At-a-Glance

- **Proposal to Improve the Packaging, Labeling and Shipping of Living Donor Organs, Vessels and Tissue Typing Materials**

- **Affected Policy:** Policy 12.7 (Responsibility for the Transport of Living Donor Organs)

- **Living Donor Committee**

  The majority of living donor organs recovered for transplant are not shipped or transported outside the recovery center, and therefore would not be affected by this proposal. However, the packaging and shipping of living donor organs is increasing, especially as "kidney paired" donation increases throughout the country.

  Changes to the policies for the packaging and shipping of deceased donor organs, vessels, and tissue typing materials were approved by the OPTN/UNOS Board in November 2010, and took effect in January 2011. The implementation of these new policies has created a situation where the rules for packaging, labeling and shipping deceased donor organs are more stringent than policies for the packaging, labeling and shipping of living donor organs. In response, this proposal would update living donor policy to more closely align with recent changes to the policy requirements for the packaging, labeling and shipment of deceased donor organs, vessels and tissue typing materials. The proposal also clarifies procedures when the living donor organ is not packaged, shipped or transported. The Committee anticipates both transplant centers and Organ Procurement Organizations (OPOs) would benefit from the standardization of packaging and shipping requirements for all organs. The Committee further expects that applying the existing requirements for the packaging and shipping of deceased donor organs to living donor organs, vessels and tissue typing materials will increase the safety of living donor organs that are packaged and transported outside the recovery facility.

  The proposal would not preclude transplant centers from entering into an agreement with an OPO to coordinate the packaging and shipping of living donor organs, vessels and tissue typing materials.

- **Affected Groups**

  Directors of Organ Procurement
  OPO Executive Directors
  OPO Medical Directors
  OPO Coordinators
  Transplant Administrators
  Transplant Data Coordinators
  Transplant Physicians/Surgeons
  PR/Public Education Staff
  Transplant Program Directors
  Transplant Social Workers

Organ Recipients
Organ Candidates
Living Donors
Donor Family Members
General Public

- **Number of Potential Living Donors and Candidates Affected**

  In 2009, there were 6609 living donors. As proposed the policy modification should increase the safety of any living donor organ transported to its intended recipient. Additionally as proposed, the policy modification could affect any candidate who receives a living donor organ transplant.

- **Compliance with OPTN Strategic Goals and Final Rule**

  The proposal is consistent with the Final Rule and will meet HHS Program goals by:

  - Potentially increasing the number of transplanted organs by eliminating organ wastage due to labeling or transportation errors.

  The proposal meets strategic plan goals as it will:

  - Potentially increase the number of transplants by eliminating wastage due to labeling or transportation errors.
  - Optimize a safe environment for living donor transplantation by requiring specific labeling to avoid errors.
  - Improve compliance through clarification of the policies in order to protect patient safety and preserve public trust.

- **Specific Requests for Comment**

  Does the proposal adequately define transplant center responsibilities for the packaging, labeling and shipping of living donor organs, vessels and tissue typing materials?

Proposal to Improve the Packaging, Labeling and Shipping of Living Donor Organs, Vessels and Tissue Typing Materials

Affected Policy: Policy 12.7 (Responsibility for the Transport of Living Donor Organs)

Living Donor Committee

Summary and Goals of the Proposal:

The majority of living donor organs recovered for transplant are not shipped or transported outside the recovery center, and therefore would not be affected by this proposal. However, the packaging and shipping of living donor organs is increasing, especially as "kidney paired" donation increases throughout the country.

Changes to the policies for the packaging and shipping of deceased donor organs, vessels, and tissue typing materials were approved by the OPTN/UNOS Board in November 2010, and took effect in January 2011. The implementation of these new policies has created a situation where the rules for packaging, labeling and shipping deceased donor organs are more stringent than policies for the packaging, labeling and shipping of living donor organs. In response, this proposal would update living donor policy to more closely align with recent changes to the policy requirements for the packaging, labeling and shipment of deceased donor organs, vessels and tissue typing materials. The proposal also clarifies procedures when the living donor organ is not packaged, shipped or transported. The Committee anticipates both transplant centers and Organ Procurement Organizations (OPOs) would benefit from the standardization of packaging and shipping requirements for all organs. The Committee further expects that applying the existing requirements for the packaging and shipping of deceased donor organs to living donor organs, vessels and tissue typing materials will increase the safety of living donor organs that are packaged and transported outside the recovery facility.

The proposal would not preclude transplant centers from entering into an agreement with an OPO to coordinate the packaging and shipping of living donor organs, vessels and tissue typing materials.

Background and Significance of the Proposal:

Prior to June 2009, requirements for the transport of all organs (both deceased and living donor organs) were located in policy sections 2.0 and/or 5.0, and in general those policies listed requirements that OPOs and transplant programs were required to follow for the packaging and shipment of living and deceased donor organs. At that time, policies 2.0 and 5.0 provided requirements that OPOs should follow in the packaging and shipment of deceased donor organs, and similarly provided requirements that transplant programs should follow for the packaging and shipment of living donor organs.

