



# KAISER PERMANENTE®

<b>DOCUMENT NUMBER:</b> SCPMG-PPP-0074
<b>DOCUMENT TITLE:</b> Transfusion Service Medical Director Responsibility
<b>DOCUMENT NOTES:</b>  Bench: TS Audits, QIMS

<b>LOCATION:</b> SCPMG-rel	<b>VERSION:</b> 03
<b>DOC TYPE:</b> Transfusion Service	<b>STATUS:</b> Release

<b>EFFECTIVE DATE:</b> 14 Sep 2018	<b>NEXT REVIEW DATE:</b> 14 Sep 2020
<b>RELEASE DATE:</b> 14 Sep 2018	<b>EXPIRATION DATE:</b> 01 Oct 2018

<b>AUTHOR:</b> G938509	<b>PREVIOUS NUMBER:</b>
<b>OWNER:</b> G938509	<b>CHANGE NUMBER:</b> SCPMG-CR-0464

## Transfusion Service Medical Director Responsibility

---

**Purpose**

This document outlines the responsibilities of the Transfusion Service Medical Director.

---

**Policy**

- The Transfusion Service Medical Director is responsible for
  - The development and approval of policies, processes and procedures related to transfusion.
    - This includes intraoperative and perioperative collection and reinfusion activities.
  - Establishing criteria for transfusion and reviewing cases not meeting transfusion audit criteria.
  - Monitoring transfusion practices and related quality indicators.
  - Consultative and support services that relate to the care of transfusion recipients
- The Transfusion Service Medical Director may delegate the responsibilities listed above to another qualified physician; however, the medical director shall retain ultimate responsibility for medical director duties.
- The Transfusion Service Medical Director or another designated qualified physician is responsible for the oversight of therapeutic apheresis procedures.

## Transfusion Service Medical Director Responsibility, Continued

---

### Supporting Documentation, Cont'd

- Establishing transfusion criteria and reviewing cases not meeting transfusion audit criteria:
  - Criteria are defined by the Transfusion Medicine Committee and documented in the minutes.
  - The criteria are noted in transfusion triggers and approved by the CLIA medical director and the Transfusion Services Medical Director.
  - Documentation may be found in local Transfusion Committee reports using the criteria from the Transfusion Medicine Committee.
- Monitoring transfusion practices and related quality indicators
  - The Transfusion Medical Director reviews cases that do not meet audit criteria and may discuss cases with physicians, local Transfusion Committee, Regional Operations Committee or other groups or committees as applicable. The goal is to investigate cause, and if needed try to implement change or process improvement to ensure that problems do not continue to occur.
  - The Transfusion Medicine Committee reviews new devices, processes and publications to determine if the medical centers should consider new process or change existing processes to improve patient safety, physician education etc.
  - Further audits/reviews are directed toward the number of type of transfusion reactions reported, number of emergency releases noted, number of discards or wastages of blood products. The audits also include benchmarking between medical centers. Corrective action or process improvement would be developed based on these audits.
  - The Transfusion Medical Director or designee reviews cases involving product recalls, market withdrawals, transfusion transmitted diseases, and lookbacks.
  - The Transfusion Medical Director or physician designee is responsible for prompt evaluation of suspected transfusion reactions or other adverse events associated with blood transfusion.
  - All validations of new equipment, reagents, computer upgrades, etc. are reviewed by the CLIA medical director and Transfusion Service Medical Director.

## Transfusion Service Medical Director Responsibility, Continued

**Duties and Responsibilities which can be delegated**

The Transfusion Service Medical Director may delegate the following duties and responsibilities to the Transfusion Services manager or qualified designee:

- Proficiency Testing Program (includes Alternative PT)
  - PT Worksheets/Attestation
    - Signing of proficiency testing attestation statements in the specialty of immunohematology cannot be delegated to the Transfusion Manager (General Supervisor). A qualified designee is defined as a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine with specified qualifications and experience per 42CFR493.1449.
  - PT Results Evaluations
  - PT Exceptions and Internal Investigations
- Quality Assessment and Quality control program
  - High level QA Investigation
  - Monthly/Quarterly QA Monitoring
  - QC Monitoring
  - Equipment Preventative Maintenance
- Training, Annual Performance Evaluation and Annual Competency Assessment Program
- Biennial Review of Policies and Procedures (Which require no or minor changes)

---

**Uncontrolled documents**

AABB Standards, current ed.  
CAP Requirements, TRM checklist, current ed.  
Federal Register, 42 CFR 493

---

**Authors**

SCPMG Transfusion Medicine Committee  
SCPMG Transfusion Service Managers  
Regional Blood Bank Compliance Officer

