At-a-Glance

- **Proposal to clarify, reorganize and update OPTN policies on OPO and transplant center packaging, labeling and shipping practices**

- **Policy affected: Policy 5.0 (Standardized Packaging, Labeling and Transporting of Organs, Vessels and Tissue Typing Materials)**

- **Organ Procurement Organization (OPO) Committee**

  The proposed modifications to Policy 5.0 will clarify the policy requirements, eliminate redundant language and give OPOs and transplant centers guidance on how to package, label and ship organs, vessels and tissue typing materials. We have reorganized the entire content to promote clarity. We defined types of organ packaging and we clearly described labeling and documentation requirements for solid organs, tissue typing materials and vessels. We listed vessel recovery and storage requirements and transportation responsibilities.

- **Affected groups**

  OPO Executive Directors and Directors of Procurement, Transplant Center Administrators, Transplant Surgeons, and all OPO and transplant center staff who are involved with the packaging, labeling and transporting of organs, vessels and tissue typing materials.

- **Specific requests for comment**

  Please pay attention to and comment on the "substantive" changes that are highlighted in the document. Please provide comment on the entire document or any portion that you feel requires further Committee discussion or clarification. In particular, the Committee would like the community to focus on the following issues:

  - Whether the proposed policy changes clarify and adequately define the OPO and transplant center staff roles required to package and transport organs, vessels and tissue typing materials.
  - Whether the proposed changes can be applied locally.
  - Whether the changes reflect current practice.

Proposal to clarify, reorganize and update OPTN policies on OPO and transplant center packaging, labeling and shipping practices

Policy affected: Policy 5.0 (Standardized Packaging, Labeling and Transporting of Organs, Vessels and Tissue Typing Materials)

Organ Procurement Organization (OPO) Committee

Summary and Goals of the Proposal:

The proposed modifications to Policy 5.0 will clarify the policy requirements, eliminate redundant language and give OPOs and transplant centers guidance on how to package, label and ship organs, vessels and tissue typing materials. We have reorganized the entire content to promote clarity. We defined types of organ packaging and we clearly described labeling and documentation requirements for solid organs, tissue typing materials and vessels. Vessel recovery and storage requirements are listed, as is transportation responsibilities for renal, non renal and tissue typing materials.

The goal is to define terms and responsibilities to promote safe and efficient packaging and labeling, and clearly list the requirements for recovering, storing and use of vessels in solid organ transplant recipients. Host OPOs are responsible for packaging and labeling deceased donor organs and transplant centers are responsible for packaging and labeling living donor organs.

Background and Significance of the Proposal:

The OPO Committee was charged to review OPTN policies that may be confusing, outdated or that might place the OPO at risk for non-compliance. The Operations Committee requested that the OPO Committee specifically review Policy 5.0 as it addresses OPO standards for labeling and packaging. The OPO Committee formed a Policy Review Subcommittee and worked with UNOS staff to rewrite Policy 5.0 in order to:

- provide clarity
- make it more concise
- ensure that it reflects current practice.

Several Committee staff liaisons participated in the rewriting of this policy on behalf of their Committees. Liaisons from the Operations, Policy Oversight, and OPO Committees worked with staff from the Organ Center, the Department of Evaluation and Quality (DEQ), and Membership to craft the proposed language. The members of the OPO Committee's Policy Review Subcommittee, comprising OPO Executive Directors and Directors of Procurement, reviewed all of the Policy 5.0 language and used their expertise to determine if the policy is consistent with current practice. DEQ provided the subcommittee with a list of the most commonly seen labeling and transportation violations. The subcommittee used the list of violations to review specific aspects of the policy and to determine if the wording was confusing or outdated. Appropriate changes were recommended.

The strengths of the proposed policy change lie in the updated packaging requirements and assignment of roles responsible for packaging and verifying information. The proposed changes merely clarify language and reorganize the policy so there is no financial burden on the OPO or transplant center. There are also no programming requirements for the policy changes.

The Committee did not identify specific weaknesses of the proposed changes to the policy. As it is a reorganization of current policy, there are only a few changes regarding the shipping containers that might require an OPO or transplant center to make sure that their containers meet the specifications. The policy actually 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 policy also clearly specifies the roles for the OPO and 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 proposed policy change should not have unintended consequences.

