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|  | | General Guidelines for Lookbacks    BB.Special.1016.3 | Dept: | 324311 |
| Dept Name | Blood Bank |
| Effective Date: | 4/10/2002 |
| Revised Date: |  |
| Name & Title: CLIA Laboratory Medical Director | | | Contact: | MR Jones/JH Simmons |
| Signature: |  | | Date: |  |

1. General Protocol Statement:

1. Purpose:

A recipient investigation is conducted to notify individuals who may have been exposed to a transfusion-transmissible disease from a blood transfusion. These investigations are most commonly initiated subsequent to market withdrawal, and when the confirmatory test is positive for one of the following:

Anti-HIV-1

Anti-HIV-2

HIV NAT

Anti- HCV

T. cruzi antibody (Chagas)

Zika

West Nile virus

Other positive markers for infectious disease determined to be medically significant by the Blood Centers

To comply with the requirements of the Food and Drug Administration (FDA) with regard to Lookback notifications when a recipient has received blood or blood components from a donor who has donated and tested repeatedly reactive for evidence of hepatitis C virus (HCV) and Human Immunodeficiency Virus (HIV) infection at a later date and the results of additional tests as provided for in CFR 610.46 and CFR 610.47 are positive or otherwise determined to be unsuitable when tested in accordance with section 610.45 Code of Federal Regulations (CFR), Title 21 and CFR 482.27.

To follow published guidelines for notification when a recipient has received blood or blood components from a donor who has tested positive for Zika, T. cruzi and WNV.

1. Responsible Department/Scope:

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

1. Definitions:

Lookback: The tracking and identification of the location and disposition of blood component products that

were manufactured from donations by a particular donor; the steps taken to track and quarantine

unsuitable blood or blood components and to notify consignees when a donor subsequently tests

positive or provides information regarding a diagnosis for the most significant infectious disease

markers.

HCV: Hepatitis C Virus

HIV: Human Immunodeficiency Virus

T.cruzi: Trypanasoma cruzi

WNV: West Nile Virus

2. Protocol: General Guidelines for Lookbacks

* 1. Blood Center Notification to the Hospital
  2. If the blood center notifies the hospital of the reactive screening test results, the hospital must

determine the disposition of the blood or blood product and quarantine all blood and blood components. *CFR 482.27 (4)*

* 1. If the blood center notifies the hospital that the results of the supplemental test or other follow-up

testing required by FDA is negative, absent other informative test results, the hospital may release the blood and blood components from quarantine. *CFR 482.27 (4)(i)*

* 1. If the blood center notifies the hospital that the results of the supplemental, or other follow-up testing required by FDA is positive, the hospital must

1. Dispose of the blood and blood components
2. Notify the patient as in Step 4.0

*CFR 482.27 (6) (ii) (a,b) (iii)*

1. For HIV and HCV the transfusion service is responsible for notification, including basic explanations to the recipient and referral for counseling and shall document the notification or attempts to notify the attending physician or recipient. *CFR 482.27 (6)*
   1. Other infectious disease markers will be managed when not specified in the CFR according to the directions of the blood center.
2. Documentation will occur on the Lookback Tracking form.

*Refer to Attachment 1: Lookback Tracking Form*

1. Notification HCV and HIV CFR 482.27
   1. For HIV, HCV tracking methods to locate recipients shall include; but, are not limited to: Medical Records, Social Security Index, and the use of Medical Business Solutions.
   2. For donor tested on or after February 20,2008: The hospital must make reasonable attempts to give notification over a period of 12 weeks unless
2. The patient is located and notified, or
3. The hospital is unable to locate the patient and documents in the patient’s medical record the extenuating circumstances beyond the hospital’s control that caused the notification timeframe to exceed 12 weeks. *CFR482.27 (7)(a)(b)*
   1. For donors tested before February 20, 2008: the notification effort begins when the blood collecting establishment notifies the hospital that it received potentially HCV infectious blood and blood components. The hospital must make reasonable attempts to give notification and must complete the actions within 1 year of the date on which the hospital received notification from the outside blood collecting establishment*. CFR 482.27 (7)(b) (ii)*
   2. Upon receipt of the letter from the blood supplier, the manager or designee will complete the top section of the Lookback Tracking form which includes: Infectious Disease, Name, Medical Record Number and Region Case ID.
   3. Management or designee will give the notification paperwork and the Lookback form to the medical director.
   4. The Medical Director will notify the attending physician via email and letter.
4. If the attending physician is unavailable or declines to notify the recipient, the medical director will notify the recipient and inform the recipient of the need for HCV and/or HIV testing and counseling. *CFR482.27 (6)(iii)*
5. The notification letter will contain information on obtaining testing and counseling, enough oral or written information so that an informed decision can be made about whether to obtain HIV or HCV testing and counseling, a list of programs or places where the person can obtain HIV or HCV testing and counseling. *CFR482.27 (8)(i)(ii)(iii)*
   1. The hospital must establish policies and procedures for notification and documentation that

conform to Federal, State, and local laws, including requirements for the confidentiality of medical records and other patient information. *CFR 482.27 (9)*

