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 Kidney Donors.

Introduction:

Education is important to enable the potential donor to understand all aspects of the donation process, especially the risks and benefits.

The goal of informed consent is to ensure that a potential donor understands:

1) That he or she will undertake risk and will receive no medical benefit from the donor nephrectomy.
2) That there are both general risks of the operation as well as center specific risks.

Living Kidney Donor Consent

The recovery hospital must obtain informed consent from any potential living kidney donor which must include, but is not limited to, documentation in the donor chart of the following:

a. Written assurance by the potential donor that he or she is willing to donate, free from inducement and coercion, and has been informed that he or she may decline to donate at any time. Potential donors must be offered an opportunity to discontinue the donor consent or evaluation process and to do so in a way that is protected and confidential. The independent donor advocate (IDA) must be available to assist the potential donor during this process. (see Policy 12.4)

b. Instruction about all phases of the living donation process, which include consent, medical and psychosocial evaluations, pre- and post-operative care, and required post-operative follow-up. (Policy 7.2) Teaching or instructional material can include any media (e.g., written, video, audio) or one-on-one or small group interaction. Teaching or instruction must be provided in a language in which the donor is able to engage in a meaningful dialogue with the transplant program staff.

c. Disclosure that the recovery hospital will take all reasonable precautions to provide confidentiality for the donor and recipient.

d. Disclosure that it is a federal crime for any person to knowingly acquire, obtain or otherwise transfer any human organ for valuable consideration (i.e., for anything of value such as cash, property, vacations).

e. Disclosure that the recovery hospitals must provide an Independent Donor Advocate (IDA).

f.

If the recovery hospital and the recipient hospital…	Then…	Including *all* the following information….
Are the same	The recovery hospital must provide the potential donor with both national and that hospital's program-specific transplant recipient outcomes from the most recent SRTR center-specific reports.	1. National 1-year patient graft survival 2. The hospital's 1-year patient and graft survival 3. Notification about all CMS outcome requirements not being met by the transplant hospital
Will not be the same and the recipient hospital is known	The recovery hospital must provide the potential donor with both national and the recipient hospital's program-specific transplant recipient outcomes from the most recent SRTR center-specific reports.	1. National 1-year patient and graft survival 2. The recipient hospital's 1-year patient and graft survival 3. Notification about all CMS outcome requirements not being met by the recipient hospital

g. Education about expected post-donation kidney function and how chronic kidney disease (CKD) and end-stage renal disease (ESRD) might potentially impact the donor in the future to include:

- On average, donors will have a 25-35% permanent loss of kidney function at donation.
- Baseline risk of ESRD does not exceed that of members of the general population with the same demographic profile.
- Donor risks must be interpreted in light of the known epidemiology of both CKD and ESRD. When CKD or ESRD occur, CKD generally develops in mid-life (40-50 years old) and ESRD generally develops after age 60. The medical evaluation of a young potential donor cannot predict lifetime risk of CKD or ESRD.
- Donors may be at a higher risk for CKD if they sustain damage to the remaining kidney. The development of CKD and subsequent progression to ESRD may be more rapid with only one kidney.
- Dialysis is required when reaching ESRD.
- Current practice is to prioritize prior living kidney donors who become kidney transplant candidates. (Policy 12.9.3)

h. Disclosure of alternate procedures or courses of treatment for the recipient including deceased donor transplantation.

- The donor must be informed that a deceased donor kidney might become available for the recipient before the donor evaluation is completed or the living donor transplant occurs.
- The donor must be informed that any transplant candidate might have-risk factors for increased morbidity or mortality that are not disclosed to the potential donor.

i. The disclosure that the donor will receive a thorough medical and psychosocial evaluation.

j. Inform the donor that health information obtained during their evaluation will be subject to the same regulations as all records and could reveal conditions that the transplant center must report to local, state or federal public health authorities.

k. Disclosure that recovery hospitals are required to report living donor follow-up information at the time intervals specified in Policy 12.8.3, and have the potential donor commit to post-operative follow-up testing coordinated by the living donor recovery hospital.

l. Disclosure that any infectious disease or malignancy pertinent to acute recipient care discovered during the potential donor's first two years of post-operative follow-up care:

- will be disclosed to the donor;
- may need to be reported to local, state or federal public health authorities;
- will be disclosed to their recipient's transplant center; and
- will be reported through the OPTN Improving Patient Safety Portal.

