At-a-Glance

- **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**

- **Affected/Proposed Policy and Bylaws:** 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

- **Living Donor Committee and Membership and Professional Standards Committee**

- The purpose of this proposal is to clarify and, in some cases, change which transplant program is responsible for specific elements of the living donation process. Under this proposal, the transplant program that performs the donor nephrectomy (surgical removal of a kidney) or hepatectomy (surgical removal of a portion of the liver) will be responsible for that process, which includes the consent, medical and psychosocial evaluations, perioperative care, and required follow-up reporting of the donor. The intended goals for this policy include improving living donor follow-up by shifting the responsibility for living donor follow-up to the hospital that has an established relationship with the living donor. Additionally, the revisions may lead to improved living donor safety by requiring that transplant hospitals can only accept living donor organs from transplant programs that have the appropriate protocols and staff in place to recover that type of living donor organ.

- **Affected Groups**

  Directors of Organ Procurement
  Lab Directors/Supervisors
  OPO Executive Directors
  OPO Medical Directors
  OPO Coordinators
  Transplant Administrators
  Transplant Data Coordinators
  Transplant Physicians/Surgeons
  PR/Public Education Staff
  Transplant Program Directors
  Transplant Social Workers
  Organ Recipients

Organ Candidates
Living Donors
Donor Family Members
General Public

- **Number of Potential Candidates Affected**

  There should be no impact on the candidate pool. However, this proposal does have the potential to affect all living donors. In 2009, there were 6610 living donors.

- **Compliance with OPTN Strategic Goals and Final Rule**

  These policy revisions are expected to improve the operational efficiency of the OPTN by clearly assigning responsibility for living donor follow-up.

- **Specific Requests for Comment**

  Do you agree that the transplant program that performs the donor nephrectomy or hepatectomy should be responsible for the living donation process, that include consent, medical evaluation, perioperative care, and required follow-up reporting? Why or why not?

Proposal to Clarify which Transplant Program has Responsibility for Elements of the Living Donation Process and to Reassign Responsibility for Living Donation from the Recipient Transplant Program to the Transplant Program Performing the Living Donor Nephrectomy or Hepatectomy

Affected/Proposed Policy and Bylaws: 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

Living Donor Committee and Membership and Professional Standards Committee

Summary and Goals of the Proposal:

The purpose of this proposal is to clarify and, in some cases, change which transplant program is responsible for specific elements of the living donation process. Under this proposal, the transplant program that performs the donor nephrectomy or hepatectomy will be responsible for that process, which includes the consent, medical and psychosocial evaluations, perioperative care, and required follow-up reporting on the donor. The intended goals for this policy include improving living donor follow-up by shifting the responsibility for living donor follow-up to the hospital that has an established relationship with the living donor. Additionally, the revisions may lead to improved living donor safety by requiring that transplant hospitals can only accept living donor organs from transplant programs that have the appropriate protocols and staff in place to recover that type of living donor organ.

Background and Significance of the Proposal:

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, 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 living donor follow-up forms. Beginning in October 1999, transplant hospitals, which are required to be OPTN members, have been responsible for submitting living donor follow-up forms.

In June 2007, the Living Donor 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 Living Donor 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 Living Donor Committee considered the request and recommended proposing to change responsibility for living donor follow-up. The Living Donor 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 Living Donor 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. The working group decided to divide into subcommittees, with one subcommittee specifically addressing 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. The subcommittee of the working group 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 transplant hospital could be responsible for submitting living donor follow-up forms: the evaluating hospital, the recovery hospital, or 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.

Table 1. Rationale for Policy and Bylaw Changes in this Proposal.

Policy or Bylaw Change	Rationale
Transfer of responsibility for living donor follow-up from transplanting hospital to recovery hospital	• Allows the hospital that has the relationship with the living donor to follow the donor • Creates an appropriate link between living donor surgical outcomes and follow-up reporting so that a hospital is not held responsible for another hospital having poor follow-up • As opposed to the term "evaluating hospital", "recovery hospital" makes it clear which hospital is recovering the organ. There can only be one recovery hospital, whereas multiple hospitals may take part in the evaluation. The work group recommends that the recovery hospital be the evaluating hospital and provide the donor advocacy. Any testing done by any other hospitals should be considered preliminary and done to avoid inconveniencing the donor.
Transfer of responsibility for living donor feedback from transplanting hospital to recovery hospital	• Is consistent with changes to follow-up form responsibility • Allows the Donor ID to be created by the hospital where the follow-up forms will be assigned
Requirement for recovery hospital to be approved to perform living donor transplants for respective organ	• Closes loophole that would allow a member hospital to recover an organ for another hospital even if the recovering hospital does not have a program for that organ (e.g., a hospital with only a heart program recovering a living donor kidney) • Provides for the rare instances of heart, lung, or pancreas living donation
Changing bylaw category of transplants program that performs living donor transplant to transplant program that performs living donor recovery	• Places responsibility for the living donation process as a whole on the transplant hospital that is actually performing the donor nephrectomy or hepatectomy, making the surgical facility responsible for the overall medical care of the living donor

Supporting Evidence:

Trends in kidney transplantation, such as an increase in kidney paired donation (KPD), will likely lead to an increasing number of living donors who opt to donate their kidneys at transplant hospitals other than the transplant hospital where the recipient is located. The number of transplants attributed to a KPD exchange has increased over the past several years from 74 transplants in 2006 to 308 transplants in 2009. Similarly, the number of instances where the recovery and transplanting hospital are different for a living donor kidney transplant has increased over the same time period from 94 in 2006 to 204 in 2009. The number of instances where the recovery and transplanting hospital are different for a living donor liver transplant has held steady at approximately 20 to 30 cases per year.