---

**Distribution**

All SCPMG Transfusion Services

---

## Transfusion Service Medical Director Responsibility, Continued

<b>MasterControl History of Change:</b>		
<b>Change type: new, major, minor etc.</b>	<b>Version #</b>	<b>Description of Change</b>
New	1	
Major	2	<ul style="list-style-type: none"> <li>• Added statement indicating that intra and perioperative transfusion activities are included in TS MD responsibilities.</li> <li>• Defined responsibility for therapeutic apheresis oversight.</li> <li>• Removed audits of blood warmer, intra and perioperative devices.</li> <li>• Added “or physician designee” to promptly evaluate cases of suspected transfusion reaction or other adverse events associated with blood transfusion.</li> <li>• Added “or designee” to review cases of market withdrawals, recall, TTDs and lookbacks.</li> <li>• Added duties and responsibilities which can be delegated section</li> </ul>
Minor	3	<ul style="list-style-type: none"> <li>• Added statement clarifying who is qualified to sign proficiency testing attestation statements for immunohematology.</li> </ul>

## Signature Manifest

Document Number: SCPMG-PPP-0074

Revision: 03

Title: Transfusion Service Medical Director Responsibility

All dates and times are in Pacific Standard Time.

### TS MD Responsibility-Minor

#### Minor Change Request

Name/Signature	Title	Date	Meaning/Reason
Test BB Mgr (Z123456)	NA		
Helen Noriega (S688941)	ASST DIR AREA LAB		
Ann Sintef (G938509)	Regional Blood Bank Compliance	01 Aug 2018, 10:24:06 AM	Approved

#### RL TS LM Collaboration

Name/Signature	Title	Date	Meaning/Reason
Duane Doerr (T865608)	MGR OPER AREA LAB		
Richard Ulep (H355837)	MGR AREA LAB		
Monica Flores (K112468)	LIS Application Specialist		
Stephanie L Soliven (K215385)	Lab Area Manager		
Armineh Amirian (K230074)	LIS Application Specialist		
Gloria Escobedo (K255208)	AREA LAB MGR		
Jeremiah Ocampo (K607321)	MGR AREA LAB		
Nancy Messiah (O126459)	MGR AREA LAB		
Joanne Jocom (P170170)	MGR AREA LAB		
Test BB Mgr (Z123456)	NA		
Jennifer Aidikoff (Q382370)	Blood Bank Manager		
Marie Rutledge (G533048)	Area Lab Manager		
Helen Noriega (S688941)	ASST DIR AREA LAB		
Brevet. Dao (Y363374)	MRG AREA LAB		
Jane Byrne (Y784700)	MGR AREA LAB		
Alejandra Salazar (K233690)	MRG AREA LAB	01 Aug 2018, 02:55:39 PM	Complete
Jennifer Zalamea (P303429)	MGR AREA LAB	04 Aug 2018, 01:29:34 PM	Complete
Alberto Armijo (K139082)	LEAD CLINICAL LAB SCIENT	07 Aug 2018, 10:24:03 AM	Complete
Cynthia Calderon (A088729)	MGR OPER AREA LAB	13 Aug 2018, 10:37:10 AM	Complete
Ann Sintef (G938509)	Regional Blood Bank Compliance	14 Aug 2018, 02:18:22 PM	Complete

#### Final Approval

Name/Signature	Title	Date	Meaning/Reason
Brevet. Dao (Y363374)	MRG AREA LAB	14 Aug 2018, 02:29:08 PM	Approved
Alejandra Salazar (K233690)	MRG AREA LAB	15 Aug 2018, 10:22:11 AM	Approved
Jennifer Zalamea (P303429)	MGR AREA LAB	15 Aug 2018, 02:32:06 PM	Approved
Nancy Messiah (O126459)	MGR AREA LAB	17 Aug 2018, 11:01:45 AM	Approved
Richard Ulep (H355837)	MGR AREA LAB	20 Aug 2018, 09:11:33 AM	Approved
Duane Doerr (T865608)	MGR OPER AREA LAB	20 Aug 2018, 10:25:48 AM	Approved
Jeremiah Ocampo (K607321)	MGR AREA LAB	20 Aug 2018, 05:41:56 PM	Approved
Jane Byrne (Y784700)	MGR AREA LAB	24 Aug 2018, 11:15:29 AM	Approved
Marie Rutledge (G533048)	Area Lab Manager	29 Aug 2018, 06:23:10 PM	Approved

Gloria Escobedo (K255208)	AREA LAB MGR	30 Aug 2018, 10:53:41 AM	Approved
Cynthia Calderon (A088729)	MGR OPER AREA LAB	31 Aug 2018, 04:21:39 PM	Approved
Jennifer Aidikoff (Q382370)	Blood Bank Manager	05 Sep 2018, 01:38:00 PM	Approved
Stephanie L Soliven (K215385)	Lab Area Manager	11 Sep 2018, 05:25:27 PM	Approved
Joanne Jocom (P170170)	MGR AREA LAB	14 Sep 2018, 09:31:03 AM	Approved
Ann Sintef (G938509)	Regional Blood Bank Compliance	14 Sep 2018, 01:48:09 PM	Approved

### Select Effective Dates

Name/Signature	Title	Date	Meaning/Reason
Test BB Mgr (Z123456)	NA		
Helen Noriega (S688941)	ASST DIR AREA LAB		
Ann Sintef (G938509)	Regional Blood Bank Compliance	14 Sep 2018, 01:49:54 PM	Approved