* 1. For HIV, HCV if the recipient has been adjudged incompetent by a State court, a legal

representative designated in accordance with State law as stated in CFR 610.47(c) will be notified.

1. If the patient is competent, but state law permits a legal representative or relative to receive the information on the patient’s behalf, the physician or hospital must notify the patient or his/or her legal representative or relative.
2. For possible HIV infectious transfusion beneficiaries that are decreased, the physician or hospital must inform the decreased patient’s legal representative or relative. *CFR 482.27 (10)*
3. For HIV, HCV if the recipient is a minor at the time of notification, the parents or legal representative must be notified.
4. Testing of the recipient for HCV, HIV, West Nile, Zika and T. cruzi will be performed by the blood supplier at no charge.
5. For HIV, if the recipient is deceased, the medical director must continue notification process and inform the deceased recipient’s legal representative or relative.
6. For Zika, T.cruzi, and WNV, the FDA recommends that the blood supplier notify the transfusion services so that they may consider notifying treating physicians of prior recipients of blood and blood components collected from that donor.
7. Documentation of notification and/or attempts will occur on the Lookback Tracking form.
8. When notification is by mail, arrange for letter to be sent registered mail so that a confirmation of receipt is obtained and can be added to the case file.

10.0 Once notification has occurred or three attempts have been made, then the supplier notification form

will be completed by the Medical Director.

* 1. All attempts need to be documented.

1. Management or designee will fax or email the completed supplier notification form to the number or

email address noted on the form.

* 1. Copies must signify the method of how the supplier notification form is sent along with initials and date of who sent the document.
  2. The paperwork will be stapled together (notification, computer printout of unit, Lookback Tracking form).

12.0 Medical Director will make available the letter to the provider/recipient in Wake One.

12.1 The letter can be either scanned or copied/pasted into Wake One.

* 1. If patient file is not active, make an encounter and document message and letter. *CFR382.27(6) (iii)*

13.0 All completed closed cases will be added to the Lookback list of cases.

13.1 All closed cases will be filed in the “lookback” files located in Irradiator room.

13.2 All closed cases will be scanned when time permits and saved to the Blood Bank iShare site

indefinitely.

13.3 Once closed cases are scanned, checked, and available on the Blood Bank iShare site, the

Paperwork may be sent to offsite storage.

1. Retention

14.1 Paperwork is retained 10 years

14.2 Scanned files is indefinite.

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

*Records Scanned in Department*

3. Review/Revised Implemented:

All procedures must be reviewed according to the Document Control Protocol.

All new procedures and procedures that have major revisions must be signed by the CLIA Director.

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

Director or designee.

4. Related Protocols/Procedures:

Specials: Recalls and Market Withdrawals

Specials: Suspected Post Transfusion Recipient Complications

5. References:

“Lookback” requirements, Title 21 Code of Federal Regulations Section 610.46. 2013..

“Lookback” notification requirements for transfusion services, Title 21 Code of Federal Regulations

Section 610.47. 2000.

e-CFR 482.27

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

Standards for Blood Banks and Transfusion Services. Revised periodically

“The Transfusion Service Customer Handbook”. American Red Cross 2017-06-19 11.4ref025.