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.

Supporting Evidence and/or Modeling:

The members of the OPO Committee Policy Review Subcommittee, comprising OPO Executive Directors or Directors of Procurement, reviewed all of the Policy 5.0 language and used their expertise and current knowledge of organ procurement practices to determine if the policy was in line with current practice. (DEQ) provided the subcommittee with a list of the most commonly seen labeling and transportation violations. The subcommittee used the list of violations to review specific aspects of the policy in order to determine if the wording was confusing, might be interpreted differently by individuals, or what is out of pace with current practice. Appropriate changes were then recommended by the subcommittee.

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

The proposed changes are consistent with the Final Rule[1] and will meet HHS Program goals by:

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

The changes meet the strategic plan goals as it will:

- 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 OPO Policy Review Subcommittee will request a list of labeling and transportation policy violations reported to DEQ. The subcommittee will review each infraction and identify which section of the policy is in question. They will then review the

[1]The Final Rule, Chapter 1-Public Health Service, Department of Health and Human Services, Part 121- Organ Procurement and Transplantation Network. Section 121.7 Identification of Organ Recipient, Section C Transportation of organ to potential recipient.

policy to determine if there is confusion or lack of clarity in the policy, and make appropriate recommendations to the Committee at that time.

- ***What questions or hypotheses are guiding the evaluation of the proposal?*** Will the changes in Policy 5.0 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 Policy Review Subcommittee will review the policy violations every 6 months for two years following implementation.

Additional Data Collection:

This proposal does not require additional data collection.

Expected Implementation Plan:

OPO and transplant center staff will need to review their individual policies and modify those policies as necessary to ensure congruency. They should also evaluate their packaging containers to ensure that they are compliant with current changes in policy.

DEQ will need to evaluate the policy changes that affect the containers and packaging to ensure that the member's packaging policies are congruent with current changes. The UNOS auditors will also need to assess whether the appropriate documentation is provided.

This proposal will not require programming in UNet[SM].

Communication and Education Plan:

Communication Activities			
Type of Communication	**Audience(s)**	**Deliver Method(s)**	**Timeframe**
Policy Notice	Appropriate OPO and TX center staff.	Email from the UNOS Communications mailbox	30 days after the board meeting where the changes are approved.
Sidebar in the UNOS Update Magazine in the Policy section.	Update readers	Mailing of print copy of magazine.	Earliest appropriate issue after the policy has been approved.
A system notice won't be necessary because this change won't involve changes to UNet.			

Monitoring and Evaluation:

OPOs and transplant centers will be expected to comply with this policy. DEQ will evaluate member compliance with this policy.

Transplant centers and OPOs are expected to:

- Follow policy requirements regarding external and internal packaging.
- Follow policy requirements regarding external and internal labeling.
- Follow policy requirements for documentation accompanying the organ or vessel.
- Establish and implement procedures for verifying labeling and documentation included with the organ.
- Establish and implement procedures for verifying certain information upon receipt of an organ.
- Establish and implement policies and procedures addressing tissue typing specimen, medium, and shipping requirements and have an agreement with an OPTN member laboratory.
- Establish and implement policies and procedures addressing living or deceased donor organs that remain in the same operating room suite as the intended candidate(s).
- Establish and implement policies and procedures addressing vessel recovery and transplant and vessel storage requirements.
- Pay transportation costs as required by policy.

DEQ staff may detect potential violations of this proposed policy by:

- Conducting site surveys.
- Researching confidential reports of complaints received through the OPTN Member Reporting Line or Patient Services Line.
- Reviewing OPTN data.
- Receiving referrals from OPTN/UNOS Committees, OPTN/UNOS staff, or OPTN/UNOS members.

During site surveys, UNOS staff may do any or all of the following:

- Request and review copies of member policies and procedures addressing Policy 5.0 requirements.
- Request a demonstration of internal and external packaging and labeling procedures.
- Review records to verify appropriate internal and external labeling.
- Verify that disposable shipping boxes meet requirements.
- Verify that reusable coolers are properly cleaned and sanitized.
- Verify that mechanical preservation machines are properly labeled.
- Interview staff to verify knowledge of procedures and that staff follow procedures.
- Review OPO agreements with OPTN member laboratories.
- Review vessel recovery consent forms.
- Review vessel storage records.
- Review vessel refrigeration temperature logs.
- Verify the implanting transplant program notified the OPO and the OPTN of final disposition of the vessels.
- Review any other available documentation and records to verify compliance with Policy 5.0.