When a new and separate policy section for living donation (Policy 12.0) was established (June 2009), policies applicable to living donation were removed from Policies 2.0 and 5.0 and relocated to Policy 12.0, and at the same time all references to OPOs were removed from the policies, thus making the policies in 12.0 only applicable to transplant centers.

Beginning on February 6, 2009 the OPO Committee proposed revisions to Policies 2.0 and 5.0 through the public comment process. The proposed revisions were the result of collaboration between the Operations and Safety, Policy Oversight, Membership and Professional Standards and OPO committees.

Additionally, staff from the OPTN/UNOS Organ Center and Department of Evaluation and Quality (DEQ) contributed to the proposed revision of Policy Section 5.0. DEQ provided information on the most common packaging, labeling and transportation policy violations, which were addressed during the revision process.

Since that time, three separate proposals each modifying Policy 2.0 and/or 5.0 have been distributed for public comment:

- Proposal to Clarify, Reorganize and Update OPTN policies on OPO and Transplant Center Packaging, Labeling and Shipping Practice (public comment period beginning 2/6/2009)

- Proposal to Change Requirements for Labeling and Packaging Organs Procured by Visiting Transplant Center Teams and for OPO Labeling of Tissue Typing Materials (public comment period beginning 7/10/09)

- Proposal to Require Use of a Standardized, Internal Label that is Distributed by the OPTN and that Transplant Centers Notify the Recovering OPO when they Repackage an Organ (public comment period beginning 3/19/10)

The full text for each of these proposals is available on the OPTN website @ http://optn.transplant.hrsa.gov/policiesAndBylaws/publicComment/proposals.asp

These proposals clarified policy requirements, eliminated redundant language and gave OPOs guidance on how to package, label and ship organs, vessels and tissue typing materials. Other modifications included reorganization of existing policies, defined types of organ packaging and described the labeling and documentation requirements for solid organs, tissue typing materials and vessels of deceased donors.

Each of the three proposals were ultimately approved by the OPTN/UNOS Board. The OPTN now has different requirements for the packaging and labeling of deceased donor organs (Policy 5.0) and the packaging and labeling of living donor organs (Policy 12.0). This inconsistency in existing policy is being addressed with this proposal.

Under this proposal, when appropriate, the packaging and shipping requirements for living donor organs, vessels and tissue typing materials will match the recently approved packaging and shipping requirements for deceased donor organs, vessels and tissue typing materials. As proposed, the recent OPTN/UNOS Board approved requirements from Policy 5.0 (deceased donor organ packaging and shipment requirements) are being copied virtually intact and relocated to Policy 12.7 (living donor organ packaging and shipment requirements), and would replace all previous policy content in Policy 12.7. The Committee understands that all the requirements in Policy 5.0 to Policy 12.7 are not applicable to living donors and therefore are to be excluded from the new proposed requirement for the packaging and shipping of living donor organs.

The primary difference between Policy 5.0 and the new proposed requirements in Policy 12.7 is that OPOs maintain responsibility for the packaging, labeling, and shipping of deceased donor organs and transplant centers will have the responsibility for the packaging, labeling, and shipping of living donor organs.

During the development of this proposal the Committee consulted or invited members of the OPO, Transplant Administrators, Liver, Kidney and Operations and Safety Committees to comment on the proposal. They were asked to consider if the previously approved requirements for the packaging and shipping deceased donor organs, vessels and tissue typing materials should also apply to living donor organs. Additionally representatives from the previously listed committees were asked to provide feedback on specific circumstances where the rules of the packaging and shipment of deceased or living donor organs, vessels and tissue typing materials should be different.

The Committee did consider alternatives to the proposed policy modification. The Committee favored taking recently approved requirements for deceased donor organs in Policy 5.0, without modification, and making those policies applicable to the packaging and shipment of living donor organs. Under that scenario, OPOs would become responsible for the packaging and shipment of living donor organs, vessels and tissue typing materials. The Committee favors making OPOs exclusively responsible for the packaging and shipment of living donor organs, vessels and tissue typing material because OPOs have experience with the packaging and shipment of deceased donor organs. However, the Committee understood it could not require transplant centers to relegate responsibility for packaging, labeling and shipping of living donor organs to OPOs. Consultation with members of the OPO Committee demonstrated that some OPOs would not be receptive to assuming responsibility for handling living donor organs.

The Committee anticipates the strengths of the proposed policy change will include improved safety for living donors and for the intended recipients of living donor organs related to new rules for the packaging and shipping of living donor organs, vessels, and tissue typing materials. There are no programming requirements associated with the proposed policy changes.

The Committee did not identify specific weaknesses with the proposed policy. The proposal takes existing policies, which have been distributed for public comment and approved by the OPTN/UNOS Board, and would make those policies apply to all organ donors. The proposal broadens the variety of external containers that can be used and is more flexible with the type of plastic bag used between the outer container and the insulated container. The proposal also clearly specifies the role of the transplant center, which should help to avoid confusion as to who is responsible for specific tasks related to shipping and labeling. As a result of reduced confusion and consistent interpretation of the policy, there should be less packaging and transportation violations.