Expected Impact on Living Donors or Living Donation

These policy revisions and clarification of bylaws requirements may contribute to improved follow-up for living donors by clearly assigning responsibility for follow-up to the hospital that performs the donor nephrectomy or hepatectomy. In cases where the recipient's transplant hospital is geographically distant from the hospital performing the organ removal, living donors may find obtaining follow-up more convenient and less burdensome at the hospital where their organ was removed.

These revisions may lead to improved living donor safety by requiring that transplant hospitals can only accept living donor organs from transplant programs that have the appropriate protocols and staff in place to recover that type of living donor organ. This will also eliminate the challenges faced by pediatric transplant hospitals that are currently expected to follow-up adult living donors.

Expected Impact on Specific Patient Populations

There should be no impact on the candidate pool. However, this proposal does have the potential to affect all living donors. In 2009, there were 6610 living donors

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

These policy revisions are expected to improve the operational efficiency of the OPTN by clearly assigning responsibility for living donor follow-up.

Plan for Evaluating the Proposal:

- **What questions or hypotheses are guiding the evaluation of the proposal?**
    - Will living donor follow-up improve with the change in responsibility for submitting forms?
    - Will the changes to the responsibility for living donor follow-up make the policies and bylaws easier to understand by members, thus increasing compliance and living donor safety?

- **Policy Performance Measures*:***
    - the status of living donor follow-up forms (% submitted) before and after the policy and bylaw changes
    - the percentage of donors reported as lost to follow-up before and after the policy and bylaw changes
    - the percentage of living donors reporting lab values on follow-up forms before and after the policy and bylaw changes

- the number of cases where the transplant hospital and recovery hospital are different before and after the policy and bylaw changes and whether an increase is correlated with a change in any of the above metrics

- **Time Line for Evaluation:**
  The Living Donor Committee currently evaluated follow-up metrics on a yearly basis and will continue to do so after any policy or bylaw changes. These data will also be available to the MPSC.

Additional Data Collection:

These proposed policy revisions do not require collection of new data fields. Rather, the responsibility for submitting living donor follow-up data is being reassigned to the hospital that performs the living donor nephrectomy or hepatectomy.

Expected Implementation Plan:

Transplant hospitals that perform living donor nephrectomies and hepatectomies will now be required to submit registration and follow-up data on their living donors. Currently, the living donor registration must be submitted within 6 weeks of the transplant date. Living donor follow-up forms must be submitted at 6 months, 1 year, and 2 years from the date of donation. This proposal will require programming in UNet^{SM} to transfer the responsibility of this data reporting.

Communication and Education Plan:

To clearly communicate which living transplant program (donor hospital or recipient hospital) is responsible for which specific elements of the living donation process, including evaluation and follow-up forms submission we need to communicate to members beyond the routine policy notice and system notice. A feature article in the Nov/Dec 2010 or Jan/Feb issue of the UNOS Update will help inform our target audience and communicate the policy change. Additionally, the format of a feature article gives us enough space to provide the necessary context and fully explain the need for the policy revision and clarification. Select articles from the UNOS Update Magazine also appear on the UNOS website and the living donation article will be one of them.

We will further communicate the new information to our targeted audience with one or two short articles that will appear in the UNOS Communications e-Newsletter/Member Archive and we will link readers to the relevant bylaws. The member archive articles will be brief, but we will allow readers to link to the full-length UNOS Update article online.

Finally, we will target transplant administrators specifically by posting a brief announcement on the transplant administrators listserv and again, will provide links to appropriate bylaws and the online Update article.

The changes in UNet^{SM} should not be significant enough to require UNet training.

The tables below outlines the proposed communication and education activities.

Communication Activities			
Type of Communication	**Audience(s)**	**Deliver Method(s)**	**Timeframe**
Policy Notice (summary of all policy changes approved by the board in a PDF format)	Transplant Coordinators, Transplant Surgeons, Transplant Physicians, Transplant Center Program Directors, Transplant Administrators, OPO Staff	Electronic – Included in the monthly e-newsletter sent on the 3rd Monday of each month	30 days after the board approves the change.
System Notice	UNet℠ users	Through UNet℠	8 weeks, 4 weeks, and 2 weeks before implementation, upon implementation
Full-length feature article in UNOS Update	Transplant Coordinators, Transplant Surgeons, Transplant Physicians, Transplant Center Program Directors, Transplant Administrators, OPO Staff	U.S. Mail & via Internet for Update articles available on the UNOS website	Publish in the issue that is distributed closest to the distribution of the policy notice. Either Nov/Dec 2010 issue or Jan/Feb.2011
Brief explanatory blurbs in the policy-related section of the UNOS communication e-Newsletter.	Transplant Coordinators, Transplant Surgeons, Transplant Physicians, Transplant Center Program Directors, Transplant Administrators, OPO Staff	Email/member archive site http://communication.unos.org	January 2011 e-newsletter
Announcement on the Tx Administrators Listserv linking them to the blurb on the member archive	Transplant Administrators	TX Administrators listserv post	January 2011

Monitoring and Evaluation:

Staff will review a sample of living donor follow-up forms during on-site reviews at recovery centers.

Policy and Bylaw Proposal:

Please note that another proposal currently out for public comment also makes changes to the sections of the bylaws included below. The changes noted in this document reflect the changes that are a part of this proposal only.

Policies

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 UNet^{SM}, 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 t~~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 t~~Transplant centers that recover living donor organs must submit LDF forms for each living donor at six months, one year and two years from the date of donation.

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

(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~~ 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~~ 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~~ 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.

(iii) 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)
D

(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 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.