

OPTN/UNOS Living Donor Committee
Report to the Board of Directors
June 28-29, 2010
Richmond, VA

Summary

Action Items for Board Consideration

- The Board of Directors is asked to approve a proposal to clarify which transplant program has responsibility for elements of the living donation process and to reassign reporting responsibility for living donation from the recipient transplant program to the transplant program performing the living donor nephrectomy or hepatectomy. Modifications to Policy 7.0 (Data Submission Requirements); 12.6 (Center Acceptance of Living Donor Organs); 12.8 (Reporting Requirement); UNOS Bylaws, Appendix B, Attachment I, Section XIII (Transplant Programs) D (2) Kidney Transplant Programs that Perform Living Donor Kidney Transplants; UNOS Bylaws, Appendix B, Attachment I, Section XIII (Transplant Programs) D (4) Liver Transplant Programs that Perform Living Donor Liver Transplants Recovery. (Item 1, Page 3)
- The Board of Directors is asked to approve a revised charge for the Living Donor Committee. (Item 2, Page 14)

Other Significant Items

- The Committee continues its efforts to improve living donor follow-up. (Item 3, Page 15)
- The Committee has completed work on a new resource titled “Guidance for Developing and Implementing Procedures to Collect Post-Donation Follow-up Data from Living Donors”. (Item 4, Page 18)
- The Committee is working with the Joint Society Working Group. (Item 5, Page 18)
- The Committee is working on new living donation policy proposals. (Item 6, Page 19)
- The Committee recommended changes to the KPDPP Operational Guidelines. (Item 7, Page 19)
- The Committee continues to examine the issue of transportation delays or failures for living donor organs. (Item 8, Page 19)

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

**Richmond, VA
June 28-29, 2011**

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

The following report is a summary of the Living Donor (LD) Committee's deliberations and discussions during its full Committee meetings held on September 13, 2010, and April 3-4, 2011.

- 1. Proposal to Clarify which Transplant Program has Responsibility for Elements of the Living Donation Process and to Reassign Reporting Responsibility for Living Donation from the Recipient Transplant Program to the Transplant Program Performing the Living Donor Nephrectomy or Hepatectomy. Modifications to Policy 7.0 (Data Submission Requirements); 12.6 (Center Acceptance of Living Donor Organs); 12.8 (Reporting Requirement); UNOS Bylaws, Appendix B, Attachment I, Section XIII (Transplant Programs) D (2) Kidney Transplant Programs that Perform Living Donor Kidney Transplants; UNOS Bylaws, Appendix B, Attachment I, Section XIII (Transplant Programs) D (4) Liver Transplant Programs that Perform Living Donor Liver Transplants.**

The consent, medical and psychosocial evaluation, and perioperative care of living organ donors have become increasingly complex and may involve multiple transplant hospitals. Since 2000, more than 1247 living donors have had an organ recovered at one transplant hospital which was later transported and transplanted at a different transplant hospital.

Policy 7.3.2 states that the living donor organ **recipient's** transplant hospital is responsible for submitting the Living Donor Registration (LDR) and Living Donor Follow-up (LDF) forms at periodic intervals (six months, 1 year, and 2 years from the date of donation regardless of where the donation occurred).

Historically, some living donor organ recoveries have occurred at healthcare facilities that were not OPTN members. Since these facilities were not OPTN members, they were not subject to OPTN rules; therefore, they could not be made responsible for submitting LDF forms. Beginning in October 1999, transplant hospitals, which are required to be OPTN members, have been responsible for submitting LDF forms.

In June 2007, the Committee received a request from the OPTN/UNOS Pediatric Transplantation (Pediatric) Committee to consider changing which healthcare facility should be responsible for submitting the LDR and LDF forms. The request stated that the submission of LDR and LDF forms should be the responsibility of the OPTN member transplant hospital that recovered the living donor organ, rather than the organ recipient's transplant hospital. The request further argued that compliance with policies addressing submission of living donor follow-up forms was difficult for some pediatric transplant hospitals, especially in cases where an organ from an adult living donor is recovered at one hospital, then transported to and transplanted in a pediatric recipient at another hospital. In such cases, the pediatric transplant hospital is required to submit follow-up forms on adult living donors. The pediatric hospital may not be equipped to conduct the medical and psychosocial evaluation of an adult and submit the required data in the follow-up forms.

