

**OPTN/UNOS Living Donor Committee**  
**Report to the Board of Directors**  
**November 14-15, 2011**  
**Atlanta, GA**

**Summary**

**I. Action Items for Board Consideration**

- The Board of Directors is asked to approve Modifications to Policy 12.7 (Responsibility for the Transport of Living Donor Organs that are intended to improve the packaging, labeling and shipping of living donor organs, vessels and tissue typing materials. (Item 1, Page 3)

**II. Other Significant Items**

- Living Donor Deaths Within Two Years of Donation (Item 2, Page 12)
- Disseminating Information about and Learning from Living Donor Adverse Events (Item 3, Page 13)

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**REPORT OF THE  
OPTN/UNOS LIVING DONOR COMMITTEE  
TO THE BOARD OF DIRECTORS**

**November 14-15, 2011  
Atlanta, GA**

**Connie Davis, MD, Chairperson  
Amy Waterman, PhD, Vice Chair**

*The following report is a summary of the Living Donor (LD) Committee's deliberations and discussions during a LiveMeeting on July 20, 2011, and its full Committee meeting held on September 19, 2011.*

**1. Proposal to Improve the Packaging, Labeling and Shipping of Living Donor Organs, Vessels and Tissue Typing Materials. Modification to Policy 12.7 (Responsibility for the Transport of Living Donor Organs).**

Prior to June 2009, requirements for the transport of all organs (both deceased and living donor organs) were contained in Policies 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. 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 was ultimately approved by the 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 Board approved requirements from Policy 5.0 (Deceased Donor Organ Packaging and Shipment Requirements) are being copied virtually intact and placed in Policy 12.7 (Living Donor Organ Packaging and Shipment Requirements), and would replace all previous content in Policy 12.7. The

Committee understands that all of the requirements in Policy 5.0 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.

The Committee considered 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 delegate 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 may 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 fewer packaging and transportation policy violations.

This proposal was released for public comment between March 11, 2010, and June 10, 2011. The Committee considered all public comments received on the proposal at its September 19, 2011 meeting. Overall, there was strong public, regional, and other committee support for the proposal (**Exhibit A**). The Committee opined it would not be necessary to modify the proposal.

The Resource Assessment and Impact Statement for this proposal are provided as **Exhibit B**.

The Committee recommends that the proposed policy language be considered by the Board.  
Committee vote: 27-0-0

The following proposal is recommended for consideration by the Board.

The proposed modifications to Policy 12.7 appear below. Please note that the starting point for these proposed changes are 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 policy 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.

**\*\* RESOLVED, that modifications to the Policy: Modifications to Policy 12.7 (Responsibility for the Transport of Living Donor Organs), set forth below, are hereby approved, effective pending distribution of notice:**

### **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 an living donor organ ever requires is repackaging repackaged 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, L~~ivers, 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,~~ Transplant Center donor recovery transplant center, 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~~ 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.

## 2. Living Donor Deaths within Two Years of Donation

The Committee reviewed current data on living liver and kidney donor deaths that had been reported to the OPTN or discovered through the use of Social Security Death Master File (SSDMF) data. The data did not reveal a trend of increasing donor deaths over the past decade. The Committee expressed interest in receiving regular updates to these data, as well as further analysis of the causes of donor deaths.

In response, OPTN data from the Living Donor Registration (LDR) form and Living Donor Follow-up (LDF) form as of July 26, 2011, were merged with SSDMF death data through June 30, 2011, to attempt to identify donor deaths that were not reported to the OPTN. Note that the SSDMF dataset does not contain all deaths that occur in the U.S. UNOS staff contacted transplant programs by telephone to try to confirm living donor deaths and obtain information about the cause of death. These data were supplemented with information reported by transplant centers to the OPTN Patient Safety System (PSS).

