#### Reporting Transfusion Reaction Investigations

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| Purpose | Provide instructions for reporting results of transfusion reaction investigations. |

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| Policy | * The patient’s physician must be notified immediately of findings when investigation reveals the possibility of:
* hemolytic transfusion reactions
* bacterially contaminated component
* other serious reaction
* In the case of a transfusion related fatality, Transfusion Service Supervisor/designee must notify Center for Biologics Evaluation & Research (CBER) by phone or fax within 24 hours, with written report submitted with 7 days.
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| Definition | Sentinel Event: A *sentinel event* is an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase “or risk thereof” includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. |

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| Initiation of Report | Follow the steps below to initiate the investigation report.

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| Step | Action |
| 1 | Place a patient Accession label on a blank “Report for Suspected Transfusion Reaction” form. |
| 2 | Notify the Pathologist ***immediately*** for any unusual serological findings or TRALI/TACO. NOTE: The pathologist may request ancillary testing needed for the investigation. Preliminary findings will be reported to the patient’s physician by the pathologist. |

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| Sample Testing and Computer Entry |

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| Step | Action |
| 1 | Was the ABORh testing required?

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| If… | Then… |
| Yes | Enter result in the reaction grid for post transfusion specimen. |
| No | * Enter “not done” [ND] in the reaction grid.
* Use [HIDE] as the interpretation.
* Add credit test **(CABR)** if applicable to your facility.
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| 2 | Was DAT testing required?

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| If… | Then… |
| Yes | Enter result in the reaction grid for post transfusion specimen. |
| No | * Enter “not done” [ND] in the reaction grid.
* Use [HIDE] as the interpretation.
* Add credit test **(CDBS or CDIG)** if applicable to your facility.
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| 3 | Enter the date of the transfusion reaction under test ***DATERX***. |
| 4 | Enter the time of the transfusion reaction under test ***TIMERX***. |
| 5 | Scan the unit number on the ***UNUMB*** line by first entering “;;” then scanning or manually enter the number.**NOTE**: an “=” sign will populate in front of the unit number when scanned. |
| 6 | Enter a “;” then free text appropriate component core code (i.e. PAL, PAIL, PPL, PPIL, etc) under test ***CMPT***. |

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| Step | Action |
| 7 | Check appropriate box on the “Report for Suspected Transfusion Reaction” form and initial and date the Review Completed By section. Enter results for ***CLCK*** (clerical check) into the LIS using the following table.

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| If… | Then… |
| No errors found on clerical check | Enter ACC (accurate) |
| Error found on clerical check | * Enter IACC (inaccurate)
* Free text in comment regarding the error
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| 8 | Select appropriate response from the list below to result ***PRSA*** (Pre transfusion Specimen appearance):

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| If… | Then… |
| No hemolysis or icterus in pre transfusion sample | * Enter NORM
* Press TAB key
 |
| Icterus:* Slightly icteric
* Moderately icteric
* Markedly icteric
 | Enter one of the following ETC codes and then press the TAB key:* SLTICT
* MODICT
* MKDICT
 |
| Hemolysis:* Slight hemolysis
* Moderate hemolysis
* Marked hemolysis
 | Enter one of the following ETC codes and then press the TAB key:* SLH
* MODH
* MKDH
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| Step | Action |
| 9 | Use mouse or TAB down to line ***POSA*** (Post transfusion Specimen Appearance) and performing the following:

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| If… | Then… |
| Pre and post sample is the same  | * Enter NCHG
* Press the TAB key
 |
| Pre to post ample is NOT the same, for example:* Slight Change
* Moderate Change
* Marked Change
 | Enter one of the following ETC codes and then press the TAB key:* SLTC
* MODC
* MKDC
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| 10 | Enter result for ***POUAP*** (Post transfusion reaction unit appearance) using the following table:

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| If unit appears… | Then… |
| Normal | * Enter NORM
* Press the TAB key
 |
| Clotted | * Enter CLOT
* Press the TAB key
 |
| Hemolyzed:* Slight Hemolysis
* Moderate hemolysis
* Marked hemolysis
 | Enter one of the following ETC codes and then press the TAB key:* SLH
* MODH
* MKDH
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| Step | Action |
| 11 | Enter the appropriate response from the table below in the ***IVVC*** (IV/Admin Set visual check) field.

