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|  | | Suspected Post Transfusion Recipient Complications    BB.Special.1014.2 | Dept: | 324311 |
| Dept Name | Blood Bank |
| Effective Date: | 7/10/2001 |
| Revised Date: |  |
| Name & Title: CLIA Laboratory Medical Director | | | Contact: | MR Jones/JH Simmons |
| Signature: |  | | Date: |  |

1. General Protocol Statement:

1. Purpose:

To comply with regulatory requirements all cases of suspected post transfusion complications shall be thoroughly investigated and reported to the supplier.

1. Responsible Department/Scope:

1. Protocol owner/Implementer: Mary Rose Jones/Julie H. Simmons
2. Protocol prepared by: Julie H. Simmons
3. Who performs policy: Department staff/management

1. Definitions:

CBER: Center for Biologics Evaluation and Research

Mail: FDA/CBER/OCBQ, 1401 Rockville Pike, Suite 200N, HFM-600, Rockville, MD 20852-1448

Electronic: hyyp://www.fda.gov/cber/biodev.htm

MRN: Medical Record Number

1. Sections: NA

2. Protocol: General Guidelines for Recalls and Market Withdrawals

1. All cases of suspected post transfusion complications will be investigated and reported to the supplier.
2. Sources of reports of complications resulting from transfusion may be nurses, physicians, infection control personnel, laboratory results, etc.
3. When a complication of transfusion is confirmed to be fatal, the Director, Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research (CBER) will be notified by telephone, fax, express mail or electronically transmitted mail as soon as possible. A written report of the investigation will be submitted to the Director, Office of Compliance and Biologics Quality, CBER, within 7days after the fatality by the collecting facility in the event of a donor reaction, or by the facility that performed the compatibility tests in the event of a transfusion reaction.
4. Reports (telephone calls, letters) of transfusion complications must be documented and referred to management and/or medical director.
5. Management or designee will obtain the Recipient Complications –Infectious Disease Case Report or Transfusion Reaction Case Report for American Red Cross involved units and give to Medical Director or Pathology Resident.

*Refer to: Attachment 1: Recipient Complications – Transfusion Reaction Case Report and*

*Attachment 2: Recipient Complications – Infectious Disease Case Report*

1. Medical Director or Pathology Resident will complete the Recipient Complications – Infectious Disease Case Report or Transfusion Reaction Case Report. Management may complete this form if needed and have medical director review and sign.
2. For other blood suppliers, management or designee will contact the supplier and request a copy of the appropriate form to complete.
3. Blood supplier will investigate donation and send a formal report back to the medical director.
4. Blood supplier medical director may request additional information to complete the investigation.
5. MRN should be the only patient identifier present on any information submitted.
6. The report and the initial documentation will be reviewed and filed in a folder in the Irradiator Room temporarily.
7. Designated Tech will compile a list of Suspected Post Transfusion Complications patients which will be placed in folder until documentation is scanned.
8. Documentation will be scanned and saved to the Blood Bank iShares site indefinitely.

*Refer to Front Desk: Records Retention and Storage. Section VIII. Scanning and Scan Verification of Records Scanned in Department*

1. Once documents are available on the Blood Bank iShares site, the paperwork may be sent to offsite

storage.

*Refer to Front Desk: Records Retention and Storage*

3. Review/Revised Implemented:

All procedures must be reviewed at least every 2 years.

All new procedures and procedures that have major revisions must be signed by the Department Chairman.

All reviewed procedures and procedures with minor revisions can be signed by the designated section medical

Director or designee.

4. Related Protocols/Procedures:

Routine: Investigation of Suspected Adverse Reactions to Transfusion

Front Desk: Records Retention and Storage

5. References:

Technical Manual, American Association of Blood Banks (AABB). Revised periodically

Standards for Blood Banks and Transfusion Services. Revised periodically

Code of Federal Regulations (CFR), revised periodically.

6. Attachments:

Attachment 1: Recipient Complications – Transfusion Reaction Case Report

Attachment 2: Recipient Complications – Infectious Disease Case Report

7. Revised/Reviewed Dates and Signatures:

See Document Change Control

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| Document Change Control | | | | | | | | | | | | | | | | | | |
| Title: Suspected Post Transfusion Recipient Complications | | | | | | | | | | | | | | | | | | |
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| Written date | | | | |  | | | | Written by: | | | |  | | | | | |
| Validation date | | | | |  | | | | Validation by | | | |  | | | | | |
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| Approved date | | | | |  | | | | Approved by | | | |  | | | | | |
| Effective date in use | | | | | 7/10/2001 | | | | In use by | | | | Refer to archive history | | | | | |
| Revisions | | | | | | | | | | | | | | | | | | |
| Revised Date | By | | | MD  Date | | By | | MD  Date | | By | | Review Date | | | By | | Effective Date | By |
| 7/28/15 | JHS | | |  | |  | |  | |  | |  | | |  | |  |  |
| Validate Date | By | | | Revisions: Put into standard format. | | | | | | | | | | | | | | |
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Biennial Reviews: Record date/initials

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| 10/21/11 | EF |  |  |  |  |  |  |
| 9/5/13 | GP |  |  |  |  |  |  |
| 11/12/13 | MRJ |  |  |  |  |  |  |