Department	Laboratory
Laboratory	Blood Bank
Section	Quality Systems Standards Regulations
Site(s)	UMMC/UMMCH
Document #	D-5825 BB v11

Subject **DEVIATION FROM STANDARD OPERATING PROCEDURE**

Purpose Blood Bank physician pre-approval must be obtained and documented whenever a deviation from standard operating procedures is necessary in the provision of blood components.

In addition, in the event a deviation is discovered that was not approved prior to the provision of blood components, or a deviation is identified that may or may not have had an impact on patient care or safety, this procedure engages and guides Blood Bank staff through its investigation and reporting. Through the steps in this procedure, a deviation can be used as an educational tool for Blood Bank staff as they analyze the situation and initiate resolution and process improvement. It also ensures that a Blood Bank physician is notified of any deviations affecting patient care or safety immediately upon discovery of the situation.

Policy All pre-approved procedure deviations must be documented.

All deviations identified that were not pre-approved must be investigated and reported.

Procedure Deviation: A departure from the standard operating procedure that may or may not affect the quality of a product or service.

Special Situation Approval (Pre-Deviation)

Examples of situations that may require a deviation:

- A physician calls and requests that we use the same RBC unit for all transfusions for a pediatric patient, but they require fresh blood. We would normally need a fresh unit each time, as >60mL is ordered.
- A patient is using a high number of O Neg RBCs. You would like to see if the patient can be approved to receive Rh Positive RBCs.

1. Obtain a "Special Situation Approval Documentation" form. This form is originated by any Blood Bank staff noting the need for a deviation.
2. The Blood Bank staff member will fill in patient name, medical record number, date, description of the situation (with unit numbers if applicable), deviation

requested, and prepared by blanks on the form.

3. Contact the Blood Bank physician to notify them of the deviation request. They will assess the situation and either approve or disapprove of the deviation. This decision is documented in the "Physician Decision" section of the form.

4. If the deviation is approved, add a free text comment to the Blood Bank Administrative Data file to document the approval.

5. Forward the complete “Special Situation Approval Documentation” form to the Quality Technical Specialist.
   a. The Quality Technical Specialist is responsible for reviewing the situation, and will forward the form to the Blood Bank physician for their signature.
   b. After the form is signed, it is returned to the Quality Technical Specialist to put in the proper file.

Deviations Not Pre-Approved (Post-Deviation)

1. If the identified deviation does not have an impact on patient care or safety, the situation should be investigated and reported directly in an I-CARE by Blood Bank staff before the end of his or her shift.

   a. *Examples of deviations that **do not have** an impact on patient care/safety:*
      i. An error was made during the re-labeling of an irradiated red cell. (e.g. incorrect expiration date or product code on the new ISBT label.)
      ii. A unit of platelets is found in the refrigerator.

   b. Refer to **Event Detection, Reporting and Follow-Up** procedure when filling out the I-CARE.

   c. Print the page that displays after the I-CARE is submitted.

   d. The Blood Bank physician does not need to be notified in these situations.

   e. A Deviation SBAR (SBAR Report: Blood Bank Deviation Impacting Patient Care or Safety) is not required in these situations.

   f. If applicable, make copies of any paperwork or orders that would help document the situation and discover a root cause, and staple these to the printed I-CARE submission confirmation. (e.g. Make copies of the SBAR, or on the prepare order, etc.)

   g. Place the printed I-CARE submission confirmation and all other documentation in the Quality Technical Specialist’s mail slot.