The Committee will review data regarding labeling and transportation errors six months after these policy changes are implemented to determine if there are ongoing issues contributing to policy violations and respond accordingly.

Supporting Evidence:

Table 1. Living Kidney and Liver Donors Recovered at a Center other than the Transplanting Center
January 1, 2000 – December 31, 2009
Includes Living Donors with Validated LDR Forms

	Organ		
	Kidney Total	Liver Total	Combined Total
Year			
2000	154	25	179
2001	150	39	189
2002	99	15	114
2003	125	22	147
2004	109	23	132
2005	95	26	121
2006	94	24	118
2007	83	33	116
2008	134	23	157
2009	204	21	225
All	1,247	251	1,498

Based on OPTN data as of January 28, 2011
Data subject to change based on future data submission or correction

Expected Impact on Living Donors or Living Donation:

The Committee expects that applying consistent and more stringent rules for the packaging and shipping of deceased donor organs, vessels and tissue typing materials to all organs will increase the safety of living donor organs that are packaged and shipped – both for the organ donor and the anticipated organ recipient. Standardization and improved safety in the packaging and shipping of living donor organs is especially important especially important due to the increase in living donor organs being transported in kidney paired donation.

Expected Impact on Specific Patient Populations:

In 2009, there were 6609 living donors. The policy modification would increase the safety of any living donor organ transported and help safeguard the safety of its intended recipient.

Expected Impact on Program Goals, Strategic Plan, and Adherence to OPTN Final Rule:

The proposed changes are consistent with the Final Rule and will meet HHS Program goals by:

- Potentially increasing the number of transplanted organs by eliminating organ wastage due to labeling or transportation errors.

The changes meet the strategic plan goals they will:

- Potentially increase the number of transplants by eliminating wastage due to labeling or transportation errors.
- Optimize a safe environment for living donor transplantation by requiring specific labeling to avoid errors.
- Improve compliance through clarification of the policies in order to protect patient safety and preserve public trust.

Plan for Evaluating the Proposal:

Six months after these proposed changes are implemented; the Living Donor Committee will request a report on packaging, labeling and transportation policy violations. The subcommittee will review each infraction and consider if other policy modification may be required.

- ***What questions or hypotheses are guiding the evaluation of the proposal?*** Will the changes in Policy 12.7 result in a reduction in packaging and transportation policy violations?

- ***Policy Performance Measures:*** Policy violations that are reported to DEQ will be reviewed and evaluated.

- ***Time Line for Evaluation:*** The Living Donor Committee Practice Subcommittee will review the policy violations every 6 months for the first two years following implementation.

Additional Data Collection:

This proposal would not require additional data collection.

Expected Implementation Plan:

Living donor transplant programs will need to develop and implement procedures to comply with new requirements for the packaging, labeling and shipping of living donor organs.

Communication and Education Plan:

Most of the standard communication methods will apply with this proposal. However, we may need to communicate this change to transplant centers more frequently since, unlike OPOs, they don't typically ship and package organs and are therefore less familiar with the procedures. Transplant centers will also not be performing this process as often as OPOs do, again requiring more frequent explanation and communication.

Communication Activities			
Type of Communication	**Audience(s)**	**Deliver Method(s)**	**Timeframe**
Policy Notice	Relevant staff at transplant centers and OPOs.	Policy notice delivered through e-newsletter and stored in member archive.	30 days after the board of directors votes to approve the policy change.
Article in UNOS Update in the Spotlight on Policy section.	Update readers	Print copy delivered by US Mail	The earliest possible issue following board approval of the policy change.
System Notice	Relevant staff at transplant centers and OPOs.	Email	30 days prior to implementation and again at implementation.
Brief mention in e-newsletter in Policy-related category.	Relevant staff at transplant centers and OPOs.	E-mail and access to member archive website.	Publish in e-newsletter the month the policy change is implemented and in the e-newsletter issue the following month.

Education/Training Activities			
Education/Training Description	**Audience(s)**	**Deliver Method(s)**	**Timeframe and Frequency**
Webinar to explain the new packaging and labeling requirements for living donor organs.	Relevant staff at transplant centers	Live Meeting	

Monitoring and Evaluation Plan:

Policy 12.7
During on-site reviews, the Department of Evaluation and Quality (DEQ) staff reviews and verifies donor recovery transplant centers' policies and procedures, and verifies the presence and accuracy of the documentation for a sample of records during site surveys.

Policy 12.7.1
During on-site reviews, DEQ staff reviews and verifies transplant centers':

- Written policies related to the required external packaging specifications; and
- External packaging supplies during onsite reviews.

Policy 12.7.2 and 12.7.3
During on-site reviews, DEQ staff reviews packaging requirements with each donor recovery transplant center.

