

12.0 LIVING DONATION

The following policies apply to the entire continuum of organ donation from living donors. The process of living donation begins at the time that an individual considers donating an organ, continues through the evaluation of the donor, placement of the organ (whether directed or nondirected), recovery of the organ, and post-donation care and follow-up of the donor.

The following policies apply to member institutions involved in living donation. These policies do not supplant medical judgment or decision-making by transplant professionals or potential or realized living donors.

12.1 Definitions.

Reserved.

12.2 Informed Consent of Living Donors.

Reserved.

12.3 Medical Evaluation of Living Donors

12.3.1 ABO Identification. The member transplant hospital must ABO type, each living donor on two separate occasions prior to the donation. Two separate occasions are defined as two ABO samples taken at different times, and sent to the same or different laboratories.

12.3.2 ABO Subtype Identification. The member transplant hospital subtyping a living donor whose initial subtype test indicates the donor to be non-A₁ (negative for A₁) or non-A₁B (negative for A₁B), must complete a second determination test prior to donation to assess the accuracy of the result. Blood samples for subtype testing must be taken on two separate occasions, defined as two samples taken at different times and sent to the same or different laboratories. Samples tested must not be taken after a blood transfusion. When the initial and second determination subtypings are the same result, the result can be used to determine transplant compatibility with the intended recipient or any other potential recipient (e.g., in a paired exchange program or allocation of non-directed donor). If the results do not indicate the same subtype, the donor must be allocated based on the primary blood type, A or AB.

12.4 Independent Donor Advocates.

Reserved.

12.5 Placement of Living Donor Organs.

12.5.1 Kidney Placement.

12.5.1.1 Prospective Crossmatching. A prospective crossmatch is mandatory for all potential living donor recipients. Guidelines for policy development, including assigning risk and timing of crossmatch testing, are set out in Appendix D to Policy 3.

12.5.2 Liver Placement.

Reserved.

12.5.3 Thoracic Placement.

Reserved.

12.5.4 Pancreas Placement.

Reserved.

12.5.5 Intestinal Placement.

Reserved.

12.5.6 Placement of Non-directed Living Donor Organs

Prior to determining the placement of a non-directed living donor kidney, the transplant center must acquire a match run of its waitlist candidates. The transplant center may obtain the match run from its local OPO or the Organ Center of the OPTN Contractor. The transplant center must document the rationale used to place the non-directed living donor kidney. If the transplant center deviates from the sequence defined by the match run, the transplant center must document its rationale for not following the match run in addition to documenting the criteria used to select the kidney recipient. This documentation must be maintained and made available to the OPTN contractor upon request. This policy does not apply to non-directed living kidney donors who consent to participate in a Kidney Paired Donation arrangement.

12.6 Center Acceptance of Living Donor Organs. Transplant Centers that perform living donor transplants must only accept and transplant living donor organs recovered at OPTN member transplant hospitals that are approved to perform living donor recovery for that organ. If the OPTN does not have approval criteria for a living donor recovery hospital associated with a particular organ (e.g., lung, heart, intestine, or pancreas), then Transplant Centers that perform living donor transplants must only accept and transplant living donor organs recovered at OPTN member transplant hospitals that have an approved transplant program for that organ.

12.7 Standardized Packaging, Labeling and Transporting Of Living Donor Organs, Vessels, and Tissue Typing Materials

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

- state requirements for packaging and labeling living donor organs (when applicable), 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.

The responsibility for packaging and labeling living donor organs is assigned to the donor recovery transplant center. If a living donor organ ever requires repackaging by a transplant center for transport, the transplant center will package, label and ship the organ in accordance with this policy.

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 must use both internal and external transport containers to package a living donor organ, which travels outside the recovery facility.

12.7.1.1 Disposable shipping box

- If living donor organs, vessels and/or tissue typing that are packaged with the organ 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).

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.