12.2.1 Living Kidney Donor Evaluation Consent

The recovery center must maintain documentation in the donor chart that it informed the potential donor of the following:

- That the potential donor must undergo a medical and psychosocial evaluation as required in Policy 12.3.

- That the transplant hospital may refuse the potential donor. In such cases, potential donors must be informed that they could be evaluated by another transplant program that may have different selection criteria.

- That the following are inherent risks associated with evaluation for living donation:

  i. allergic reactions to contrast,
  ii. discovery of reportable infections,
  iii. discovery of serious medical conditions,
  iv. discovery of adverse genetic findings unknown to the donor, and discovery of certain abnormalities that will require more testing at the donor's expense or create the need for unexpected decisions on the part of the transplant team.

- The following surgical, medical, psychosocial, and financial risks are associated with living kidney donation. This disclosure must state that these risks may be transient or permanent and include, but are not limited to the following:

  i. Potential Medical or Surgical Risks:
     - Death;

     - Scars, pain, fatigue, and other consequences typical of any surgical procedure;

     - Decreased kidney function;

- Abdominal or bowel symptoms such as bloating and nausea and developing bowel obstruction;
- Kidney failure and the need for dialysis or kidney transplant for the donor; and
- Impact of obesity, hypertension, or other donor-specific medical condition on morbidity and mortality of the potential donor.

ii. Potential Psychosocial Risks:

- Problems with body image;
- Post-surgery depression or anxiety;
- Feelings of emotional distress or bereavement if the transplant recipient experiences any recurrent disease or in the event of the transplant recipient's death; and
- Impact of donation on the donor's lifestyle.

iii. Potential Financial Impacts:

- Personal expenses of travel, housing, child care costs, and lost wages related to donation might not be reimbursed; however, resources might be available to defray some donation-related costs;
- Need for life-long follow-up at the donor's expense;
- Loss of employment or income;
- Negative impact on the ability to obtain future employment;
- Negative impact on the ability to obtain, maintain, or afford health, disability, and life insurance; and,
- Future health problems experienced by living donors following donation may not be covered by the recipient's insurance.

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-A_1 (negative for A_1) or non-A_1B (negative for A_1B), 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.

12.3.3 Psychosocial Evaluation of the Living Kidney Donor This psychosocial evaluation must be performed by a psychiatrist, psychologist, and/or clinical social worker. Documentation of the psychosocial evaluation must be maintained in the donor record. The psychosocial evaluation must include the following components:

- Assess for any psychosocial (including mental health) issues that might complicate the living donor's recovery and identify potential risks for poor psychosocial outcome;
- Assess for the presence of high-risk behaviors as defined by the US Public Health Service (PHS) that have the potential to increase the risk of disease transmission to the recipient;
- Assess history of smoking, alcohol, and drug use/abuse and dependency;
- Identify factors that warrant educational or therapeutic intervention prior to final donation decision;
- Determine that the potential donor understands the short and long-term medical and psychosocial risks associated with living donation, for both donor and recipient;
- Assess whether the decision to donate is free of inducement, coercion, and other undue pressure by exploring the reason(s) for volunteering to donate and the nature of the relationship (if any) to the transplant candidate;
- Assess the potential donor's ability to make an informed decision and the ability to cope with the major surgery and related stress. This includes the potential donor having a realistic plan for donation and recovery, with social, emotional and financial support available as recommended; and
- Review the occupation, employment status, health insurance status, living arrangements, and social support of the potential donor and determine if the potential donor understands the potential financial implications of living donation.