In November 2008, the OPTN/UNOS Board approved Policy 3.3.7 (Center Acceptance and Transplant of Organ from Living Donors), which requires that transplant hospitals only accept living donor organs recovered at OPTN member transplant hospitals. (Policy 3.3.7 became Policy 12.6 effective 6/09.) With this change, responsibility for submission of LDR and LDF forms could be reconsidered, because all transplant hospitals involved in the recovery and transplant of living donor organs were now required to be OPTN members.

In January 2009, given that Policy 3.3.7 (now Policy 12.6) was in effect, the Pediatric Committee again requested that the Committee reconsider whether the recipient's transplant program should be responsible for submitting living donor follow-up forms. The Pediatric Committee stated that requiring the recipient's transplant hospital to be responsible for obtaining and submitting the living donor follow-up forms was not practical, especially in the case of freestanding pediatric transplant hospitals that transplant an organ from an adult living donor which may not be equipped to conduct the medical and psychosocial evaluation of an adult.

The Committee considered the request and recommended changing the responsibility for living donor follow-up. The Committee originally planned to seek public comment on changing which center is responsible for submission of living donor follow-up in early 2009.

At this same time, the Membership and Professional Standards Committee (MPSC) was beginning a review of OPTN living donation Bylaw requirements, and requested that the Committee delay public comment on any proposal to change which center would be responsible for living donor follow-up (a policy change) until a review of the living donation bylaws could be completed.

In July 2009, the MPSC formed a working group to review the living donor program bylaw requirements for currency and relevance, determine whether the original goal of the requirements was being met, and recommend bylaw modifications if necessary. A primary driver for this review was that some conditionally approved living donor liver transplant programs had reached the end of their conditional approval periods without successfully identifying a second qualified primary surgeon. As several hospitals had completed their living donor kidney transplant program applications, the timing was appropriate to assess whether the bylaws were current and relevant in the area of living donor program requirements.

The working group was comprised of members from the Kidney Transplantation Committee, Liver and Intestinal Organ Transplantation Committee, Living Donor Committee, and Membership and Professional Standards Committee. This working group divided into subcommittees, having one specifically address the issue of responsibility for living donor follow-up. Representatives from the Transplant Coordinators and Transplant Administrators Committees were added to that subcommittee to provide the necessary expertise for the discussion on living donor reporting responsibility. This subcommittee was charged with clarifying which hospital is responsible for pre- and post-donation living donor-related activities when:

- Donation takes place in one institution and the transplant in another; or
- The donor participates in paired donation at a hospital geographically removed from his or her local transplant hospital.

The subcommittee considered three options for which the transplant hospital could be responsible for submitting living donor follow-up forms: 1) the evaluating hospital, 2) the recovery hospital, or 3) the transplanting hospital. The evaluating hospital is the hospital responsible for the psychosocial and medical/surgical pre-procedure evaluation of the donor. Identifying the evaluating hospital as the responsible entity would establish a clear link between the responsibilities of the physicians at the donor hospital and objective measures for fulfilling that responsibility. However, this requirement would be a new (and currently unfunded) resource burden on evaluating hospitals. The recovery hospital is the hospital that performs the nephrectomy or hepatectomy (in donor-only hospitals). The benefits of identifying the recovery hospital as responsible are similar to

those of the evaluating hospital described above. Additionally, in this case, the hospital reimbursed for the donor surgery would be the hospital with the responsibility for donor follow-up. The transplant hospital is the hospital responsible for the recipient of the living donor kidney or liver. In most cases, it is identical to the hospital where the donor evaluation and procedure are done, and in these cases, resources for donor follow-up are consolidated. However, when the donor and the recipient are in separate hospitals, it is not logical to impose responsibility for donor follow-up burdens on the recipient hospital which had neither the responsibility for evaluating the donor, undertaking the donor surgery, nor billing for all of the above.

The subcommittee noted that the recovery hospital should be the entity responsible for the completion of the living donor evaluation, including the provision of the independent donor advocate. Any testing performed at another hospital should be considered preliminary screenings and done to avoid inconveniencing the donor. The decision on the suitability of the living donor is the responsibility of the hospital that performs surgery on that donor. Therefore, the evaluating hospital and the recovery hospital are in essence the same hospital. The subcommittee proposed that the recovery hospital be the hospital that is responsible for the living donation process, which includes consent, medical and psychological evaluation, perioperative, and follow-up reporting.