DEQ staff will explore all potential policy violations and forward any results to the OPTN/UNOS Membership and Professional Standards Committee for confidential medical peer review.
Policy or Bylaw Proposal:

The modifications to Policy 5.0 appear below. The proposed changes to Policy 5.0 were made to clarify and reorganize the content in order to decrease the chance of misinterpretation and to make the policy consistent with current practice. Because the changes would be difficult to read with numerous strikethroughs and underlines typically seen in public comment proposals, we are presenting these policy changes differently. For your convenience, we present the new language as it would look if this proposal is approved and we highlighted the substantive changes. The other changes (reorganization and rewording) are outlined in Table 1 to help you identify specific changes.. Following the proposed new language is the existing language marked with ~~strikethroughs~~.

5.0 STANDARDIZED PACKAGING, LABELING AND TRANSPORTING OF ORGANS, VESSELS, AND TISSUE TYPING MATERIALS

The purpose of policy 5.0 and its subsections is to:

- state requirements for packaging and labeling organs, tissue typing specimens, and vessels to prevent wastage (and/or to promote safe and efficient use);
- define terms and responsibilities related to packaging, labeling, and transporting organs, tissue typing specimens, and vessels; and
- State requirements for recovering, storing, and using vessels in solid organ recipients.

The responsibility for packaging and labeling deceased donor organs is assigned to the Host OPO. The responsibility for packaging and labeling living donor organs is assigned to the transplant center. For the purposes of this policy, the term organ includes organ segments and pancreas islets.

5.1 ORGAN PACKAGING, 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 or living donor organ that travels outside the recovery facility.

5.1.1 Disposable shipping box

- If organs 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 wax coated corrugated cardboard with at least 200 pound burst strength.
- The inner container must be 1.5 inch thick insulated container.
- 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. water tight).
- 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 Cooler

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

5.1.3 Mechanical preservation machine

- Mechanical preservation machines are permitted for transporting an organ.
- The external surface of a mechanical preservation machine must be labeled with:
    - the standardized label provided 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 for the previous donor organ must be removed**.**

5.2 ORGAN PACKAGING, 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, pancreata and hearts must be placed in a rigid container, which, if sterile, can be part of the triple sterile barrier
- Livers, lungs, and intestines do not require a rigid container
- Vessels must be protected by a triple sterile barrier.

5.3 EXTERNAL LABELING REQUIREMENTS

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

The external transport container must be labeled with the: UNOS Donor I.D. Number, 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.

5.4 INTERNAL LABELING REQUIREMENTS

5.4.1 Solid organ

The Host OPO or the transplant center, as applicable, is responsible for ensuring that the UNOS Donor I.D. number, donor ABO type, and a secure label identifying the specific contents (e.g., liver, right kidney, heart) are attached to the outer bag or rigid container housing the donor organ.

5.4.2 Tissue typing materials

Each separate specimen container of tissue typing material must have a secure label with the UNOS Donor I.D. Number, donor ABO type, date and time the sample was procured and the type of tissue. In the preliminary evaluation of a donor, if the UNOS ID is not available and donor ABO is not yet confirmed, it is permissible to use a locally assigned unique ID for the transportation of initial screening specimens.

5.4.3 Vessels

The vessels must be packaged in a rigid, sterile sealed container, protected by a triple sterile barrier, labeled with the: recovery date, ABO, all serology results, container contents, and the UNOS Donor ID Number. If the donor is in a "high risk"[2] group as defined by the Centers for Disease Control and Prevention (CDC), the label must indicate that the vessels are from a donor who meets the CDC criteria for high risk. The appropriate packaging of the vessel should be completed in the donor operating room. The label should clearly state "for use in organ transplantation only."

