


Name of Policy: <u>Extra Vessel Policy</u> Policy Number: 3364-140-48 Department: Kidney Transplant Administration (Nursing Service) Approving Officer: Chief Nursing Officer Program Director, Kidney Transplant Program Program Director, Pancreas Transplant Program Responsible Agent: Transplant Surgeon/OR staff/Lab Scope: The University of Toledo Medical Center	 Effective Date: 4/1/2024				
<table> <tr> <td><input type="checkbox"/> New policy proposal</td> <td><input checked="" type="checkbox"/> Minor/technical revision of existing policy</td> </tr> <tr> <td><input type="checkbox"/> Major revision of existing policy</td> <td><input type="checkbox"/> Reaffirmation of existing policy</td> </tr> </table>		<input type="checkbox"/> New policy proposal	<input checked="" type="checkbox"/> Minor/technical revision of existing policy	<input type="checkbox"/> Major revision of existing policy	<input type="checkbox"/> Reaffirmation of existing policy
<input type="checkbox"/> New policy proposal	<input checked="" type="checkbox"/> Minor/technical revision of existing policy				
<input type="checkbox"/> Major revision of existing policy	<input type="checkbox"/> Reaffirmation of existing policy				

An extra vessel is defined by the OPTN as:

A vessel taken during procurement of deceased or living donor organ(s) with the intent to be used for vasculature reconstruction or modification of a transplanted organ. Vessels directly attached to the transplantable organ are not considered extra vessels. Extra vessels are routinely taken from areas not immediately connected to the transplantable organ (i.e. iliac artery or vein, aorta, carotid artery or jugular)

(A) Policy Statement

Extra Vessels that accompany organs for transplantation will be stored for use at a later date or for another transplant recipient. This policy will assure consistency with the management for the recovery, storage and transplant of vessels, while adhering to United Network for Organ Sharing (UNOS) regulations.

(B) Purpose of Policy

To comply with OPTN/UNOS regulations regarding vessel storage, use, disposition.

C) Procedure

1. The vessels cannot be used other than for the implantation or modification of a solid organ transplant, or for the repair of vasculature of a solid organ transplant recipient. The recipient must be consented prior to the procedure.
2. If UTMC receives and implants a vessel from another transplant program, UTMC will report the vessel disposition in UNET TIEDI extra vessels.
3. If the donor has tested positive for any of the following, extra vessels that are not transplanted into the recipient during the original transplant procedure must be discarded and may not be stored for subsequent use.
 - a. HIV by antibody, antigen or nucleic acid test (NAT)
 - b. Hepatitis B Surface antigen (HBsAg)
 - c. Hepatitis B (HBV) by NAT
 - d. Hepatitis C (HCV) by antibody or NAT
4. If the donor is in a "Risk Identified" group as defined by the U.S./Public Health Service (PHS) guidance, the label must indicate that the vessels are from a donor who meets the PHS criteria for risk identified.
5. If the vessels are stored and subsequently used for the intended recipient or another transplant recipient, the OPTN will be notified through UNET TIEDI extra vessels and disposition of the vessel will be reported.

6.If the vessels are being stored, the following procedures apply:

- a. Stored extra vessels will be used **ONLY** for organ transplantation recipients
- b. Designate at least one person to monitor extra vessels storage, use, destruction and reporting
- c. The vessels are stored in a Federal Drug Administration (FDA) approved preservation solution.
- d. Package and Label vessels according to UNOS Policy:

1. The vessels must be stored in a rigid, sterile, sealed container that is protected by a triple sterile barrier (one of which must be the rigid container). The rigid container must be labeled with an OPTN extra vessels label (standardized label). The internal label on the outermost layer of the triple sterile barrier must be completed using the OPTN organ tracking system. The labels must include all the following information:

This information must be included:	On the rigid container:	On the outermost layer of the triple sterile barrier:
1. Donor ID	●	●
2. Donor blood type	●	●
3. Donor blood subtype, if used for allocation	●	●
4. Recovery date	●	●
5. Description of the container contents	●	●
6. That the extra vessels are for use in organ transplantation only	●	●
7. Infectious disease donor screening test results for <i>all</i> of the following: a. anti-HIV I/II b. HIV Ag/Ab combo c. HIV NAT d. total anti-HBc e. HBsAg f. HBV NAT g. anti-HCV h. HCV NAT		●
8. Whether the extra vessels are from a donor with a positive result (NAT included) for any of the following: ● HIV, HBV, or HCV ● total anti-HBc	●	
9. Whether the extra vessels are from a donor that has any risk criteria for acute HIV, HBV, or HCV infection, according to the <i>U.S. Public Health Service (PHS) Guideline</i>	●	●

2. If the vessels are removed from the triple sterile barrier, the vessels will be re-labeled prior to storage.

- e. The vessels will be stored in a secured refrigerator within a range of 2 to 8 °C. The refrigerator will be monitored for daily temperature checks. If the temperature goes out of range, an alert is generated.

- f. Maintain a log of stored extra vessels. Monitor extra vessels daily, log disposition and refrigerator temperature checks. All logs will be returned to the Transplant department for appropriate UNET reporting.
 - g. Maintain all records relating to the monitoring and use of extra vessels
 - h. Destroy unused vessels within 14 days after the recovery date.
7. Report to the OPTN the disposition of all extra vessels, including their use, sharing or destruction within 7 days of their use, sharing or destruction.
8. Extra Vessel Verification
- a. When the extra vessel used is from the same donor as the organ transplanted and used during the transplant of that organ, the Pre-Transplant verification of the organ will be performed according to policy (3364-124-67 Organ Transplantation).
 - b. When the extra vessel is recovered with an organ but will be used in the transplantation of a different organ, when the extra vessel will be used in the repair of vessels of a transplant recipient or extra vessels will be used in the modification of a transplanted organ, then prior to transplant of the extra vessel, the transplant hospital must complete the following:
 - i. Meet the requirements of Pre-Transplant Verification according to UNOS policy and UPMC policy (3364-124-67 Organ Transplantation) for the organ that will be transplanted.
 - ii. The O.R. circulating nurse and surgeon must also perform an extra vessel verification in the EMR that includes the following:
 - 1. Verify the extra vessels are within 14 days of the recovery date.
 - 2. Verify the extra vessels donor's infectious disease testing results for HIV, hepatitis B (HBV), and hepatitis C (HCV)
 - 3. The operating surgeon will document that extra vessels were used in the operative note.
 - 4. Documentation of this verification must be in the recipient medical record.
9. The initial policy was effective immediately as of 5/25/2023.

Approved by: <div style="display: flex; justify-content: space-between; border-bottom: 1px solid black; margin-bottom: 5px;"> /s/ </div> <div style="display: flex; justify-content: space-between; margin-bottom: 5px;"> Kurt Kless, MSN, MBA, RN, NE-BC Chief Nursing Officer Date </div> <div style="display: flex; justify-content: space-between; border-bottom: 1px solid black; margin-bottom: 5px;"> /s/ </div> <div style="display: flex; justify-content: space-between; margin-bottom: 5px;"> Michael Rees, MD, PhD Director, Kidney Transplant Program Date </div> <div style="display: flex; justify-content: space-between; border-bottom: 1px solid black; margin-bottom: 5px;"> /s/ </div> <div style="display: flex; justify-content: space-between;"> Kunal Yadav, MD, FACS Director, Kidney Transplant Program Date </div>		Review/Revision Date: 5/25/2023 3/20/2024
Review/Revision Completed By: Transplant Administrator/Transplant Coordinator		
Next Review Date: 4/1/2027		
Policies Superseded by This Policy:		