Current UNOS Bylaws address kidney and liver programs that perform living donor transplants. In response, this proposal includes recommended changes to Policy 12.6 (Center Acceptance of Living Donor Organs), to address living donor lung, (domino) heart, intestine, or pancreas recovery. Specifically, to include a requirement that transplant centers must only accept and transplant living donor organs recovered at transplant hospitals that have an approved transplant program for that organ.

This proposal was released for public comment between October 1, 2010, and February 5, 2011. On March 10, 2011, public comment responses were presented to the MPSC, and that committee was informed that the Living Donor Committee would likely recommend the proposal be considered by the Board without modification. The Committee considered all public comments received on the proposal at its April 3-4 meeting. Overall, there was strong public, regional, and other committee support for the proposal (**Exhibit A**). The Committee opined that no modification to the proposal was necessary and supported asking the Board to consider the proposal.

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

The Committee approved the final version to be considered by the Board. Committee vote: 25-0-0

The following proposal is recommended for consideration by the Board.

**** RESOLVED, that modifications to the Policies and Bylaws: Modifications to Policy 7.0 (Data Submission Requirements); 12.6 (Center Acceptance of Living Donor Organs); 12.8 (Reporting Requirement); UNOS Bylaws, Appendix B, Attachment I, Section XIII (Transplant Programs) D (2) Kidney Transplant Programs that Perform Living Donor Kidney Transplants; UNOS Bylaws, Appendix B, Attachment I, Section XIII (Transplant Programs) D (4) Liver Transplant Programs that Perform Living Donor Liver Transplants Recovery, set forth below, are hereby approved, effective pending distribution of notice:**

7.0 DATA SUBMISSION REQUIREMENTS

Members must submit data to the OPTN through use of standardized forms. Data requirements include submission of information on all deceased and living donors, potential transplant recipients, and actual transplant recipients. All transplant data forms must be submitted through UNetSM, beginning January 1, 2003.

All OPOs are responsible for submission of patient level data for all consented donors, consent not recovered potential donors, imminent neurological and eligible deaths in its DSA. All OPOs are also responsible for submission of the total number of reported deaths by donor hospital. The OPO responsible for allocation of the donor organs will be responsible for submission of the Deceased Donor Feedback information, Deceased Donor Registration (DDR) Forms and Potential Transplant Recipient (PTR) Forms.

Histocompatibility laboratories will be responsible for submission of the Donor and Recipient Histocompatibility forms for each donor and actual transplant recipient typed by the laboratory.

Recipient transplant centers are responsible for submission of Recipient Feedback information, ~~Living Donor Feedback information, Living Donor Registration Forms, Living Donor Follow-up Forms,~~ Transplant Candidate Registration Forms, organ-specific Transplant Recipient Registration Forms, organ-specific Transplant Recipient Follow-up Forms, and Recipient Malignancy Forms for each recipient on the waiting list; or transplanted ~~or followed~~ at the center.

Transplant centers that recover living donor organs are responsible for submitting Living Donor feedback information, Living Donor Registration Forms, and Living Donor Follow-up Forms for each living donor whose organ was recovered at that center within the time frame established in Policy 12.8.3 or who is being followed at that center. The transplant center that intends to recover the living donor organ is responsible for generating the Donor ID and reporting whether the recovery procedure occurred.

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.

12.8 Reporting Requirement. 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 the source documents from both ABO typings to enter the living donor's ABO 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 was correctly entered on the Living Donor Feedback Form. A transplant program must document that each ABO 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. ~~Recipient~~ Transplant centers that recover living donor organs must complete the LDR form when the donor is discharged from the hospital or ~~by~~ within six weeks following the transplant date, whichever is first. ~~The recipient~~ Transplant centers that recover living donor organs must submit LDR forms for each living donor at six months, one year and two years from the date of donation.