5.5 DOCUMENTATION ACCOMPANYING THE ORGAN OR VESSEL

5.5.1 Documentation accompanying the organ

- Complete donor documentation, as described in Policy 2.5.7.1, must be sent in the container with all transported organs.
- 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 donor organ is transported, the Host OPO or the transplant center, as applicable, must include 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 documentation must be included with the vessel as is included with the organ.

[2] Rogers MF, Simonds RJ, Lawton KE, et al. Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissue and Organs. CDC MMWR Recommendations and Reports. 1994;May 20/ 43(RR-8):1-17. http://www.cdc.gov/mmwr/preview/mmwrhtml/00031670.htm

5.6 VERIFICATION OF LABELING AND DOCUMENTATION INCLUDED WITH ORGAN

When a donor organ or vessel(s) is procured, the Host OPO or transplant center must ensure the accuracy of the donor's ABO on the container label and within the donor's documentation. Each OPO or transplant center 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 5.2 and 5.3. The OPO or transplant center must maintain documentation that such separate verification has taken place and make such documentation available for audit.

5.7 VERIFICATION OF INFORMATION UPON RECEIPT OF ORGAN

Upon receipt of a living or deceased donor organ and prior to implantation, the 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 transplant center must maintain documentation that this verification has taken place and make such documentation available for audit.

5.8 MATERIALS FOR TISSUE TYPING AND ABO CONFIRMATION

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

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

5.8.2 Blood for ABO Confirmation

A "red top" tube of blood, specifically for confirmation of ABO must be sent to the receiving OPO or transplant center with each deceased organ and tissue typing material. This tube must be labeled as described in Policy 5.4.2 and placed within the insulated container. The Host OPO is responsible for ensuring that the tube is appropriately labeled.

5.8.3 Typing material for each kidney and pancreas

In view of the frequent need for regional shipment of pancreas and kidney allografts, sufficient specimens for several crossmatches are required. However, 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 Typing material for all other organs

- The Host OPO will provide specimens for tissue typing if requested.

5.9 LIVING OR DECEASED DONOR ORGANS THAT REMAIN IN THE SAME OPERATING ROOM SUITE AS THE INTENDED CANDIDATE(S)

In the case of donor organs that remain in the same operating room suite 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. The transplant center must document that the correct organ was identified for the correct candidate prior to transplant (refer to Policy 3.1.2). A "time out" prior to leaving the donor operating room and an additional "time out" upon arrival in the candidate operating room is required.

5.10 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 different donor (for example, when the vessels and the liver or pancreas allograft are being transplanted from different donors with different numbers).

5.10.1 Vessel Recovery and Transplant

- The consent forms used by the recovering OPO must include language that indicates that vessels will be used for transplant.
- The vessels cannot be used other than for the implantation or modification of a solid organ transplant.
- Vessels can be shared amongst 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 OPO and the OPTN of subsequent disposition of the vessels.
- If the transplant center stores vessels and subsequently uses the vessels for the intended recipient or another transplant recipient, the Host OPO and 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 Vessel Storage

The transplant center must designate a person to monitor and maintain records, destroy, and notify the ~~Host~~ recovering OPO and 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 (i.e. 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, destroy the vessel when expired, and notify the recovering OPO 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 Number for tracking. The appropriate packaging of the vessel should be completed in the donor operating room. Label should clearly state for use in organ transplantation only.
- The vessels must be stored in a secured refrigerator with a temperature monitor and maintained within a range of 2 to 8 °C.
- There must be daily monitoring of the vessels with documented security and temperature checks by the transplant center.
- The vessels 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 in a recipient other than the intended recipient.

5.11 TRANSPORTATION RESPONSIBILITY

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

5.11.1 Renal Organs

The Host OPO is responsible for transportation costs for deceased donor kidney(s) and associated tissue typing material pursuant to CMS regulations.

5.11.2 Non-Renal Organs

The member that accepted the organ is responsible for transportation costs for deceased 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 Tissue Typing Material

The Host OPO is responsible for payment of transportation costs for tissue typing material sent to crossmatch potential recipients of a deceased donor kidney. The

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.

