Clarification to Extra Vessels Storage Policy

Sponsoring Committee:	**Operations and Safety Committee**
Policy/Bylaws Affected:	**Policy 16.7.B: Vessel Recovery, Transplant, and Storage**
Public Comment:	**No**
Effective Date:	**April 14, 2016**

Problem Statement

Current *Policy 16.7.B: Vessel Recovery, Transplant, and Storage* prohibits storage of extra vessels from donors who test positive for HIV (antibody, antigen, or NAT), HBV (HBsAg or NAT), or HCV (antibody or NAT) to reduce the risk of accidental use of these vessels and potential disease transmission in recipients.

Since October 2015, UNOS staff have been notified of the possible storage of extra vessels from donors who were positive for hepatitis B (surface antigen) or hepatitis C. reviewed and further research by staff indicates that ambiguity of the policy language may have caused some members to misinterpret the policy so that they thought it allowed storage of these extra vessels. This clarified policy language will help eliminate any potential ambiguity regarding storage of these extra vessels.

Summary of Changes

Language in Policy 16.7.B was revised to be more succinct and more clearly state that extra vessels may **not** be stored from donors positive for any of the following:

- HIV by antibody, antigen, or nucleic acid test (NAT)
- Hepatitis B surface antigen (HBsAg)
- Hepatitis B (HBV) NAT
- Hepatitis C (HCV) by antibody or (NAT)

What Members Need to Do

Members must not store extra vessels positive for HIV (antibody, antigen, or NAT), HBV (HBsAg or NAT), or HCV (antibody or NAT). This is not a new requirement. Members should review their protocols and practices to ensure that extra vessel storage, use, and reporting comply with OPTN Policy.

Affected Policy/Bylaw Language:

New language is underlined and language that will be deleted is ~~struck through~~.

16.7.B Vessel Storage

Transplant hospitals ~~may~~ must not store ~~for later use any~~ a donor's extra vessels ~~from donors~~ if the donor has tested positive for *any* of the following ~~who are HIV positive by antibody, antigen, or nucleic acid test (NAT), hepatitis C antibody positive (HCV), hepatitis C (HCV) nucleic acid test (NAT) positive, hepatitis B surface antigen positive (HBsAg), or hepatitis B (HBV) NAT positive.~~:

- HIV by antibody, antigen, or nucleic acid test (NAT)
- Hepatitis B surface antigen (HBsAg)
- Hepatitis B (HBV) by NAT
- Hepatitis C (HCV) by antibody or NAT

~~If the~~ Extra vessels from donors that do not test positive for HIV, HBV, or HCV as above may be stored. When a transplant hospital stores extra vessels ~~and later uses the vessels for the intended recipient or another recipient,~~ it must ~~notify the OPTN Contractor~~ do *all* of the following:

1. Use stored extra vessels *only* for organ transplantation
2. Designate at least one person to monitor extra vessel storage, use, destruction, and reporting
3. Package and label extra vessels as required by *Policy 16.3: Packaging and Labeling* and *Policy 16.4: Documentation Accompanying the Organ or Vessel*
4. Store extra vessels in a Food and Drug Administration (FDA) approved preservation solution
5. Store extra vessels in a secured refrigerator with a temperature monitor and maintain the temperature no colder than 2 degrees Celsius and no warmer than 8 degrees Celsius
6. Maintain a log of stored extra vessels
7. Maintain all records relating to the monitoring and use of extra vessels
8. Monitor extra vessels daily and log security and refrigerator temperature checks
9. Destroy unused extra vessels within 14 days after the recovery date
10. Report the extra vessel's use or destruction to the OPTN Contractor within seven days of the transplant hospital's use or destruction of the extra vessels

~~The Transplant hospital must designate a person to do *all* of the following:~~

~~1. Monitor and maintain all records relating to the use and management of vessels~~
~~2. Monitor the refrigerator where the vessels are stored~~
~~3. Destroy expired vessels~~
~~4. Report the vessel's use or disposal to the OPTN Contractor within seven days of the transplant hospital's use or disposal of the vessels.~~

~~Additionally, the transplant hospitals must do *all* of the following:~~

~~1. Store vessels in a Food and Drug Administration (FDA) approved preservation solution~~
~~2. Package and label vessels as required by *Policy 16.3: Packaging and Labeling*~~
~~3. Store vessels in a secured refrigerator with a temperature monitor and maintain the temperature no colder than 2 degrees Celsius and no warmer than 8 degrees Celsius~~
~~4. Monitor vessels daily with documented security and temperature checks~~
~~5. Destroy unused vessels within 14 days after the recovery date~~
~~6. Maintain a log of stored vessels~~
~~7. Have accessible at all times the vessel deceased donor information for the transplant surgeon prior to using the vessels in any recipient other than the originally intended recipient~~

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