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 subtyping (when used to determine transplant compatibility), and UNOS ID.
- The external surface of a mechanical preservation machine must be labeled with the standardized external label distributed by the OPTN contractor.
- Before re-using a mechanical preservation machine that was used to transport an organ, all labels from the previous donor must be removed.

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.
- 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.

12.7.3 External Labeling Requirements

When a disposable shipping box or cooler is used to transport a living donor organ, the donor recovery transplant center must use the standardized external label distributed by the OPTN contractor.

The external transport container must be labeled with the: UNOS Donor I.D., Donor ABO type and subtyping (when used to determine transplant compatibility), 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, which must be utilized.

12.7.4 Internal Labeling Requirements

12.7.4.1 Solid organ

The donor recovery transplant center is responsible for ensuring that a secure label identifying the specific contents (e.g., liver or right or left kidney 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 and subtyping (when used to determine transplant compatibility).

12.7.4.2 Tissue typing materials

Each separate specimen container of tissue typing material that is packaged with the organ 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 I.D., (donor ABO is not considered a unique identifier). Additionally each specimen should be labeled with Donor ABO and subtyping (when used to determine transplant compatibility, date and time the sample was procured and the type of tissue. In the preliminary evaluation of a donor, if the UNOS I.D. or ABO is not available, it is permissible to use a locally assigned unique I.D. and one other identifier for the transportation of initial screening specimens.

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 and subtyping (when used to determine transplant compatibility, all serology results, container contents, and the UNOS Donor I.D.). If the donor is in a "high risk" group as defined by the 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.

12.7.5 Documentation Accompanying the Organ or Vessel

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;
 - Consent form; and
 - Complete medical record of the living donor.

- 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 living donor organ is transported, the donor recovery transplant center, must include the source documentation in the donor documentation.

12.7.6 Verification of Labeling and Documentation Included with Organs or Vessels

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

When a living donor organ or vessel(s) is procured, the donor recovery transplant center must ensure the accuracy of the donor's ABO and subtyping (when used to determine transplant compatibility) on the container label and within the donor's documentation.

Each donor recovery 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. The donor recovery transplant center must maintain documentation that such separate verification has taken place and make such documentation available for audit.

12.7.7 Verification of Information Upon Receipt of Organ

Upon receipt of a 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 subtyping (when used to determine transplant compatibility), and UNOS Donor ID. The recipient's transplant center must maintain documentation that this verification has taken place and make such documentation available for audit.

12.7.8 Materials for Tissue Typing and ABO Confirmation

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

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.

12.7.8.2 Blood for ABO Confirmation

A "red top" tube of blood, specifically for confirmation of ABO must be sent to organ recipient's transplant center with each living donor organ and tissue typing material that is packaged with the organ. This tube must 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 and subtyping (when used to determine transplant compatibility), date and time the sample was procured, and the type of tissue. The donor recovery transplant center is responsible for ensuring that the tube is appropriately labeled.

12.7.8.3 Typing material for each kidney

The minimal typing material to be obtained for EACH kidney will include 2 ACD (yellow top) tubes.

12.7.8.4 Typing material for all other organs

The donor recovery transplant center will provide specimens for tissue typing if requested.

12.7.9 Living Donor Organs that Remain in the Same Recovery Facility as the Intended Candidate(s)

12.7.9.1 When living donor organs are recovered and remain in the same facility 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. 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.

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.

12.7.10.1 Vessel recovery and transplant

- The consent forms used by the donor recovery transplant center must include language that indicates that vessels may be used for transplant.
- The vessels from a living donor can only be used for the implantation or modification of a solid organ transplant for the original intended recipient.

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. This person must monitor the refrigerator, ensure records are up to date and available with the 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, and subtyping (when used to determine transplant compatibility)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. The 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.

12.7.11 Transportation Responsibility

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

12.7.11.1 Renal organs

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

12.7.11.2 Non-renal organs

The member that accepted the organ is responsible for transportation costs for living donor non-renal organ(s) 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.