Policy 12.7.4
During on-site reviews, UNOS staff may verify that the center has a documented solid organ, tissue typing material and vessel internal labeling procedure that is consistent with policy requirements.

Policy 12.7.5
During on-site reviews, UNOS staff reviews and verifies the completion of documentation related to a donor organ and inclusion with packaged organ or vessel.

Policy 12.7.6
During on-site reviews, UNOS staff reviews and verifies the donor recovery centers' written policies related to the verification of internal and external packaging labels and documentation that accompanies organs or vessels. UNOS staff also reviews documentation that a second person verified the accuracy of organ labels and contents.

Policy 12.7.7
During on-site reviews, UNOS staff reviews documentation verifying the donor and recipient ABO and the Donor ID upon the receipt of an organ.

Policy 12.7.8
DEQ staff investigates all reports of failure to include required materials related to tissue typing and ABO confirmation reported by members.

Policy 12.7.9
During onsite reviews at transplant centers, UNOS staff may verify the transplant center's procedures for verifying the correct organ for the correct recipient.

Policy 12.7.10
During on-site reviews at transplant centers, UNOS staff will evaluate compliance with this policy through interviews, observations, and obtaining copies of the following:

- The consent form used by the donor recovery center that must include language indicating that vessels will be used for transplant; and

- The packaging label to verify that it contains the recovery date, ABO, serology, container contents, and the Donor ID number, indicating if the donor is CDC high risk. Also, the label should clearly state "for use in organ transplant only."

During on-site reviews at transplant centers, UNOS staff will interview the designated staff who monitor and maintain the extra vessels and obtain a copy of the center's policy and procedure for handing vessels. The vessel monitoring log will be reviewed to verify the following:

- Vessels are stored for a maximum of 14 days from their original recovery date; and
- Daily monitoring of vessels includes: documented security checks, and recorded daily temperature checks (note: policy requires vessels to be stored between 2 and 8 degrees Celsius).

Policy 12.7.11

- For 12.7.11.1, the organ recipient's transplant center assumes responsibility for transportation costs for deceased donor kidney(s) and associated tissue typing material pursuant to CMS regulations.
- For 12.7.11.2, the member that accepted the organ is responsible for transportation costs to its destination for deceased donor non-renal organs and associated tissue typing material.
- For 12.7.11.3, the organ recipient transplant center is responsible for payment of transportation costs for tissue typing material sent to crossmatch potential recipients of a deceased donor kidney. The organ recipient transplant center that requested the tissue typing material is responsible for the payment of transportation costs for the tissue typing material sent to crossmatch potential recipients for a non-renal organ.

DEQ staff will request a corrective action plan if the center does not comply with the requirements of Policy 12.0 and forward the survey results to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for review.

Policy Proposal:

The proposed modifications to Policy 12.7 appear below. Please note that the starting point for these proposed changes are OPTN/UNOS Board approved updates to Policy 5.0 that became effective over the past year. Those updates to the packaging and shipping requirements for deceased donor organs are now being proposed for living donor organs. What follows are policies taken verbatim from Policy 5.0 which will replace existing requirements in Policy 12.7. Some policy language being copied and duplicated in Policy 12.7 is not applicable to living donation, and consequently are proposed to be modified or deleted for the packaging and shipping of living donor organs. Since the proposed changes would be difficult to read with numerous strikethroughs and underlines typically seen in public comment proposals, the proposed changes are being presented differently. For your convenience, we present the current language from Policy 5.0 and have used strikeouts and underlines to identify how current language from Policy 5.0 would be changed to make it applicable for the packaging and shipping of living donor organs.

~~5.0~~ 12.7 STANDARDIZED PACKAGING, LABELING AND TRANSPORTING OF LIVING DONOR ORGANS, VESSELS, AND TISSUE TYPING MATERIALS

The purpose of Policy ~~5.0~~ 12.7 and its subsections apply only to living donor organs, tissue typing specimens and vessels which are transported outside the recovery facility and ~~is~~ to:

• state requirements for packaging and labeling living donor organs, tissue typing specimens, and (when applicable) vessels to prevent wastage (and/or to promote safe and efficient use);
• define terms and responsibilities related to packaging, labeling, and transporting organs of living donor organs, and if applicable living donor~~,~~ tissue typing specimens, and vessels; and
• state requirements for recovering, storing, and using (when applicable) living donor vessels ~~in solid organ recipients.~~

The responsibility for packaging and labeling ~~deceased~~ living donor organs is assigned to the ~~Host OPO~~ donor recovery Transplant Center. ~~Transplant Center staff may not leave the operating room without allowing the OPO to package and label the organ in accordance with OPTN policy. The OPO must submit a report through the Patient Safety System when a Transplant Center fails to comply with this policy. The OPO will make all reasonable efforts to package and label the organ in a timely fashion~~. If a~~n~~ living donor organ ever requires ~~is~~ repackaging r~~epackaged~~ by a transplant center for transport, the Transplant Center will package, label and ship the organ in accordance with this policy. ~~and immediately notify the recovering OPO of the repackaging.~~

~~5.1~~ 12.7.1 EXTERNAL PACKAGING SPECIFICATIONS

An external transport container is defined as a: disposable shipping box, cooler or mechanical preservation machine. The transplant center ~~or OPO~~ must use both internal and external transport containers to package a ~~deceased~~ living donor organ, which travels outside the recovery facility.