12.3.4 Medical Evaluation of the Living Kidney Donor The medical evaluation must be performed by the recovery hospital and by a physician or surgeon experienced in living donation. The goal of the medical evaluation is to:

- Assess the immunologic compatibility of the donor to the recipient;
- Assess the general health and surgical risk of the donor including screening for conditions that may predict complications from having one kidney in the future;
- Determine if there are diseases present that may be transmitted from donor to recipient; and
- Assess the anatomy and function of the kidneys.

Documentation of the medical evaluation must be maintained in the donor record. The medical evaluation must include the following components:

A) General History:

- Evaluate for a personal history of significant medical conditions which include but are not limited to hypertension, diabetes, genetic renal diseases, lung disease, heart disease, gastrointestinal disease, autoimmune disease, neurologic disease, genitourinary disease, hematologic disorders, bleeding or clotting disorders, history of cancer and history of infections.

- Evaluate for Kidney Specific Personal History:

    - Kidney disease, proteinuria, hematuria
    - Kidney injury
    - Diabetes including gestational diabetes
    - Nephrolithiasis
    - Recurrent urinary tract infections

- Active and past medications with special consideration for known nephrotoxic medications
- Allergies
- Evaluation for coronary artery disease

B) Family history of coronary artery disease and cancer

C) Kidney Specific Family History:

- Kidney disease
- Diabetes
- Hypertension
- Kidney Cancer

D) Social History:

The medical evaluation must determine:

- Occupation, employment status, health insurance status, living arrangements, and social support
- Smoking, alcohol and drug use/abuse
- High risk behavior as defined by the US PHS
- Psychiatric illness, depression, suicide attempts

E) Physical Exam:

- Height, weight, BMI
- Examination of all major organ systems
- Blood pressure
    - Taken on at least two different occasions; or
    - Perform 24-hour or overnight blood pressure monitoring

F) General Laboratory Tests:

- Complete Blood Count (CBC) with platelet count
- Blood type and screen
- Prothrombin Time (PT)
- International Normalized Ratio (INR) or Partial Thromboplastin Time (PTT)
- Metabolic testing (to include electrolytes, BUN, creatinine, transaminase levels, albumin, calcium, phosphorus, alkaline phosphatase, bilirubin)

- HCG quantitative pregnancy test for premenopausal women without surgical sterilization
- Chest X-Ray
- Electrocardiogram (ECG)

G) Other Metabolic Testing:

- Fasting blood glucose
- Fasting lipid profile (Cholesterol, Triglycerides, HDL Cholesterol, and LDL Cholesterol)
- Glucose Tolerance Test and/or Glycosylated Hemoglobin in first degree relatives of diabetics and in high risk individuals

H) Kidney-Specific Tests:

- Urinalysis; Urine microscopy
- Urine culture if clinically indicated
- Measurement of urinary protein and albumin excretion
- Measurement of glomerular filtration rate by isotopic methods or a creatinine clearance calculated from a 24-hour urine collection
- Centers must establish a protocol and follow their protocol for screening for Polycystic Kidney Disease or other inherited renal disease as guided by family history
- Patients with a history of nephrolithiasis or nephrolithiasis (>3mm) identified on radiographic imaging must have a 24 hour urine stone panel measuring calcium, oxalate, uric acid, citric acid, creatinine and sodium excretion

I) Anatomic Assessment:

An assessment to determine whether the kidneys are of equal size or have masses, cysts, or stones or other anatomical defects and to determine which kidney is more anatomically suitable for transplantation.

- The choice of test for radiologic imaging may be determined based upon the local radiological expertise and surgical preference, and may include CT angiogram or MR angiogram.