2. If the identified deviation does have an impact on patient care or safety, the situation should be investigated and Blood Bank physicians and patient care staff need to be notified as soon as possible.

b. *Examples of deviations that **do have** an impact on patient care/safety:*

i. The incorrect ABO/Rh blood component was issued.

ii. Requirements noted in the patient's history were not honored when a blood component was issued. (e.g. irradiation needs, antigen negative needs, washed product needs, special crossmatching needs, etc.)

iii. An error was made during testing that requires correction of results, and those results could impact patient care.

c. **If risk is known to be serious (e.g. wrong ABO/Rh was given), call the nurse immediately,** prior to contacting the Blood Bank physician, to alert the clinical team to stop the transfusion. If level of risk is less serious, or if the level of risk is unknown, contact the Blood Bank physician STAT so that they can decide if the transfusion should be stopped.

d. Refer to the Technical Specialists or Lead Technologist with any questions. If it is unknown if the deviation has impacted a patient, proceed with filling out a Deviation SBAR (**SBAR Report: Blood Bank Deviation Impacting Patient Care or Safety**) as a precaution.

e. Obtain a Deviation SBAR (**SBAR Report: Blood Bank Deviation Impacting Patient Care or Safety**). This form can be originated by any Blood Bank staff member.

f. Complete the "Situation" section prior to notifying the Blood Bank physician so that all information can be readily available.

i. Record date and time that deviation occurred. If it cannot be determined, record "unknown" in those fields.

ii. Record the names of all Blood Bank staff involved.

iii. Record the patient's full name, location, and medical record number.

iv. Record how the deviation was discovered and record brief, factual notes for the description of the deviation.

g. At the bottom of the form, record the name of the person who is preparing the form and the date on which it is prepared.

h. Complete the "Assessment of Patient" section next.

i. **If risk is known to be serious (e.g. wrong ABO/Rh was given), call the nurse immediately,** prior to contacting the Blood Bank physician, to alert the clinical team to stop the transfusion. Record the name of the nurse or physician notified, date, and time in the appropriate field.

ii. If level of risk is less serious, or if the level of risk is unknown, contact the Blood Bank physician STAT so that they can decide if the transfusion should be stopped.

iii. Record the name of the Blood Bank physician notified, date, and time in the appropriate field.

iv. Together with the Blood Bank physician, determine the level of risk to the patient (no risk, low risk, or high risk), and circle the answer decided upon.

v. Discuss with the Blood Bank physician whether or not a blood product is transfusing. If it is currently transfusing, ask if it should be stopped. Circle the answer decided upon (yes, no, or N/A).

vi. Determine if there is now a delay in blood products, and circle the answer decided upon (yes, no, or N/A). If there is a delay, document how long the delay will be, and communicate this to the PCU or clinic. Document who the delay was called to in the appropriate field.

vii. Ask the Blood Bank physician if there are any other immediate actions that should be taken, and document the requested actions in the appropriate field.

viii. If not already notified by Blood Bank staff, or if follow up is needed, ask that the Blood Bank physician speaks with the patient care unit and providers. Record the name(s), date, and time(s) of whom was notified in the appropriate field.

i. Perform any other immediate actions that the Blood Bank physician requested.

j. Complete the "Recommendation section next.

i. List any follow up testing that needs to be done, any results that still need to be corrected, other computer work, etc. The Blood Bank physician may request further follow up, and these recommendations should be documented here.

ii. These recommendations should be checked off and initialed as completed by Blood Bank staff.

k. Once the "Situation," "Assessment of Patient," and "Recommendation" sections have been completed, an I-CARE should be completed. The Deviation SBAR should assist with placing the I-CARE.

i. Refer to **Event Detection, Reporting and Follow-Up** procedure when filling out the I-CARE.

ii. Print the page that displays after the I-CARE is submitted.

iii. If applicable, make copies of any paperwork or orders that would help document the situation and discover a root cause. (e.g. Make copies of the regular daily SBAR, the prepare order, etc.)

l. Staple the completed Deviation SBAR, the printed I-CARE submission confirmation, and any additional documentation together. Place all documentation in the Quality Technical Specialist's mail slot.

Related Procedures and Forms	**Special Situation Approval Documentation** **Event Detection, Reporting and Follow-Up** **SBAR Report: Blood Bank Deviation Impacting Patient Care or Safety**
Summary of Changes	Clarified how to get pre-approval for a deviation, and added example situations. Added a section regarding deviations that were not pre-approved, and how to use the Deviation SBAR.

Document History	
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Document Signatures

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