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| If solution… | Then… |
| Attached is 0.9% saline only and it appears normal | Enter NORM |
| Appears turbid | Enter TURB |
| Appears cloudy | Enter CLDY |
| Other than 0.9% saline is attached or piggy backed to unit | Enter free text comment as to what solution is attached |

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| 12 | Print the following reports:* TRXN2 reaction result report from Blood Bank Inquiry (BIQ) module.
* Interim culture report if indicated from Laboratory Inquiry module.
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| 13 | Submit “Report for Suspected Transfusion Reaction” form, EPIC transfusion report, BIQ printout and Transfusion Reaction Worksheet (if needed) to pathologist for interpretation or if after hours follow the instructions in the table below.

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| If facility is… | Then… |
| SMCS and SRMC | * Notify pathologist for any unusual findings, or signs and symptoms of Hemolytic, Anaplylactic,

TRALI or TACO reaction. Document physician name, instructions, approval or disapproval to continue transfusion, date & time using BBCNC.* Submit to pathologist for review & signature on next available shift.
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| SAFH and SDH | * Reactions other than mild allergic notify the pathologist to get approval to continue transfusion.
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| SAH | * Notify pathologist for any findings to obtain approval to continue transfusion.
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| 14 | Complete a PSR if abnormal findings were identified. |

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| Cultures and Reporting | Upon return of paperwork from the pathologist perform the following steps.

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| Step | Action |
| 1 | Is culture or other tests pending?

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| If… | Then… |
| No | Proceed to step 3 |
| Yes | * Insert a test BBC comment
* Result with free text as preliminary followed by ETC codes selected by pathologist
* Proceed to step 2
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| 2 | When all testing is complete including component culture resubmit paperwork including the Culture Report to a pathologist for final interpretation. |
| 3 | Enter pathologist interpretation, resulting pathologist ETC code and date on the **MDEVAL** test in the laboratory computer. |
| 4 | Enter Problem Comment test (PB) in the laboratory computer system and result with the following:* Date of reaction
* Reaction type (i.e. allergic, febrile, hemolytic, etc).
 |
| 5 | * Submit unit culture report to be scanned into the EHR. NOTE: Not required if unit culture is performed on patient MRN.
* File the original report in Transfusion Service (including all attachments submitted to the pathologist for review).
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| Step | Action |
| 6 | The Transfusion Services Supervisor/designee and/or Medical Director are responsible for ensuring notification of all necessary departments and/or outside agencies.

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| If… | Then… |
| Possible TRALI or bacterial contamination | * Blood Supplier
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| Sentinel event | * Integrated Quality Services/Risk Management
* Joint Commission of Accreditation of Healthcare Organizations
 |
| Patient fatality | * Integrated Quality Services/Risk Management
* Center for Biologics Evaluation & Research (CBER):

 Phone: 301-827-6220 Fax:301-827-6748 Email: fatalities2@cber.fda.gov* CA Dept of Health Services:

 Phone: 916-732-3820* County Coroner
* Blood Supplier
 |
| Biological Product Deviation | * Integrated Quality Services/Risk Management
* Blood Supplier or CBER. Refer to “Reporting Biological Product Deviation” procedure.
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| Related Documents | * Reporting Biological Product Deviation
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| Forms |

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| * Report for Suspected Transfusion Reaction TS.POST 12.06-F:A-RV.03
* Report for Suspected Transfusion Reaction Downtime-EPIC form #S1130
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| Attachments | * Pathologist Codes for Pathology Review in Sunquest-Document #

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