J) Screening for transmissible diseases:

Infectious disease testing must include:

- CMV (Cytomegalovirus) Antibody
- EBV (Epstein Barr Virus) Antibody
- HIV 1,2 (Human Immunodeficiency Virus) antibody testing
- HepBsAg (Hepatitis B surface antigen)
- HepBcAB (Hepatitis B core antibody)
- HepBsAB (Hepatitis B surface antibody)
- HCV (Hepatitis C Virus) antibody testing
- RPR (Rapid Plasma Reagin Test for Syphilis)

For tuberculosis (TB), living donor recovery centers must determine if the potential donor is at increased risk for this infection, and if so testing must include:

- Screening for latent TB using either intradermal PPD or Interferon Gamma Release Assay (IGRA)

For the following infectious diseases, transplant centers must determine if the potential donor is from an endemic area, and if so testing must include:

- Strongyloides
- Trypanosoma cruzi
- West Nile

K) Cancer screening:

Centers must develop protocols consistent with the American Cancer Society (ACS), and once developed follow their own protocols for screening:

- Cervical Cancer
- Breast Cancer
- Prostate Cancer
- Colon Cancer
- Skin Cancer
- Lung cancer

L) Exclusion Criteria:

Transplant programs that perform living kidney donor recoveries may exclude a donor with any condition that, in the Transplant Program's medical judgment, causes the donor to be unsuitable for organ donation.

Transplant programs that perform living kidney donor recoveries must exclude all donors who meet any of the following exclusion criteria:

- Both age less than 18 years and mentally incapable of making an informed decision
- Uncontrollable hypertension or history of hypertension with evidence of end stage organ damage
- HIV
- Diabetes
- Active malignancy, or incompletely treated malignancy
- High suspicion of donor coercion
- High suspicion of illegal financial exchange between donor and recipient
- Evidence of acute symptomatic infection (until resolved)
- Diagnosable psychiatric conditions requiring treatment before donation, including any evidence of suicidality

12.4 Independent Donor Advocates.

The living kidney donor recovery hospital must provide an independent donor advocate (IDA) who is not involved with the potential recipient evaluation and is independent of the decision to transplant the potential recipient.

12.4.1 The IDA must assist the potential living kidney donor with the evaluation process and focus on their needs and questions. The IDA must be knowledgeable about risks and benefits associated with all phases of the donation process. IDA responsibilities include, but are not limited to the following:

- Promote the best interests of the potential living donor

- Advocate for the rights of the potential donor

- Assist the potential donor in obtaining and understanding information regarding the:

  i. Consent process;

  ii. Evaluation process;

  iii. Surgical procedure;

  iv. Medical and psychosocial risks;

  v. Benefit and need for follow-up.

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

Unless otherwise stated, Policy 12.7 and its subsections apply only when organs, tissue typing specimens, or vessels are recovered from living donors and transported outside the recovery facility. The purpose of Policy 12.7 is to:

- 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 compatability), 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. The living donor recovery center must document in the donor record all unique identifiers used to label tissue typing 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

- A recovery hospital may only recover extra vessels for transplant if the living donor consents to the removal of extra vessels 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 Reporting Requirements 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. Living Donor Registration Forms (LDR) must be submitted to the OPTN within 60 days of the form generation date.

12.8.3.1 Transplant centers that recover living donor organs must submit Living Donor Follow-up (LDF) forms for each living donor at six months, one year, and two years from the date of donation.

The transplant center must report accurate, complete, and timely follow-up data for donor status and clinical information using the LDF form for at least:

- 60% of their living kidney donors who donate between February 1, 2013 and December 31, 2013
- 70% of their living kidney donors who donate between January 1, 2014 and December 31, 2014
- 80% of their living kidney donors who donate after December 31, 2014.

The transplant center must report accurate, complete, and timely follow-up kidney laboratory data using the LDF form for at least:

- 50% of their living kidney donors who donate between February 1, 2013 and December 31, 2013
- 60% of their living kidney donors who donate between January 1, 2014 and December 31, 2014
- 70% of their living kidney donors who donate after December 31, 2014.

- Donor Status and Clinical Information
  - Patient status
  - Working for income, and if not working, reason for not working
  - Loss of medical (health, life) insurance due to donation
  - Has the donor been readmitted since last LDF form was submitted?
  - Kidney complications
  - Maintenance dialysis
  - Donor developed hypertension requiring medication
  - Diabetes
  - Cause of death, if applicable and known

- Kidney Laboratory Data
  - Serum creatinine
  - Urine protein

Living donor follow-up data collected within 60 days of the six-month, one-year, and two-year anniversary of donation is considered timely.

