PROCEDURE

Title: Tissue Look Back Policy

Procedure #: 2015Tissue01

Institution: Highlands Regional Medical Center

Address: 3600 Highlands Avenue, Sebring Florida 33870

Prepared by: Anita Smith Date: 6/4/2015

Title: Laboratory Administrative Director

Accepted by: _____ Date: 6-9-15

Title: Laboratory Medical Director

Date Patient Testing Implemented: 4/23/2008

Review of procedure every two years

Reviewed by: _____ Date: _____

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Reviewed by: _____ Date: _____

Discontinued testing date: _____

Policy Title: "Lookback" Policy - Tissue

Audience: Laboratory Staff, Operating Room (OR) Staff

References and Citations: FDA Rule 21 CFR 610.46 & 47 Federal Register, Sep 9, 1996, pgs 47413-47434.

PURPOSE: When a tissue donor, whose blood sample initially tested negative for Human Immunodeficiency Virus (HIV or HTLV), Hepatitis C virus antibody (anti- HCV), West Nile Virus (WNV), Crutchfield Jakob Disease (CJD or nv-CJD) or other bloodborne diseases during a previous donation, later provides a sample which appears repeatedly reactive for HIV or HCV or other bloodborne infectious disease the tissue supplier will notify the hospital if any tissue from this donor was previously shipped to us. The hospital is required by federal regulation to determine the disposition of all tissue from the implicated donor and notify the attending physician of any recipient of such tissue.

DISPOSITION PROCEDURES:

When notified of a potential infectious disease, HIV, or HCV "Lookback" incident, investigate all necessary records to determine the disposition of the affected tissue unit(s). Action to be taken depends on the disposition of the component:

a. Tissue Component Currently In-stock: Immediately quarantine the unit by placing it in a biohazard bag, conspicuously labeled "DO NOT USE", and place it on the quarantine shelf of the Blood Bank refrigerator. Contact the supplier and request disposition instructions.

b. Tissue Component Transfused - Determine the name and hospital number of the patient who received the potentially infectious tissue component. Notify the Blood Bank Medical Director, Lab Administrative Director, and hospital Risk Manager. Follow all procedures under "Recipient Notification" below.

c. Tissue Component Destroyed - document on the Lookback Investigation Form the date the component was destroyed and by whom.

RECIPIENT NOTIFICATION:

1. Verify in the patient's medical record that the implicated tissue component was transfused/transplanted.

2. Promptly attempt to notify the recipient's attending physician (i.e. the physician who originally ordered the blood component transfusion or allograft) by phone or pager. At least 3 attempts must be made within 7 days to contact the physician. If deemed necessary, contact the physician in writing using certified mail. Include a copy of the original supplier notification letter.

3. Ask the physician to immediately notify the patient or authorized individual to accept notification for the patient. Notification should include a basic explanation of the situation, the possible implications, and the need for counseling and testing. Enough information should be provided so that the patient can make informed decisions concerning his/her follow-up care. However, the identity of the tissue donor must remain confidential.

4. If the treating physician cannot be contacted, declines to notify the patient, or later informs the hospital that he/she was unable to contact the patient, the hospital must assume responsibility

for contacting the patient. The hospital Risk Manager (or designee) will make at least 3 attempts over the next 8 weeks to contact the patient. Telephone notification is preferred but certified mail may also be used. A person trained in HIV/HCV and infectious disease counseling may be designated to make or assist in patient notifications.

5. Document all notification attempts on the Lookback Investigation Form. A copy of this form must be placed in the patient's medical record. The notification process should not end until all good faith efforts to locate the patient have been unsuccessful.

NOTES:

1. If the patient is deceased, the physician or hospital must continue the notification process and inform the deceased' relative or legal representative. If the patient has been adjudged incompetent by State court, the physician or hospital must notify a legal representative in accordance with applicable State law. If the patient is competent but State law permits a relative or legal representative to receive information on the patient's behalf, the physician or hospital may notify the patient or his/her relative or legal representative. The Risk Manager and/or Hospital Counsel will make this determination.

2. If the physician who orders the tissue component is not the same as the admitting physician, the hospital may ask either physician to perform the notification.

3. Documentation on the Lookback Investigation Form should include all efforts to notify the patient and/or patient's physician. This includes any extenuating circumstances that prevented notification within the specified time frames. This document is considered a Risk Management document and is subject to the normal safeguards regarding access of information and release, patient comment, and other precautions for confidential information.
4. Regulations do not require the hospital to provide infectious disease testing or counseling, but merely to inform the patient of the need for testing and counseling.