needs not met	
☐ Issue factor/not issued in Tx	

HPC

HPC	SOP(s)
☐ Donor screening	
☐ Collection	
☐ Labeling	
Other:	

Section G – Lead Staff Review: *Section lead reviews NER- Part 1 for completeness/accuracy and submits to Transfusion Medicine QA.*

_____

ABR:abr Lead Staff/Date

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Nonconforming Event Report (NER) / Unusual Occurrence Report (UOR) - Part 2

CHLA Tracking Number: NER (UOR)_____

QA fills out Part 2 when completed Part 1 is received. Attach Part 2 to Part 1with appropriate supporting documentation.

Section H- Classification: *Choose one or more of the following to categorize the event.* Date/By: _____

☐ Accident: *end result that does not meet acceptable standards due to an unexpected event during job performance*
☐ Error: *end result that does not meet acceptable standards due to a mistake during job performance*
☐ Variance: *unplanned deviation from approved procedures or protocols that may/may not affect the end result*
☐ Incident: *unexpected event that may threaten the life, health or safety of donor/patient or staff/customer*
☐ Complaint: *issue about job performance, service or conduct by donor/patient or staff/customer*
☐ Other: _____

Section I - Contributing Factors: *Choose cause(s) of the event.* Date/By: _____

☐ SOP Not Followed	☐ Clerical Issue	☐ Computer Issue	☐ Systems Problem
☐ No/Inadequate SOP	☐ Carelessness	☐ Staffing Issue	☐ Communication Issue
☐ Staff Training Issue	☐ Equipment Issue	☐ Environmental Issue	☐ Outside Issue
☐ Technical Issue	☐ Reagent/Supply Issue	☐ Other: _____	

Section J - Corrective/Preventive Action: *Evaluate event conclusions and actions taken.* Date/By: _____

☐ SOP Change	☐ Staff Retraining	☐ Maintenance	☐ Staffing Change	☐ Facility Change
☐ Software Update	☐ Staff Counseling	☐ Supply Change	☐ Process Change	☐ Other: _____

_____

_____

_____

_____

Section K – Final Product Disposition: *Record final disposition of products involved in event.* Date/By: _____

Donor Name/ Patient Name	Donor ID/ Patient MRN	Unit Number	Products										
			ISBT Code	Description	Issued?		Final Disposition						
					No	Yes	Q	A	T	D	E	C

Description Abbreviations: PLP, RBC, FFP, WB, CRYO, RP, GRN, HPC, MAR, CPA, Cord, IRR, LR, WASH, SPLIT, Low Vol, Vol Red, No Products, No Donation
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Section L – Severity: *Evaluate risk to donor/patient and if donor/patient safety was affected.* Date/By: _____

☐ Risk Level 1: *detected at review point/redundant process barriers within section and product safety, purity, potency not affected*

☐ Risk Level 2: *detected at review point/redundant process barriers within section and product safety, purity, potency affected*

☐ Risk Level 3: *not detected at review point/redundant process barriers within section and product safety, purity, potency not affected*

☐ Risk Level 4: *not detected at review point/redundant process barriers within section and product safety, purity, potency affected*

☐ Risk Level 5: *sentinel/near-miss or adverse event; unexpected occurrence involving death or serious injury or the risk of serious adverse donor/patient outcome – requires immediate investigation and response – initiate Event Report Form*

Donor/Patient Safety Affected? ☐ Unknown ☐ No ☐ Yes: Discuss donor/patient outcome ☐ Event Report

_____

Section M – FDA Notifications: *Notify FDA within 45 days of reportable event discovery. Attach copy of eBPDR.*

FDA Reportable? ☐ No ☐ Yes BPD Code: _____ Confirmation: # _____ Date/By: _____

Unit Number	Collection Date	Products									
		Product Code		Product Description	Component Exp. Date	Disposition			Notification		
						Distributed		Description			
		ISBT	FDA			In-House	Con'd		No	Yes	RN

Section N – Customer Notifications: *Notify customers according to regulatory requirements. Attach copies of notifications.* ☐ N/A

Date/By	Unit Number	Product	Donor			Physician			Consignee		
			Letter	Verbal	N/A	Letter	Verbal	N/A	Letter	Verbal	N/A

Section O –Counseling/Retraining: *Perform staff counseling/retraining as deemed appropriate.* ☐ N/A

Date/By	Staff Name	Counsel	Retrain	SOP(s)	Staff Signature

Section P - Follow-Up: *Initiated based on recommendations by QA Evaluation/Review.* Date/By: _____

☐ N/A ☐ PDI: #_____ ☐ Audit:# _____ ☐ RCA ☐ Other: _____

Section Q - Quality Assurance Evaluation/Review: *QA Officer submits completed NER (UOR) to manager for final review.*

_____

_____ _____
Quality Assurance Officer/Date

Section R - Management Review: *Manager is final reviewer for risk level 1, 2 and 3 events (record N/A for Director signature). Manager reviews and submits NER (UOR) to Director for risk level 4 and 5 events and those generating BPDR's.*

_____ _____
Manager/Date Director/Date

ABR:abr