~~5.1.1~~ 12.7.1.1 Disposable shipping box

• If living donor organs, vessels and/or tissue typing materials are shipped commercially, a disposable shipping box must be used.
• The disposable shipping box must be labeled with the standardized label distributed by the OPTN contractor.
• Disposable boxes must not be reused.
• The outer box must be a corrugated plastic or corrugated cardboard that is coated with a water resistant substance with at least 200 pound burst strength.
• The inner container must be a 1.5 inches thick, insulated container OR have an equivalent “R” value.
• A closed colored opaque plastic bag must be placed between the outer container and the insulated container. Closed is defined as being secured in a manner to prevent leakage (i.e.watertight).
• A second closed plastic liner must also be placed inside the insulated container to encase the ice. Closed is defined as being secured in a manner to prevent leakage (i.e. water tight).

~~5.1.2~~ 12.7.1.2 Cooler

• Coolers are permitted for non-commercial transporting of organs when the organ recovery team is transporting the donor organ with them from the donor hospital to the candidate transplant center.
• Coolers must be labeled with the standardized label distributed by the OPTN contractor.
• Coolers may be reused if properly cleaned and sanitized.
• Before re-using a cooler, all labels from the previous donor organ must be removed.

~~5.1.3~~ 12.7.1.3 Mechanical preservation machine

- Mechanical preservation machines are permitted for transporting an organ.
- The cassette (if applicable) containing the organ must be labeled with the organ type (i.e. left kidney, right kidney), ABO, and UNOS ID.
- The external surface of a mechanical preservation machine must be labeled with:
  - the standardized external label distributed by the OPTN contractor~~, or~~
  - ~~an alternate label that contains all information included on the OPTN contractor standardized label~~
- Before re-using a mechanical preservation machine that was used to transport an organ, all labels from the previous donor must be removed.

~~5.2~~ 12.7.2 INTERNAL PACKAGING SPECIFICATIONS

All organs that have been packaged on the donor's back table must be handled using universal precautions. The packaged organs from the donor's surgical back table are to be placed directly into the wet iced shipping container. Proper insulation and temperature controlled packaging including adequate ice or refrigeration must be used to protect the organs during transport.

- Organs must be protected by a triple sterile barrier.
- Kidneys and pancreata must be placed in a rigid container, which, if sterile, can be one layer of the triple sterile barrier.
- ~~Hearts,~~ Livers, lungs, and intestines do not require a rigid container.
- Vessels must be protected by a triple sterile barrier; if packaged separately from the organ, one barrier must be a rigid container.

~~5.3~~ 12.7.3 EXTERNAL LABELING REQUIREMENTS

When a disposable shipping box or cooler is used to transport a ~~deceased~~ living donor organ, the ~~Host OPO~~ donor recovery transplant center must use the standardized external label distributed by the OPTN contractor. ~~When a mechanical preservation machine is used, the as applicable, may use an alternative label the label contains all of the required information~~

The external transport container must be labeled with the: UNOS Donor I.D., Donor ABO type, a description of the specific contents of the box, the sender's name and telephone number, and the Organ Center telephone number. The label must be securely affixed to the external transport container. The OPTN contractor distributes a standardized external label that includes this information ~~and~~ which must be utilized.

~~5.4~~ 12.7.4 INTERNAL LABELING REQUIREMENTS

~~5.4.1~~ 12.7.4.1 Solid organ

The ~~Host OPO~~ Donor Recovery Transplant Center is responsible for ensuring that a secure label identifying the specific contents (e.g., liver~~,~~ or right or left kidney~~, heart~~ intestines) is attached to the outer bag or rigid container housing the donor organ. The OPTN contractor distributes a standardized internal label that must be utilized for this purpose. In addition to the contents of the package, the label information must include the UNOS Donor I.D. and donor ABO type.

~~5.4.2~~ 12.7.4.2 Tissue typing materials

Each separate specimen container of tissue typing material must have a secure label with two unique identifiers, one being UNOS Donor I.D., and one of the following three: donor date of birth, donor initials or locally assigned unique ID, (donor ABO is not considered a unique identifier). Additionally each specimen should be labeled with Donor ABO, date and time the sample was procured and the type of tissue. In the preliminary evaluation of a donor, if the UNOS ID or ABO is not available, it is permissible to use a locally assigned unique ID and

one other identifier for the transportation of initial screening specimens.