Bylaws

UNOS Bylaws, Appendix B, Attachment I, Section XIII (Transplant Programs)

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(2) Kidney Transplant Programs that Perform Living Donor Kidney ~~Transplants~~

Recovery: Kidney transplant programs that perform living donor kidney ~~transplants~~ recovery (“kidney recovery hospital”) must demonstrate the following:

- a. Personnel and Resources: ~~Kidney transplant programs that perform living kidney transplants~~ Kidney recovery hospitals must demonstrate the following regarding personnel and resources:
 - (i) That the ~~center~~ kidney recovery hospital meets the qualifications of a kidney transplant program as set forth above; and
 - (ii) In order to perform open donor nephrectomies, a qualifying kidney donor surgeon must be on site and must meet either of the criteria set forth below:
 - (1) Completed an accredited ASTS fellowship with a certificate in kidney; or
 - (2) Performed no fewer than 10 open donor nephrectomies (to include deceased donor nephrectomy, removal of polycystic or diseased kidneys, etc.) as primary surgeon or first assistant within the prior 5-year period.
 - (iii) If the center wishes to perform laparoscopic donor nephrectomies, a qualifying kidney donor surgeon must be on site and must have:
 - (1) Acted as primary surgeon or first assistant in performing no fewer than 15 laparoscopic nephrectomies within the prior 5-year period.

If the laparoscopic and open nephrectomy expertise resides within different individuals then the program must demonstrate how both individuals will be available to the surgical team. It is recognized that in the case of pediatric living donor transplantation, the living organ donation may occur at a center that is distinct from the approved transplant center.

All surgical procedures identified for the purpose of surgeon qualification must be documented. Documentation should include the date of the surgery, medical records identification and/or UNOS identification number, and the role of the surgeon in the operative procedure.

- (iv) The ~~center~~ kidney recovery hospital must have the resources available to assess the medical condition of and specific risks to the potential living donor;
- (v) The psychosocial assessment should include an assessment of the potential donor's capacity to make an informed decision and confirmation of the voluntary nature of proceeding with the evaluation and donation; and
- (vi) That the ~~center~~ kidney recovery hospital has an independent donor advocate (IDA) who is not involved with the potential recipient evaluation, is independent of the decision to transplant the potential recipient and, consistent with the IDA protocol referred to below, is a knowledgeable advocate for the potential living donor. The goals of the IDA are:
 - (1) to promote the best interests of the potential living donor;
 - (2) to advocate the rights of the potential living donor; and
 - (3) to assist the potential living donor in obtaining and understanding information regarding the:
 - (a) consent process;
 - (b) evaluation process;
 - (c) surgical procedure; and
 - (d) benefit and need for follow-up.

b. Protocols: ~~Kidney transplant programs that perform living donor kidney transplants~~ kidney recovery hospitals must demonstrate that they have the following protocols:

(i) Living Donation Process: ~~Kidney recovery hospitals transplant programs that perform living donor kidney transplants~~ kidney 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-years post donation.

~~Transplant centers~~ Kidney 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: ~~Kidney recovery hospitals transplant programs that perform living donor kidney transplants~~ kidney recovery hospitals must develop, and once developed, must comply with written protocols

for the duties and responsibilities of Independent Donor Advocate (IDA) 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 the IDA:
 - (a) promotes the best interests of the potential living donor;
 - (b) advocates the rights of the potential 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.

(ii) Medical Evaluation: ~~Kidney recovery hospitals transplant programs that perform living donor kidney transplants~~ must develop, and once developed, must comply with written protocols for the medical evaluation of the potential living donors that 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 renal and infectious disease and medical co-morbidities, which may cause renal 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) to determine decision making capacity, screen for any pre-existing psychiatric illness, and evaluate any potential coercion;
- (3) screening for evidence of transmissible diseases such as cancers and infections; and
- (4) anatomic assessment of the suitability of the organ for transplant purposes.

(iv) Informed Consent: ~~Kidney recovery hospitals transplant programs that perform living donor kidney transplants~~ must develop, and once developed, must comply with written protocols for the Informed Consent for the Donor Evaluation Process and for the Donor Nephrectomy, 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 kidney recovery hospital transplant center 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 kidney recovery hospital transplant center 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.