The cohort studied includes living kidney and liver donors (analyzed separately) who donated between October 25, 1999, and March 31, 2011, in the United States. This report includes living donor deaths that occurred within two years of donation. All such deaths known to the OPTN for living donors who donated between October 25, 1999, and March 31, 2011, and died between January 1, 2000, and May 10, 2011, were included in the report. This report is provided as **Exhibit C**.

### 3. **Disseminating Information about and Learning from Living Donor Adverse Events**

Policy 12.8.4 (Submission of Living Donor Death and Organ Failure Data) requires centers to report living donor deaths and organ failures within 72 hours through the UNet<sup>sm</sup> Patient Safety System for a period of two years from the date of donation for the MPSC to review and report to the Board.

The MPSC provides blinded, non-specific reports of living donor adverse event investigations for the Committee for review. (The last reports provided to the Committee were received in March 2011). These reports provide very limited information and may determine that the cause of death is not related to living donation. In most cases, the reports do not provide enough information for the Committee and transplant community to learn from such events and improve medical care for future living donors. Additionally, if programs review their own process in the event of a donor death and design an improved procedure that increases safety, this process cannot be disseminated by the OPTN/UNOS due to peer review protections. The Committee is concerned that these new and best practices, as well as the specific details that might lead to pattern recognition of reasons for donor deaths, are not available to the transplant community at large. The Committee would like the Board to consider and recommend how this might be best accomplished.

# LIVING DONOR COMMITTEE

		MONTH/YEAR	July 2011	September 2011
		DAY	20	19
		FORMAT (select)	LiveMeeting	In Person
NAME	POSITION			
Connie Davis MD	Chair			X
Amy Waterman PhD	Vice Chair	X	X	X
Denise Morin RN, MSN	Regional 1 Rep.	X	X	X
Diane James, RN, MSN	Regional 2 Rep.			X
Linda Chen, MD	Regional 3 Rep.	X	X	X
Steven Potter MD, FACS	Regional 4 Rep.	X	X	X
Fuad S Shihab, MD	Regional 5 Rep.	X		
Jordana Gaumond M.D.	Regional 6 Rep.	X	X	X
Sandra Taler, MD	Regional 7 Rep.	X	X	X
Christie Thomas MB, FRCP, FASN, FAHA	Regional 8 Rep.	X	X	X
Carlos Marroquin MD	Regional 9 Rep.	X	X	X
Todd Pesavento MD	Regional 10 Rep.			X
Richard Stravitz MD	Regional 11 Rep.			X
Tonya Bradford PhD	At Large	X	X	X
William Freeman, MD, MPH	At Large	X	X	X
Mary Amanda Dew PhD	At Large	X	X	X
Cynthia Forland PhD	At Large	X	X	X
Margaret Frueh RN, MS	At Large	X	X	X
Cherie Hayostek MD	At Large	X		
Chris Freise MD	At Large	X	X	X
Chris Jernigan	At Large	X	X	X
Tiffany Furuya	At Large	X	X	X
Susan Light MD	At Large	X	X	X
Krystal McLear	At Large	X	X	X
Donald Olenick Esq.	At Large	X	X	X
Bradley Kornfeld JD	At Large	X	X	X
Matthew Cooper, MD	At Large	X	X	X
James Montano	At Large	X		
Rebecca Morrow, PhD	At Large	X	X	X
Vicky Young PhD	At Large	X	X	X
Michelle Desler MS	Visiting Board Member			X
Raelene Skerda, RPh BPharm	Ex. Officio	X	X	X
Bernard Kozlovsky MD, MS	Ex Officio	X		

Chris McLaughlin			X
Bertram Kasiske MD	SRTR		X
Yang Qiu	SRTR		X
Adrine Chung	SRTR	X	
Jennifer Wainright PhD	UNOS Research	X	X
Diana Marsh	DEQ	X	
Octavia Reed	DEQ	X	
Ciara Samana	Asst Director Policy	X	
Brian Shepard	Director Policy		X
Lee Bolton	Committee Liaison	X	X