~~5.4.3~~ 12.7.4.3 Vessels

The vessels must be labeled with the standardized vessel label distributed by the OPTN contractor. The information must contain the: recovery date, ABO, all serology results, container contents, and the UNOS Donor ID. If the donor is in a "high risk" group as defined by the ~~Centers for Disease Control and Prevention (CDC),~~ U.S. Public Health Service Guidelines, the label must indicate that the vessels are from a donor who meets the CDC criteria for high risk. The appropriate packaging of vessels should be completed in the donor operating room. The label should clearly state "for use in organ transplantation only." If packaged separately from the organ, the vessels must be protected by a triple sterile barrier, one of which must be a rigid container and the standardized vessel label must be affixed to the outermost barrier.

~~5.5~~ 12.7.5 DOCUMENTATION ACCOMPANYING THE ORGAN OR VESSEL

~~5.5.1~~ 12.7.5.1 Documentation accompanying the organ

- Complete donor documentation must be sent in the container with each transported organ or vessel. This documentation must include:
  - ABO typing source documentation;
  - ~~Infectious disease testing results;~~
  - ~~Medical/Behavioral History form;~~
  - ~~Donor Evaluation;~~
  - Consent form; and
  - Complete medical record of the living donor;
  - ~~Organ quality information as noted in Policy 2.5~~
- Donor documentation must be placed in a watertight container.
- Donor documentation may be placed in either:
  - a location specifically designed for documentation, or
  - between the outer and inner containers.
- Whenever a ~~deceased~~ living donor organ is transported, the ~~Transplant Center~~ donor recovery transplant center~~, as applicable~~, must include the source documentation in the donor documentation ~~in the donor documentation the source documentation~~.

~~5.5.2~~

~~**Documentation accompanying the vessel**~~

~~If the vessels are not shipped in the same package as the organ, the same complete donor documentation, as described in Policy 2.5.6.1, must be included with the~~ vessels.

~~5.6~~ 12.7.6 VERIFICATION OF LABELING AND DOCUMENTATION INCLUDED WITH ORGANS OR VESSELS

~~5.6.1~~ 12.7.6.1 Verification of labeling and documentation for ~~deceased~~ living donor organs or vessels.

When a ~~deceased~~ living donor organ or vessel(s) is procured, the ~~Host OPO~~ donor recovery Transplant Center must ensure the accuracy of the donor's ABO on the container label and within the donor's documentation.

Each donor recovery Transplant Center ~~OPO~~ must establish and implement a procedure for verifying the accuracy of organ/vessel packaging labels by an individual other than the person initially performing the labeling and documentation ~~requirements stated in policy 5.3, 5.4 and~~

~~5.5.~~ The donor recovery Transplant Center ~~Host OPO~~ must maintain documentation that such separate verification has taken place and make such documentation available for audit.

~~5.7~~ 12.7.7 VERIFICATION OF INFORMATION UPON RECEIPT OF ORGAN

Upon receipt of a ~~deceased~~ living donor organ and prior to implantation, the recipient's Transplant Center must determine that it has received the correct organ for the correct transplant candidate by verifying the recorded donor and recipient ABO, and UNOS Donor ID~~, as required by Policy 3.1.2~~. The recipient's Transplant Center must maintain documentation that this verification has taken place and make such documentation available for audit.

~~5.8~~ 12.8. MATERIALS FOR TISSUE TYPING AND ABO CONFIRMATION

~~5.8.1~~ 12.7.8.1 Policy for tissue typing specimen, medium, and shipping requirements

~~Each OPO~~ Donor Recovery Transplant centers must have a written policy established with an OPTN member laboratory(s). The policy shall include specific descriptions of the type of specimen(s) required, and medium, in addition to
the shipping requirements of same.

~~5.8.2~~ 12.7.8.2 Blood for ABO Confirmation

A "red top" tube of blood, specifically for confirmation of ABO must be sent to ~~the receiving OPO or~~ organ recipient's transplant center with each ~~deceased~~ living donor organ and tissue typing material. This tube must ~~be labeled as described in Policy 5.4.2~~ have a secure label with two unique identifiers, one being the UNOS Donor I.D., and one of the following three: donor date of birth, donor initial or locally assigned unique ID, (donor ABO is not considered a unique identifier). Additionally, each specimen should be labeled with Donor ABO, date and time the sample was procured and the type of tissue, ~~In the preliminary evaluation of the donor, if the UNOD ID and ABO is not available, it is permissible to use a locally assigned unique ID and with the exception that the blood type may not be indicated on the label, and placed within the insulated container.~~ The ~~Host OPO~~ donor recovery transplant center is responsible for ensuring that the tube is appropriately labeled.

~~5.8.3~~ 12.7.8.3 Typing material for each kidney

~~In view of the frequent need for regional shipment of pancreas and kidney allografts, sufficient specimens for several crossmatches are required. However,~~ The minimal typing material to be obtained for EACH kidney ~~and pancreas~~ will include the following:

- 2 ACD (yellow top) tubes
- ~~3 to 5 lymph nodes~~
- ~~One 2 X 4 cm. wedge of spleen in culture medium, if available~~

~~5.8.4~~ 12.7.8.4 Typing material for all other organs

- The ~~Host OPO~~ donor recovery transplant center will provide specimens for tissue typing if requested.