Follow-up rates will be calculated separately, and at least annually, for the submission of the six-month, one-year, and two-year LDF forms.

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 UNet^{SM} 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 receive 4 points and local priority for kidneys that are not shared for 0 HLA mismatching or for renal/non-renal allocation if all of the following conditions are met:

1. The candidate donated for transplantation within the United States or its territories at least one of the following:
   - Kidney
   - Liver segment
   - Lung segment
   - Partial pancreas
   - Small bowel segment.

2. The candidate's physician provides all of the following information to the OPTN Contractor:
   - The name of the recipient of the donated organ or organ segment
   - The name of the recipient's Transplant Program
   - The date of the transplant of the donated organ.

Candidates receive these points and priority for each kidney registration when the above requirements are met.

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.

12.10 Required Protocols for Kidney Recovery Hospitals

Kidney recovery hospitals must demonstrate that they have the following protocols:

(i) Living Donation Process Protocols: Kidney recovery hospitals must develop, and once developed must comply with written protocols to address all phases of the living donation process.

12.11 Required Protocols for Liver Recovery Hospitals

Liver recovery hospitals must demonstrate that they have the following protocols:

(i) Living Donation Process: Liver recovery hospitals must develop, and once developed must comply with written protocols to address all phases of the living donation process. Specific protocols shall include the evaluation, pre-operative,

operative, post-operative care, and submission of required follow-up forms at 6 months, one-year, and two-year post donation.

Liver recovery hospitals must document that all phases of the living donation process were performed in adherence to the center's protocol. This documentation must be maintained and made available upon request.

(ii) Independent Donor Advocate: Liver recovery hospitals must develop, and once developed, must comply with written protocols for the duties and responsibilities of the Independent Donor Advocate that include, but are not limited, to the following elements:

(1) a description of the duties and primary responsibilities of the IDA to include procedures that ensure that the IDA:

(a) promotes the best interests of the potential living donor;
(b) advocates the rights of the living donor; and
(c) assists the potential donor in obtaining and understanding information regarding the:

(i) consent process;
(ii) evaluation process;
(iii) surgical procedure; and
(iv) benefit and need for follow-up.

(iii) Medical Evaluation: Liver recovery hospitals must develop, and once developed, must comply with written protocols for the medical evaluation of the potential living donors must include, but are not limited to the following elements:

(1) a thorough medical evaluation by a physician and/or surgeon experienced in living donation to assess and minimize risks to the potential donor post-donation, which shall include a screen for any evidence of occult liver disease;
(2) a psychosocial evaluation of the potential living donor by a psychiatrist, psychologist or social worker with experience in transplantation (criteria defined in Appendix B, Attachment I) must also be provided to assess decision making capacity, screen for any pre-existing psychiatric illness, and evaluate potential coercion;
(3) screening for evidence of transmissible diseases such as cancers and infections; and
(4) a radiographic assessment to ensure adequate anatomy and volume of the donor and of the remnant liver.

(iv) Informed Consent: Liver recovery hospitals must develop, and once developed, must comply with written protocols for the Informed Consent for the Donor Evaluation Process and for the Donor Hepatectomy, which include, at a minimum, the following elements:

(1) discussion of the potential risks of the procedure including the medical, psychological, and financial risks associated with being a living donor;
(2) assurance that all communication between the potential donor and the transplant center will remain confidential;
(3) discussion of the potential donor's right to opt out at any time during the donation process;
(4) discussion that the medical evaluation or donation may impact the potential donor's ability to obtain health, life, and disability insurance;
(5) disclosure by the liver recovery hospital that it is required, at a minimum, to submit Living Donor Follow-up forms addressing the health information of each living donor at 6 months, one-year, and two-years post donation. The protocol must include a plan to collect the information about each donor; and

(6) the telephone number that is available for living donors to report concerns or grievances through the OPTN.
(7) documentation of disclosure by the liver recovery hospital to potential donors that the sale or purchase of human organs is a federal crime and that it is unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation. This documentation must be maintained in the potential donor's official medical record.