UNOS Bylaws, Appendix B, Attachment I, Section XIII (Transplant Programs)

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(4) Liver Transplant Programs that Perform Living Donor Liver Transplants-Recovery: Liver transplant programs that perform living donor liver recovery ("liver recovery hospital") must demonstrate the following:

(a) Personnel and Resources: ~~Liver transplant programs that perform living donor liver transplants-recovery hospitals~~ liver recovery hospitals must demonstrate the following:

- (i) That the ~~center~~ liver recovery hospital meets the qualifications of a liver transplant program as set forth above; and.
- (ii) That the ~~center~~ liver recovery hospital has on site no fewer than two surgeons who qualify as liver transplant surgeons under UNOS Bylaws Appendix B, Attachment I, and who have demonstrated experience as the primary surgeon or first assistant in 20 major hepatic resectional surgeries (to include living donor operations, splits, reductions,

resections, etc.), 7 of which must have been live donor procedures, within the prior 5-year period. These cases must be documented. Documentation should include the date of the surgery, medical records identification and/or UNOS identification number, and the role of the surgeon in the operative procedure. It is recognized that in the case of pediatric living donor transplantation, the live organ donation may occur at a center that is distinct from the approved transplant center;

- (iii) The ~~center~~liver recovery hospital must have the resources available to assess the medical condition of and specific risks to the potential living donor;
- (iv) The psychosocial assessment should include an assessment of the potential living donor's capacity to make an informed decision and confirmation of the voluntary nature of proceeding with the evaluation and donation; and
- (v) That the ~~center~~liver recovery hospital has an independent donor advocate (IDA) who is not involved with the potential recipient evaluation, is independent of the decision to transplant the potential recipient and, consistent with the protocol referred to below, is a knowledgeable advocate for the potential living donor. The goals of the IDA are:
 - (1) to promote the best interests of the potential living donor;
 - (2) to advocate the rights of the potential living donor; and
 - (3) to assist the potential living donor in obtaining and understanding information regarding the:
 - (a) consent process;
 - (b) evaluation process;
 - (c) surgical procedure; and
 - (d) benefit and need for follow-up.

b. Protocols: Liver ~~transplant programs that perform living donor liver transplants~~ recovery hospitals must demonstrate that they have the following protocols:

- (i) Living Donation Process: Liver recovery hospitals ~~transplant programs that perform living donor liver transplants~~ 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.

~~Transplant centers~~ 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 transplant programs that perform living donor liver transplants~~ 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 transplant programs that perform living donor liver transplants~~ 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 transplant programs that perform living donor liver transplants~~ 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 transplant center~~ 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 transplant center~~ 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.

c. Conditional Approval Status: If the ~~transplant center~~ liver recovery hospital does not have on site a second surgeon who can meet the requirement for having performed 7 live donor liver procedures within the prior 5-year period, but who has completed the requirement for obtaining experience in 20 major hepatic resection surgeries (as described above), as well as all of the other requirements to be designated as a primary liver transplant surgeon, the ~~program~~ liver

recovery hospital may be eligible for Conditional Approval Status. The ~~transplant program~~ liver recovery hospital can be granted one year to fully comply with applicable membership criteria with a possible one year extension. This option shall be available to new programs as well as previously approved programs that experience a change in key personnel. During this period of conditional approval, both of the designated surgeons must be present at the donor's operative procedure.

The ~~program~~ liver recovery hospital shall comply with such interim operating policies and procedures as shall be required by the Membership and Professional Standards Committee (MPSC).

This may include the submission of reports describing the surgeon's progress towards meeting the requirements and such other operating conditions as may be required by the MPSC to demonstrate ongoing quality and efficient patient care. The ~~center~~ liver recovery hospital must provide a report prior to the conclusion of the first year of conditional approval, which must document that that the surgeon has met or is making sufficient progress to meet the objective of performing 7 live donor liver procedures or that the program is making sufficient progress in recruiting and bringing to the program a transplant surgeon who meets this criterion as well as all other criteria for a qualified live donor liver surgeon. Should the surgeon meet the requirements prior to the end of the period of conditional approval, the program may submit a progress report and request review by the MPSC.

The ~~transplant program~~ liver recovery hospital must comply with all applicable policies and procedures and must demonstrate continuing progress toward full compliance with Criteria for Institutional Membership.

The ~~program~~ liver recovery hospital's approval status shall be made available to the public.

If the ~~program~~ liver recovery hospital is unable to demonstrate that it has two designated surgeons on site who can fully meet the primary living donor liver surgeon requirements [as described above] at the end of the 2-year conditional approval period, it must stop performing living donor liver ~~transplants~~ recoveries by either

- (i) inactivating the living donor part of the program for a period up to 12 months; or
- (ii) relinquishing the designated transplant program status for the living donor part of the liver transplant program until it can meet the requirements for full approval.