12.7.11.3 Tissue typing material

The organ recipient's transplant center is responsible for payment of transportation costs for tissue typing material sent to crossmatch potential recipients of a living 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

12.8 Reporting Requirements. Refer to Policy 7.0 (Data Submission Requirements) for the member that is responsible for submitting living donor forms.

12.8.1 All living donors must be registered with the OPTN Contractor via the living donor feedback form prior to surgery.

12.8.1.1 The living donor transplant program must use source documents from both an initial and second determination ABO typings and subtypings (when used to determine transplant compatibility), to enter the living donor's ABO data on the Living Donor Feedback Form. Additionally, each living donor program must develop, implement, and comply with a procedure to verify that the living donor's ABO and subtyping was correctly entered on the Living Donor Feedback Form with both the initial and second determination ABO typing and subtyping source documents by an individual other than the person initially entering the donor's ABO data. A transplant program must document that each ABO typing and subtyping entry was performed in adherence to the program's protocol. The program must maintain this documentation, and make it available to the OPTN Contractor, upon request.

12.8.2 The follow-up period for living donors will be a minimum of two years.

12.8.3 Living Donor Registration Forms (LDR) must be submitted to the OPTN within 60 days of the form generation date. Transplant centers that recover living donor organs must complete the LDR form when the donor is discharged from the hospital or within six weeks following the transplant date, whichever is first. Transplant centers that recover living donor organs must submit LDF forms for each living donor at six months, one year and two years from the date of donation.

12.8.4 **Submission of Living Donor Death and Organ Failure Data.** Transplant programs must report all instances of living donor deaths and failure of the living donor's native organ function within 72 hours after the program becomes aware of the living donor death or failure of the living donors' native organ function. Live donors' native organ failure is defined as listing for transplant for liver donors, and as transplant, listing for transplant or the need for dialysis in renal donors. Transplant centers must report these incidents through the UNetSM Patient Safety System for a period of two years from the date of the donation. The MPSC will review and report all adverse events to the Board.

12.8.5 **Reporting of Non-utilized Living Donor Organs.** The organ recovery center must report all instances of living donor organs recovered but not transplanted and all instances of living donor organs recovered but redirected and not ultimately transplanted to the intended recipient. Transplant centers must report these incidents through the Patient Safety System within 72 hours of organ recovery. The Membership and Professional Standards Committee will review and report all cases of non-utilized and redirected living donor organs to the Board of Directors.

12.8.6 **Reporting of Redirected Living Donor Organs.** If a living donor organ is ultimately transplanted to a recipient other than the intended recipient, then all required donor and recipient information must still be reported through Tiedi[®]. The Membership and Professional Standards Committee will review and report all cases of redirected living donor organs to the Board of Directors.

12.9 Long-term Care or Support of Living Donors.

12.9.1 **Follow-up**
Reserved.

12.9.2 Insurance.

Reserved.

12.9.3 Priority on the Waitlist. A candidate will be assigned 4 points if he or she has donated for transplantation within the United States his or her vital organ or a segment of a vital organ (i.e., kidney, liver segment, lung segment, partial pancreas, small bowel segment). To be assigned 4 points for donation status under Policy 3.5.11.6, the candidate's physician must provide the name of the recipient of the donated organ or organ segment, the recipient's transplant facility and the date of transplant of the donated organ or organ segment, in addition to all other candidate information required to be submitted under policy. Additionally, at the local level of organ distribution only, candidates assigned 4 points for donation status shall be given first priority for kidneys that are not shared mandatorily for 0 HLA mismatching, or for renal/non-renal organ allocation irrespective of the number of points assigned to the candidate relative to other candidates. When multiple transplant candidates assigned 4 points for donation status are eligible for organ offers under this policy, organs shall be allocated for these candidates according to length of time waiting.

12.9.4 Exception for Prior Living Donor Organs. Kidneys procured from standard criteria deceased donors shall be allocated locally first for prior living organ donors as defined in Policy 3.5.11.6 (Donation Status) before they are offered in satisfaction of kidney payback obligations.