~~5.9~~ 12.7.9 ~~DECEASED~~ LIVING DONOR ORGANS THAT REMAIN IN THE SAME RECOVERY FACILITY ~~OPERATING ROOM SUITE~~ AS THE INTENDED CANDIDATE(S)

~~5.9.1~~ 12.7.9.1 When ~~deceased~~ living donor organs are recovered and remain in the same ~~operating room suite~~ facility as the intended candidate(s), the ~~Host OPO (if applicable) and~~ Transplant Center must develop, implement, and comply with a procedure to ensure identification of the correct donor organ for the correct recipient. A "time out" prior to leaving the donor operating room and an additional "time out" upon arrival in the candidate operating room are required. These "time outs" are for the Transplant Center to confirm and document that the correct organ was identified for the correct candidate prior to transplant ~~(refer to Policy 3.1.2).~~

~~5.10~~ 12.7.10 VESSEL RECOVERY, TRANSPLANT, AND STORAGE

The intent of this policy is to permit:

• vessel recovery and immediate use in a solid organ transplant ~~(for example either a current liver or pancreas transplant); and~~

~~• vessel recovery and storage for use in a subsequent solid organ transplant from a donor with a different UNOS Donor ID (for example, when the vessel(s) and the liver or pancreas allograft are being transplanted from different donors with different numbers).~~

~~5.10.1~~ 12.7.10.1 Vessel recovery and transplant

• The consent forms used by the ~~recovering~~ ~~OPO~~ donor recovery transplant center must include language that indicates that vessels ~~will~~ may be used for transplant.

• The vessels from a living donor ~~cannot~~ can only be used ~~other than~~ for the implantation or modification of a solid organ transplant for the original intended recipient.

~~• Vessels can be shared among transplant programs. If sharing occurs between transplant programs, the implanting program must submit to the OPTN a detailed explanation justifying the sharing. The justification will be reviewed by the Membership and Professional Standards Committee (MPSC). The implanting transplant program must notify the OPTN of subsequent disposition of the vessel(s).~~

~~• If the transplant center stores vessels and subsequently uses the vessels for the intended recipient or another transplant recipient, the OPTN must be notified.~~

~~• If vascular conduits from donors with positive serology for hepatitis are subsequently used in other than the intended recipient, the implanting transplant center must provide a detailed explanation to the OPTN for the use of this conduit. The explanation will be reviewed by the MPSC.~~

~~5.10.2~~ 12.7.10.2 Vessel storage

The Transplant Center must designate a person to monitor and maintain records, destroy, and notify the OPTN of outcome and/or use of vessels. This designated person must maintain information on all donor vessels including monitoring and maintaining all records relating to the use and management of donor vessels ~~(e.g. subsequent positive serology testing, monitor inventory of stored vascular conduits).~~ This person must monitor the refrigerator, ensure records are up to date and available with the ~~conduits~~ vessels, destroy the vessels when expired, and notify the OPTN of its use or disposal.

- The vessels must be stored in a Food and Drug Administration (FDA) approved preservation solution (ex. UW, Custodial HTK).
- The vessels must be stored in a rigid, sterile sealed container labeled with the recovery date, ABO, serology, container contents, and the UNOS Donor ID for tracking. The standardized vessel label distributed by the OPTN contractor must be attached to the outer sterile barrier bag and information on the label must include all of the above information and all serology testing results. The appropriate packaging of vessels should be completed in the donor operating room. Label should clearly state for use in organ transplantation only.
- The vessel(s) must be stored in a secured refrigerator with a temperature monitor and maintained within a range of 2 - 8 degrees Celsius.
- There must be daily monitoring of the vessel(s) with documented security and temperature checks by the transplant center.
- The vessel(s) can be stored up to a maximum of 14 days from the original recovery date.
- The transplant center must maintain a log of stored vessels.

~~• The transplant surgeon must have around the clock access to the donor information~~

~~prior to using the donor vessel(s) in a recipient other than the intended recipient.~~

~~5.11~~ 12.7.11 TRANSPORTATION RESPONSIBILITY

The purpose of this policy is to define the responsibility of transportation costs for ~~deceased~~ living donor organs.

~~5.11.1~~ 12.7.11.1 Renal organs

The ~~Host OPO~~ organ recipient's transplant center is responsible for transportation costs for ~~deceased~~ living donor kidney(s) and associated tissue typing material pursuant to CMS regulations.

~~5.11.2~~ 12.7.11.2 Non-renal organs

The member that accepted the organ is responsible for transportation costs for ~~deceased~~ living donor non-renal organ(s) ~~(to include kidney-pancreas and pancreas islet)~~ and associated tissue typing material to its destination. If a donor organ is first accepted by one member and subsequently forwarded to another member, payment of transportation costs for forwarding the organ is the responsibility of the member that finally accepts the organ, unless otherwise agreed upon by the parties involved. If a non-renal organ has been accepted and transported, but cannot be used for transplantation, the member that finally accepted the organ is responsible for payment of transportation costs, unless otherwise agreed upon by the parties involved. The OPTN contractor will not incur transportation costs for non-renal organs or tissue typing material.