2. **Updated Committee Charge**

The Ad Hoc Living Donor Committee was formed in 2002, and became a permanent standing committee three years later with the following charge:

The Living Donor Committee considers issues relating to the donation and transplantation of organs from living donors to recipients. The committee also provides guidance to staff and

other Committees in development of public communications and educational materials related to living donor transplantation. The goal of the committee's work is to improve the processes of living donation and living-donor transplantation and to foster the safety of living organ donors.

The June 16, 2006, Federal Register, directed the OPTN to develop policies regarding living organ donors and living organ donor recipients, including policies for the equitable allocation of living donor organs, in accordance with section 121.8 of the Final Rule. Thus, the OPTN shall develop such policies in the same manner, and with the same public comment process, that it does for policies on deceased organ donors and deceased organ donor recipients. Non-compliance with such policies shall subject OPTN members to the same consequences as noncompliance with policies concerning deceased organ donors and deceased organ donor recipients developed under the final rule.

In response, committee members supported updating the charge of the charge to more accurately reflect its new role and responsibilities in living donor policy development, and is requesting that the charge of the committee be updated as follows:

The Living Donor Committee develops policy and guidance related to the donation and transplantation of organs from living donors to recipients. The goal of the Committee's work is to continue to improve the informed choice of prospective living donors, and the safety, protection and follow-up of all living donors.

The Committee approved the revised final version to be considered by the Board. Committee vote: 25-0-0

**** RESOLVED, that the charge of the Living Donor Committee, set forth below, is hereby approved, and any previous charge of the Living Donor Committee by the Board of Directors is revoked effective June 29, 2011:**

The Living Donor Committee develops policy and guidance related to the donation and transplantation of organs from living donors to recipients. The goal of the Committee's work is to continue to improve the informed choice of prospective living donors, and the safety, protection and follow-up of all living donors.

3. Status of Living Donor Follow-up

One of the Committee's goals for the past several years has been to evaluate available living donor data and to establish performance metrics for living donor transplant programs. The Committee began to address this work by comparing the variables on the Living Donor Registration (LDR) and Living Donor Follow-up (LDF) forms that could be considered to monitor change in living donor health between donation and follow-up. Unfortunately, metrics could not be identified because the data submitted on LDF forms was too inconsistent for analysis.

As a first step towards improving living donor data submission, the Committee led an effort to update the LDR and LDF forms to help improve living donor data collection which included:

- New options for living donor status on the LDF:

(1) Living: Donor seen at transplant center;

- (2) Living: Donor status updated by phone or email correspondence between transplant center and donor;
- (3) Living: Donor status updated by other health care facility;
- (4) Living: Donor status updated by transplant recipient;
- (5) Living: Donor contacted, declined follow up with transplant center;
- (6) Dead;
- (7) Lost: No attempt to contact donor; and
- (8) Lost: Unable to contact donor (document).

If item 8 (Lost: Unable to contact donor) is selected, the transplant center will be asked to document their efforts to contact the donor.

- Changes to the LDR form to obtain:

- (1) the date of and the living donor's status during the most recent contact between the donor and the recipient transplant center; and
- (2) whether living donor organ recovery and transplant of that organ occurred at the same center.

Next, the Committee sponsored new Bylaws which required transplant centers to disclose they are required, at a minimum, to submit LDF forms addressing the health information of each living donor at 6 months, one-year, and two-year post donation. Under the Bylaws, transplant centers must have written protocols with a plan to collect information about each donor. The Board approved these Bylaws during its September 2007 meeting.

The Committee asked the MPSC to study the issue of living donor follow-up, which was addressed through the formation of a joint workgroup with the Living Donor Committee. Final recommendations of the workgroup were issued in January 2009, and included the following:

- Enforce a minimum standard for submission of complete LDF forms (75%, to increase over time).
 - A definition for "completion" will need to be determined.
- Require, as prescribed in existing policies, that LDF forms must be submitted at 6 months, one-year and two years post donation, and that the forms may not be submitted earlier than 60 days before any of these post-donation intervals.
- Investigate any living donor transplant program that categorizes more than 10 percent of its donors as "lost to follow-up."
 - Require that such programs develop and submit an action plan to achieve complete and timely submission of 75% of required LDF forms.
- State that a lack of additional funding specific to living donor follow-up is not an acceptable excuse for failing to complete the follow-up forms. Centers should consider living donor follow-up as a mandatory component of the recovery and/or transplant of living donors.
- Support educational efforts to improve living donor follow-up data submission.
- Support the concept that completion of LDF forms and categorizing donors "as lost to follow-up" will become a metric for evaluating living donor programs at some point in the future.