6. Attachments:

Attachment 1: Lookback Tracking Form

7. Revised/Reviewed Dates and Signatures:

See Document Change Control

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| Document Change Control | | | | | | | | | | | | | | | | | | |
| Title: General Guidelines for Lookbacks | | | | | | | | | | | | | | | | | | |
| Previous title: HCV Lookback, HIV Lookback, T. cruzi Lookback, WNV Lookback | | | | | | | | | | | | | | | | | | |
| Written date | | | | |  | | | | Written by: | | | |  | | | | | |
| Validation date | | | | |  | | | | Validation by | | | |  | | | | | |
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| Approved date | | | | |  | | | | Approved by | | | |  | | | | | |
| Effective date in use | | | | | 4/10/2002 | | | | 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 | | |  | |  | | GP | | 8/4/15 | | 8/3/15 | | | Jhs | | 8/11/15 | jhs |
| Validate Date | By | | | Revisions: Put into standard format. Combined HCV, HIV, T.cruzi and WNV into one protocol. | | | | | | | | | | | | | | |
| 7/30/15 | Bt | | |  | |  | |  | |  | |  | | |  | |  |  |
| Revised Date | | By | | MD  Date | | By | | MD  Date | | By | | Review Date | | | By | | Effective Date | By |
| 2/22/18 | | mjones | |  | |  | |  | |  | |  | | |  | |  |  |
| Validate Date | | By | | Revisions:  Most of section 2 updated with CFR482.27 | | | | | | | | | | | | | | |
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| Revised Date | | By | | MD  Date | | By | | MD  Date | | By | | Review Date | | | By | | Effective Date | By |
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| Locations | | |  | | | | Out of Use: Date: | | | |  | | | By | |  | | |
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Reviews according to the Document Control Protocol: Record date/initials

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| Date | Initials | Date | Initials | Date | Initials | Date | Initials |
| 10/21/11 | EF | 11/21/17 | jhs |  |  |  |  |
| 9/5/13 | GP |  |  |  |  |  |  |
| 11/12/13 | MRJ |  |  |  |  |  |  |

Wake Forest Baptist Health

Winston-Salem, NC 27157

Blood Bank

Lookback Tracking Form

Infectious Disease \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Medical Record # \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Region Case ID \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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|  | Date/Initials | Comments |
| Notification received from ARC |  |  |
| Medical director notified |  |  |
| Entered in RL6 |  |  |
| Attending physician notified  Name: |  |  |
| Forms sent to attending physician |  |  |
| Response received from attending physician |  |  |
| Recipient notified by medical director |  |  |
| Recipient tested |  |  |
| Recipient counseled on results |  |  |
| Follow-up, if needed |  |  |
| Form returned to ARC |  |  |
| Case closed |  |  |
| Final medical director review  Signature: |  |  |
| Letter placed in Wake One |  |  |
| Message/Note written by Medical Director in Wake One |  |  |
| SCC action charge BTRX |  |  |

BB.Form.1124.3

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| Document Change Control | | | | | | | | | | | | | | | | | | |
| Title: Lookback Tracking Form | | | | | | | | | | | | | | | | | | |
| Previous title: Lookback Tracking Form | | | | | | | | | | | | | | | | | | |
| Written date | | | | |  | | | | Written by: | | | |  | | | | | |
| Validation date | | | | |  | | | | Validation by | | | |  | | | | | |
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| Approved date | | | | |  | | | | Approved by | | | |  | | | | | |
| Approved date | | | | |  | | | | Approved by | | | |  | | | | | |
| Effective date in use | | | | | <2/2004 | | | | In use by | | | | See archive history | | | | | |
| Revisions | | | | | | | | | | | | | | | | | | |
| Revised Date | By | | | MD  Date | | By | | MD  Date | | By | | Review Date | | | By | | Effective Date | By |
| 8/6/14 | JHS | | |  | |  | | 8/7/14 | | EF | | 8/7/14 | | | JHS | | 8/8/14 | JHS |
| Validate Date | By | | | Revisions: Formatted headers and footers. | | | | | | | | | | | | | | |
| 8/7/14 | SMA | | |  | |  | |  | |  | |  | | |  | |  |  |
| Revised Date | | By | | MD  Date | | By | | MD  Date | | By | | Review Date | | | By | | Effective Date | By |
| 7/28/15 | | JHS | |  | |  | | 8/13/15 | | EF | | 7/30/15 | | | MRJ | | 8/14/15 | JHS |
| Validate Date | | By | | Revisions: Created a generic form sthat can be used for HCV, HIV, WNV, and T. cruzi by adding a space to indicate infections disease. | | | | | | | | | | | | | | |
| 7/30/15 | | BT | |
| Revised Date | | By | | MD  Date | | By | | MD  Date | | By | | Review Date | | | By | | Effective Date | By |
| 2/11/18 | | Mjones | |  | |  | |  | |  | |  | | |  | |  |  |
| Validate Date | | By | | Revisions:  Added “letter placed in Wake One”  Added “ message/note written by MD in WO”  Added “SCC action charge BTRX” | | | | | | | | | | | | | | |
|  | |  | |
| Locations | | | Forms Manual | | | | Out of Use: Date: | | | |  | | | By | |  | | |
| Quality Plan | | | | Reason | | | | | | | | | | | |
| Special Procedures | | | |  | | | | | | | | | | | |
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Biennial Reviews: Record date/initials

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