~~5.11.3~~ 12.7.11.3 Tissue typing material

The ~~Host OPO~~ organ recipient's transplant center is responsible for payment of transportation costs for tissue typing material sent to crossmatch potential recipients of a ~~deceased~~ living donor kidney. The organ recipient transplant center ~~member~~ that requested the tissue typing material is responsible for the payment of transportation costs for the tissue typing material sent to crossmatch potential recipients for a non-renal organ

~~**12.7 Responsibility for Transport of Living Donor Organs.** The following policies address standardized packaging of living donor organs and tissue typing materials to be transported for the purposes of organ transplantation. When an organ from a living donor is procured, the Transplant Center shall be responsible for ensuring the accuracy of the donor's ABO on the container label and within the donor's documentation. The Transplant Center shall establish and implement a procedure for obtaining verification of donor ABO data by an individual other than the person initially performing the labeling and documentation requirements put forth in Policies 12.7.1 and 12.7.5. The Transplant Center shall maintain documentation that such separate verification has taken place and make such documentation available for audit.~~

~~Upon receipt of an organ from a living donor and prior to implantation, the Transplant Center shall be responsible for determining the accuracy and compatibility of the donor and recipient ABO and document this verification in compliance with Policy 3.1.2.~~

~~**12.7.1 Standard Labeling Specifications.** The Transplant Center shall be responsible for ensuring that the outermost surface of the transport box containing organs and/or tissue typing specimen containers has a completed standardized external organ container label (provided by the OPTN contractor). Any previous labels on the transport container must be removed prior to labeling the box so that only one label exists. The Transplant Center shall label each specimen within the package in accordance with~~

policy. The transplant center is responsible for ensuring that each tissue or donor organ container that travels outside of the recovery facility is labeled appropriately.

In the case of organs from living donors who remain in the same operating room suite as the intended candidate(s), the Transplant Center must develop, implement, and comply with a procedure to ensure identification of the correct donor organ for the correct recipient. The Transplant Center must document that the correct organ was identified for
the correct candidate prior to transplant. Some type of donor organ labeling and documentation must be present in the candidate chart. A "time out" prior to leaving the donor operating room and an additional "time out" upon arrival in the candidate operating room is recommended. Exception: In the case of a single donor organ/organ segment remaining in the same operating room suite as a single intended candidate for a simultaneous transplant, donor organ labeling and "time outs" are not necessary.

In the case of organs from living donors that travel outside of the recovery facility, the Transplant Center(s) involved shall be responsible for ensuring that packaging is consistent with the requirements of Policies 12.7.2 and 12.7.4, and that the outermost surface of the transport box containing the organ must have a completed standardized external organ container label (provided by OPTN Contractor). The recovering Transplant Center shall label each specimen within the package in accordance with these policies. The recovering Transplant Center is responsible for ensuring that each container that travels outside of the recovery facility is labeled appropriately.

12.7.2 The Transplant Center is responsible for ensuring that the Donor I.D., Donor ABO type, and a secure label identifying the specific contents (e.g., liver segment, right kidney) are attached to the outer bag or rigid container housing the donor organ prior to transport.

12.7.3 Each separate specimen container of tissue typing material must have a secure label with the Donor I.D., Donor ABO type, date and time the sample was procured and the type of tissue. The Transplant Center is responsible for labeling the materials appropriately.

12.7.4 The Transplant Center is responsible for affixing to the transport container the standardized label completed with the Donor I.D., Donor ABO type, a description of the specific contents of the box, the sender's name and telephone number, and the Organ Center telephone number. A transport container is defined as a corrugated, wax coated disposable box, cooler, or mechanical preservation cassette or machine.

12.7.5 Packaging. ABO results must be provided by the Transplant Center in all circumstances during which a donor organ is transported. Properly packaged paperwork containing complete donor information, as described in Policy 2.5.6.1, will be included with the organ transport container in all instances in which the organ is transported.

12.7.6 Packaging. In all circumstances during which a donor organ is transported outside the recovery facility, the Transplant Center is responsible for packaging, labeling, and handling the organ in a manner which ensures arrival without compromise to the organ(s). Proper insulation and temperature controlled packaging including adequate ice or refrigeration shall be used to protect the organs during transport. All packaged organs, using disposable transport boxes, must have a red plastic bio-hazard bag that is water tight secured to allow for safe handling by medical and non-medical personnel during transport. This red bag may be placed between the waxed cardboard box and the

~~insulated material holding the wet ice and the organ. All organs that have been packaged on the donor's back table must be handled using universal precautions. The packaged organs from the donor's surgical back table are to be placed directly into the wet iced shipping container.~~