1. Policy:

It is the policy of the Transfusion Service Department of Doctors Medical Center of Modesto that the Clinical Pathologist authorizes any deviation from Standard Operating Procedure in the Transfusion Service Department. Authorization of the deviation will be documented on the “Authorized Deviation Form – I.Pol.23.0”.

**This Policy addresses the following CAP accreditation requirements:**

* CAP - TRM.44996 - Deviations from SOP
* CAP - TRM.30900 - Records of Deviation From SOP

1. Procedure:
2. The Clinical Pathologist will authorize any deviation in standard operating procedure required in the transfusion service. This will include, but not limited to: pre-transfusion specimen collection, Rh positive interchange (excluding Trauma, MTP or Abdominal Aortic Aneurysm patient), compatibility testing, blood storage or distribution, transfusion, transfusion reaction protocol, or post-transfusion care.

**Examples may include**:

1. Inability to antigen-type donor unit due to rarity or unavailability of antisera.
2. Extension of the period for antibody identification of patient with warm autoantibodies requiring allo-adsorption.
3. Rh positive blood for Rh negative recipient.
4. The CLS will complete “Authorized Deviation Form” and confer with the Clinical Pathologist on the deviation. The pathologist will authorize the deviation.
5. A comment “Authorized Deviation from SOP” will be typed on the patient’s Blood Bank comment field by the CLS who obtains the deviation.
6. In the event the deviation is detected after the event, the event must be investigated according to policy “Investigating and Evaluating Incidents or Unusual Occurrences” SOP: I.Q.19.
7. During afterhours or when in-house Pathologists are unavailable, the on-call Pathologist will be contacted and asked for the approval of the Deviation from Standard Operating Procedure.

*Note: To contact the on-call Pathologist, dial phone # 209-577-1040.*

1. Documentation
2. The original copy of the Deviation from SOP form will be attached to the patient’s PINK sheet during the duration of the care of the patient involved. Once the patient is discharged, make a copy of the Deviation from SOP form and send it to Medical Record (stamped with Chart Copy) so it will be scanned to the patient’s chart. Send the original copy of the Deviation from SOP form to the Transfusion Service Supervisor for archiving. The original form will be archived in the Blood Bank records for a period of 10 years.
3. References
4. Accreditation Requirements Manual, American Association of Blood Banks, Bethesda, 1995.
5. College of American Pathologists Transfusion Medicine Checklist, Northfield, IL, 2012
6. Standards for Blood Banks and Transfusion Services, AABB, Bethesda, MD, 30th Ed., 2016
7. Appendix:
8. Deviation from SOP form

Appendix: A - Deviation from SOP Form

**Transfusion Service**

Based on the following information, a deviation from standard operating procedure has been approved:

Patient ABO/Rh: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Patient Label Here

Provider: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Start Date/Time: \_\_\_\_\_\_\_\_\_\_\_ End Date/Time: \_\_\_\_\_\_\_\_\_\_

List product types and specific product numbers if applicable:

Product Types:

* Leukocyte Reduced PRBC
* FFP/Thawed Plasma
* Cryoprecipitate
* Platelet Concentrate
* Other (s): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Unit/Product Number (s)/ Unit Group and Rh

|  |
| --- |
|  |

Standard procedure (reference SOP):

Modified procedure (include rationale):

Authorized by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date/Time: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Clinical Pathologist

CLS Initials: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

* Check if approval was done by phone

Send Original Copy to: Transfusion Service Supervisor for archiving

Copy to: Medical Record

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Director of Laboratory Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Medical Director of Laboratory Date

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Laboratory Supervisor Date