~~5.0 STANDARDIZED PACKAGING AND TRANSPORTING OF ORGANS AND TISSUE TYPING MATERIALS~~

~~The following policies address standardized packaging of live and deceased donor organs and tissue typing materials to be transported for the purposes of organ transplantation. When a deceased donor organ is procured, the Host OPO shall be responsible for ensuring the accuracy of the donor's ABO on the container label and within the donor's documentation. Each OPO 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 policy 5.2 and 5.3. The OPO shall maintain documentation that such separate verification has taken place and make such documentation available for audit.~~

~~Upon receipt of a live or deceased donor organ 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.~~

~~5.1 SPECIMEN COLLECTION AND STORAGE.~~ ~~Each OPO shall have a written policy established with (a) laboratory(s) approved by the American Society for Histocompatibility and Immunogenetics (ASHI) or the OPTN. This policy should be determined by the specimen requirements of the typing laboratory and the quality assurance criteria of ASHI or the OPTN. The policy shall include specific descriptions of the type of specimen, and medium, in addition to the shipping requirements of same.~~

~~5.2 STANDARD LABELING SPECIFICATIONS.~~ ~~The Host OPO or the Transplant Center, as applicable, shall be responsible for ensuring that the outermost surface of the transport box containing organs and/or tissue typing specimen containers must have 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 OPO shall label each specimen within the package in accordance with policy. The Host OPO is responsible for ensuring that each tissue or donor organ container that travels outside the recovery facility is labeled appropriately.~~

~~In the case of deceased or live donor organs that remain in the same operating room suite 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. 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 live donor organs that travel outside the recovery facility, the Transplant Center(s) involved shall be responsible for ensuring that packaging is consistent with the requirements of OPTN Policies 5.2.1 and 5.2.3, and that the outermost surface of the transport box containing the organ must have a completed OPTN/UNOS standardized external organ container label (provided by UNOS). The recovering Transplant Center shall label each specimen within the package in accordance with OPTN/UNOS policy. The recovering Transplant Center is responsible for ensuring that each container that travels outside the recovery facility is labeled appropriately.

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

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

5.2.3 The Host OPO or the Transplant Center, as applicable is responsible for fixing to the transport container the standardized label completed with the Donor I.D. Number, 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.

5.3 DOCUMENTATION. ABO results must be provided by the Host OPO or the Transplant Center, as applicable in all circumstances during which a donor organ is transported. Properly packaged paperwork containing complete donor information, as described in Policy 2.5.7.1, will be included with the organ transport container in all instances in which the organ is transported.

5.4 PACKAGING. In all circumstances during which donor organ is transported outside the recovery facility, the Host OPO or the Transplant Center, as applicable 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.

5.5 STANDARD ORGAN PACKAGE SPECIFICATIONS. The re-use of disposable transport boxes is prohibited. If the deceased donor organ is to be commercially shipped, such as with a courier service, commercial airline or charter service, the deceased donor organ must be packaged in a disposable transport box. Coolers are permitted for non-commercial transporting when the organ recovery team is taking the deceased donor organ with them from the donor hospital to the candidate transplant center. The re-use of coolers is permitted. All labels for the previous donor organ must be removed before re-using the cooler. The standard package used by members must have the following properties:

5.5.1 A corrugated, wax coated outer container of 200 pound burst strength, or one of equal or greater strength and moisture resistance, must be used.

5.5.2 Inside the moisture resistant outer-container, 1-1/2" thick expanded polystyrene insulated container or its R-factor equivalent must be used. A closed red plastic bio-hazard bag must be placed between the outer container and the polystyrene insulated container to encase the ice.

5.5.3 A closed plastic liner must also be placed inside the polystyrene container to encase the ice. Inside the insulated container, the organ must be protected by a triple sterile barrier and one rigid container which, if sterile, may be considered one of the triple barriers.

5.5.3.1 The rigid container is not required for livers or lungs.

5.5.4 The tissue typing specimen containers must be in a leak proof plastic bag and must not be imbedded in the ice.

5.5.5 The deceased donor paperwork must be in a watertight container. It may be placed in a location specifically designed for the paperwork or inside the outer container, outside of the insulated container.

5.5.6 Accompanying each deceased organ and tissue typing material, a "red top" tube of blood, specifically for confirmation of ABO must be sent to the receiving OPO or transplant center. This tube must be labeled as described in Policy 5.2.2 and placed within the insulated container. The Host OPO is responsible for ensuring that the tube is appropriately labeled.