After finalizing of the report, the Committee elected to delay any further action until after the Living Donor Data Task Force (LDDTF) made its final recommendations to the Board. In June 2009, the LDDTF made the following recommendation to the Board:

As currently collected, the OPTN/UNOS data are incomplete beyond the point when the discharge form is submitted (up to 6 weeks post donation) and therefore useless for research or making conclusions about living donor safety.

- There exists strong support:
 - a. for using the OPTN/UNOS data supplemented by data from the Social Security Death Master File (SSDMF) and the National Death Index (NDI) as the mechanism for tracking short- and long-term deaths.
 - b. for required center reporting and completion of data through a limited time interval (discharge through 6-12 months), with the duration depending on whether funding is made available to the centers.
 - c. for development of a self-reporting mechanism for donors of a longer duration than that required of centers.
- There is uniform support for utilizing both OPTN/UNOS and non-OPTN/UNOS sources of data to determine donor risk for the purpose of generating accurate informed consent regarding medical and Quality of Life (QoL) issues.
- There is some support for a requirement for center-specific reporting of deaths and major complications.
- The OPTN should investigate existing registries (LODN, LDAP) to determine how the OPTN could partner with and/or promote their efforts.

In March 2010, the Committee invited all living donor programs to participate in an electronic survey through which the Committee hoped to learn how centers conduct living donor follow-up, and specifically what obstacles centers encounter in their attempts to obtain follow-follow-up. Preliminary survey results were reviewed by the full Committee at the May 17, 2010, meeting. A report on the survey results was presented to the the Board of Directors at the November 2010 meeting.

As an additional step toward improving the data submitted on LDF forms, the Committee has provided letters containing center specific data (**Exhibit C**) on the status of each program's living donor follow-up annually for the past three years. This year's letter (**Exhibit D**) was distributed (electronically) on March 3, 2011, reiterated that the LDR forms and LDF forms are necessary to gather data about the short-term health of living donors, and that collection is especially important during the current climate where the public and the media seek data on the safety of living donation. This year's letter specifically reported:

- The percentage of each program's expected LDF forms submitted and validated within two months of the expected date.
- The percentage of programs with donors who have a validated one-year LDF form with a known patient status (dead or alive) at least 300 days post donation.

- The percentage of living donors who have a numerical serum creatinine (or bilirubin for liver donors) on a validated one-year LDF form with a known patient status (alive or dead) at least 300 days post donation.

The letter included a hyperlink to a new resource, developed by the Committee, designed to help program improve the collection and reporting of living donor follow-up (**Exhibit E**).

4. Guidance for Developing and Implementing Procedure to Collect Post-Donation Follow-up Data from Living Donors

In November 2009, the Board of Directors charged the Committee with developing and disseminating a resource outlining best practices for collecting and submitting living donor follow-up data, based on a review of high-performing programs. In response, the Committee developed a non-exhaustive set of recommendations to assist transplant programs to improve their protocols for maintaining contact with donors and for the collection and submission of complete and accurate living donor follow-up data. These recommendations derive directly and exclusively from actual practices employed by high-performing programs, as described further below.

This resource does not specify official policy for clinical practice with respect to the follow-up medical care of living donors and it does not prescribe or define a standard of care. It does not carry any monitoring or enforcement implications associated with any OPTN/UNOS policy. It will not be used to determine member compliance with any policy or Bylaw. Rather, this resource is intended for transplant centers' voluntary use. It is intended to help programs to review, discuss, and generate ideas on how best to develop or improve their own strategies to promote optimal follow-up of living donors. Transplant programs should consider these recommendations as suggestions, and consider the extent to which each suggestion may or may not be applicable or feasible given their own institutional setting and operational constraints.

Both new and existing living donor transplant centers can use this resource as a “toolbox” when developing or modifying their living donor follow-up protocols. The toolbox may be useful for LDF data collection specifically as well as for general issues of maintaining contact with donors after donation.