5.6 TRANSPORTATION RESPONSIBILITY. The Host OPO, as defined in Policy 2.1, is responsible for transportation of deceased donor kidney(s) and tissue typing material to the primary destination designated by the recipient member, (e.g., laboratory, transplant hospital, or OPO). In charter aircraft situations, before the Organ Center will arrange for this mode of transportation, the Host OPO must agree to use a charter aircraft, and it must be determined who will pay for the charter.

5.6.1 Transportation Costs Incurred for Renal Organs. Payment of transportation costs incurred by the OPTN contractor on behalf of a member for a donor kidney that is unconditionally accepted by a member and subsequently forwarded to another member is the responsibility of the member that forwarded the kidney. Payment of transportation costs incurred by the OPTN contractor on behalf of a member for a donor kidney that is conditionally accepted by a member and subsequently forwarded to another member is the responsibility of the Host OPO.

5.6.2 Transportation Costs Incurred for Tissue Typing Material. Payment of transportation costs incurred by the OPTN contractor on behalf of a member for tissue typing material sent to crossmatch backup recipients for a donor organ that is conditionally accepted by a member is the responsibility of the member which requested backup for the organ.

5.6.3 Transportation Costs Incurred for Non-Renal Organs. Payment of non-renal donor organ transportation costs incurred by the OPTN contractor on behalf of a member is the responsibility of the member that accepts the organ. Payment of transportation costs incurred by the OPTN contractor on behalf of a member for donor organs that have been accepted and transported, but cannot be utilized for transplantation, also is the responsibility of the member that accepted the organ. If a donor organ is first accepted by one member and subsequently forwarded to another member, payment of transportation costs incurred by UNOS on behalf of a member in forwarding the organ is the responsibility of the member that finally accepts the organ.

5.7 VESSEL RECOVERY, STORAGE, and TRANSPLANT

5.7.1 The practice of vessel recovery and immediate use in a solid organ transplant (for example either a current liver or pancreas transplant) should not be disrupted.

5.7.2 The sanction for vessel recovery and storage for use in a subsequent solid organ transplant from a different donor must be sustained: (for example, when the vessels and the liver or pancreas allograft are being transplanted from different donors with different numbers). The vessels cannot be used other than for the implantation or modification of a solid organ transplant.

5.7.3 Vessels can be shared amongst transplant programs. If sharing occurs between transplant programs, the implanting program must write a detailed explanation justifying the sharing and that justification will be reviewed by the Membership and Professional Standards Committee (MPSC). It is the responsibility of the implanting transplant program to notify the OPO and the OPTN of subsequent disposition of the vessels.

5.7.4 If the vessels are stored and subsequently used for the intended recipient or another transplant recipient, the OPO and the OPTN must be notified.

5.7.5 The consent forms used by the recovering OPO must include language that indicates that vessels will be used for transplant.

5.7.6 If the vessels are being stored, the procedure of packaging, labeling, storage, the medium and temperature, the location, and the duration of storage must be addressed by the organ transplant community using the following standards.

5.7.6.1 The vessels must be stored in a Food and Drug Administration (FDA) approved preservation solution (ex. UW, Custodial HTK).

5.7.6.2. The vessels must be stored in a sealed container labeled with the recovery date, ABO, serology, container contents, and the Donor ID Number for tracking. The appropriate packaging of the vessel should be completed in the donor operating room. Label should clearly state for use in organ transplantation only.

5.7.6.3 The vessels must be stored in a secured refrigerator within a range of 2 to 8 °C.

5.7.6.4 The vessels can be stored up to a maximum of 14 days from the original recovery date.

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

5.7.6.6 The transplant surgeon must be provided around the clock access to the donor information for his/her review prior to using the donor vessel in a recipient other than the intended recipient.

5.7.6.7 There must be daily monitoring of the vessels with documented security and temperature checks by the transplant center.

5.7.6.8 A log of stored vessels must be maintained by the transplant center at the point of storage.

5.7.7 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 for the use of this conduit for review by the MPSC.

Table 1

Summary of OPO Committee Proposed Changes to Policy 5

The proposed Policy 5 reorganization and summary of changes is detailed in Table 1 below. This information can be used to find the location of the new proposed policy language that corresponds to the existing policy language.

Existing Section of Policy 5.0	Summary of Proposed Changes to Section
5.0 (Introductory paragraph) states purpose, responsibility, requirement of OPO for second person to verify labeling/documentation of organ packaging, specifies that Policy 3.1.2 applies to organs from living donors (TXC required to verify recorded ABO of donor and recipient, and donor ID, prior to implantation).	• Defined purpose and responsibility in clearer terms, used bullets instead of long narrative. • Moved requirement of OPO for verification of labeling/documentation to new section **5.6 VERIFICATION OF LABELING AND DOCUMENTATION INCLUDED WITH ORGAN.** • Moved requirement of TXC to verify recorded ABO/donor ID to new section 5.7 **VERIFICATION OF INFORMATION UPON RECEIPT OF ORGAN.** Modified verification prior to implantation for consistency with Policy 3.1.2 (verification is that the organ is what you expect it to be, not that the organ is necessarily ABO compatible transplant).
5.1 (SPECIMEN COLLECTION AND STORAGE) states requirement for OPO to have written policy with histo lab.	• Moved into new section 5.8 **TISSUE TYPING MATERIALS.** Removed reference to ASHI and replaced with language more consistent with applicable Bylaws and existence of multiple accrediting bodies (i.e. ASHI and CAP).
5.2 (STANDARD LABELING SPECIFICATIONS), 5.4 (PACKAGING), 5.5 (STANDARD ORGAN PACKAGING SPECIFICATIONS)	• Created new sections for this content: • **5.1 ORGAN PACKAGING, EXTERNAL PACKAGING SPECIFICATIONS;** • **5.2 ORGAN PACKAGING**, **INTERNAL PACKAGING SPECIFICATIONS;** • **5.3 EXTERNAL LABELING REQUIREMENTS;** • **5.4INTERNAL LABELING REQUIREMENTS.** • Moved all applicable requirements into new sections and organized by subheadings, defined terms, and used shorter sentences / bullets instead of narrative.

Existing Section of Policy 5.0	Summary of Proposed Changes to Section
5.2 (STANDARD LABELING SPECIFICATIONS) states requirements for verification when an organ remaining in the same operating suite as the intended candidate	• Moved to new section **5.9 LIVING OR DECEASED DONOR ORGANS THAT REMAIN IN THE SAME OPERATING ROOM SUITE AS THE INTENDED CANDIDATE(S)** • **Moved to 5.4 INTERNAL LABELING REQUIREMENTS**
5.3 (DOCUMENTATION), 5.5.5 (deceased donor paperwork)	• Moved to new section **5.5 DOCUMENTATION ACCOMPANYING THE ORGAN OR VESSEL,** included applicable requirements from Policy 5.5.5
5.4 and 5.5 (PACKAGING SPECIFICATIONS) 5.5.6 "red top" tube requirement	• Moved to new sections: • **5.0 STANDARDIZED PACKAGING, LABELING AND TRASPORTING OF ORGANS, VESSELS, AND TISSUE TYPING MATERIALS** • **5.1 ORGAN PACKAGING, EXTERNAL PACKAGING SPECIFICATIONS** • **5.2 ORGN PACKAGING, INTERNAL PACKAGING SPECIFICATIONS** • **5.5 DOCUMENTATION ACCOMPANYING THE ORGAN OR VESSEL** • Moved to **5.8MATERIALS FOR TISSUE TYPING AND ABO CONFIRMATION**
5.6 (TRANSPORTATION RESPONSIBILITY)	• Reorganized with different subheadings, revised language for clarity. • Moved to **5.11 TRANSPORTATION RESSPONSIBILITY**
5.7 (VESSEL RECOVERY, STORAGE, AND TRANSPLANT)	• Clearly stated intent, grouped like requirements into subheadings for vessel recover/transplant, and vessel storage. • **5.4.3 (INTERNAL LABELING REQUIREMENTS) VESSELS** • **5.5.2 DOCUMENTATION ACCOMPANYING THE VESSEL(S)** • **5.6 VERIFICATION OF LABELING AND DOCUMENTATION INCLUDED WITH ORGAN** • **5.10 VESSEL RECOVERY, TRANSPLANT, AND STORAGE**