On February 22, 2011, this resource titled, “Guidance for Developing and Implementing Procedures to Collect Post-Donation Follow-up Data from Living Donors” (**Exhibit E**) was approved by the Executive Committee, and is now available on the OPTN website. This resource has been publicized through the UNOS electronic newsletter and the UNOS Update, the news magazine for the transplant community.

5. Joint Society Working Group

During its May 17, 2010, meeting, Walter Graham, UNOS Executive Director spoke with the Committee regarding a new process for incorporating clinical input into developing OPTN policies with the potential to direct or prescribe medical care through a Joint Society Policy Working Group. As proposed, the Joint Society Working Group would be permitted to consider any policy proposals under development that may affect clinical practice and would be composed of representatives of the American Society of Transplantation (AST); the American Society of Transplant Surgeons (ASTS); the North American Transplant Coordinators Organization (NATCO); and the Living Donor Committee.

Beginning in the fall of 2010, the working group held frequent teleconferences to prepare recommendations for the consent and medical evaluation of living donors to be considered by the Living Donor Committee in future policy development for the consent and medical evaluation of living donors.

At the Committee's recent in person meeting, the Committee's representatives on the Joint Society Working Group, and representatives of HRSA provided perspectives and updates on the working group. The Committee anticipates final recommendations from the Joint Society Steering Work Group in the next few months.

6. Living Donation Policy Development

The Committee approved developing a policy proposal for public comment to require that all recipients of living donor organs be registered in UNetsm prior to transplant. Vote: 23-0-0

The Committee anticipates it will soon begin work on policy proposals for the consent and medical evaluation of living donors.

7. Recommendations Regarding the KPDPP Operational Guidelines

The Committee reviewed the Kidney Paired Donation Pilot Program (KPDPP) Operational Guidelines, version 2.0, and responded with recommended changes. **(Exhibit F)**

8. Recommendations to Reduce Transportation Delays or Failures for Living Donor Organs

The Committee continues to be concerned over possible delays or failures in the transport of living donor organs. As an initial step to address the problem, the Committee proposed two new policies to require reporting such events, which were approved by the Board in November 2010, and took effect in January, 2011:

- 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 Submission 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 submitted through Tiedi. The Membership and Professional Standards Committee will review and report all cases of redirected living donor organs to the Board of Directors.

As a next step in this work, the Committee prepared a set of recommendations for the Kidney Paired Donation Pilot Program. **(Exhibit G)**

LIVING DONOR COMMITTEE

		MONTH	SEPTEMBER	APRIL
		DAY	13	3
		FORMAT	In Person Meeting	In Person Meeting
NAME	COMMITTEE POSITION		X	X
Connie Davis MD	Chair	X		X
Amy Waterman PhD	Vice Chair	X		X
Ronald Perrone MD	Regional Rep.	x		X
Joseph Melancon MD	Regional Rep.			X
Karyn Hanley RN, CCTC	Regional Rep.	X		X
Steven Potter MD, FACS	Regional Rep.	X		X
Suzanne McGuire RN, BSN, CCTC	Regional Rep.	X		X
Jordana Gaumond MD	Regional Rep.	X		X
Eugenia Steffens RN, BSN, CCTC, CNN	Regional Rep.	X		X
Christie Thomas MB, FRCP, FASN, FAHA	Regional Rep.	X		X
Paul Gaglio MD	Regional Rep.	X		By phone
Tim Taber MD	Regional Rep.			Flight cancelled
Richard Stravitz MD	Regional Rep.			X
Tonya Bradford PhD	At Large	X		X
Catherine Cullen	At Large	X		X
Mary Amanda Dew PhD	At Large	X		X
Cynthia Forland PhD	At Large	X		X
Margaret Frueh RN, MS	At Large	X		X
Cherie Hayostek MD	At Large	X		X
David Hulme	At Large	X		X
Chris Jernigan	At Large	X		X
Jerry Lee	At Large	X		X
Susan Light MD	At Large	X		X
Krystal McLear	At Large	X		
Donald Olenick Esq.	At Large	X		X
Christina Pippin	At Large	X		
Helen Smunt RN	At Large	X		X
Vicky Young PhD	At Large	X		X
Michelle Desler M.S.	Visiting Board Member	X		X
Matthew Cooper MD	Ex. Officio	X		X
Holly Berilla, MSW	Ex. Officio	X		By phone