At-a-Glance

- **Proposal to Establish Minimum Requirements for Living Kidney Donor Follow-Up**

- **Affected/Proposed Policy and Bylaws:** 12.8.3.1 (Reporting Requirements); UNOS Bylaws, Appendix B, Attachment I, Section XIII (Transplant Programs) D (2) Kidney Transplant Programs that Perform Living Donor Kidney Transplants

- **Living Donor Committee**

  This proposal would require transplant programs to report required fields on the Living Donor Follow-Up (LDF) form at required post-operative reporting periods (6, 12, and 24 months). The OPTN currently relies on Living Donor Follow-Up (LDF) forms to collect data on the short-term health status of living donors. Data on living donors who donated in 2006 through 2009 demonstrate that many programs do not report meaningful living donor follow-up information at required reporting intervals. Consequently, to allow for meaningful analyses to objectively study the short-term effects of living donation, the transplant community must collectively improve patient information on the LDF form. The proposed minimum reporting requirements are based on recommendations from the Joint Society Work Group, which is composed of representatives from the American Society of Transplantation (AST), the American Society of Transplant Surgeons (ASTS), and the North American Transplant Coordinators Organization (NATCO) to the OPTN/UNOS Living Donor Committee.

- **Affected Groups**
  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 Living Donors Affected**
  In 2010, there were 6275 living kidney donors in the United States, and the proposed policy has the potential to affect all living kidney donors.

- **Compliance with OPTN Strategic Goals**
  The proposed changes are consistent with the strategic plan goals to:
  - Optimize a safe environment for living donor transplantation through information gained through improved living donor follow-up reporting
  - Improve follow-up reporting through clarification of the policies in order to protect patient safety and preserve the public trust

- **Specific Requests for Comment**
  The Committee is requesting specific feedback on elements of the proposal determined to be problemmatic as well as potential solutions for the Committee to consider.

Proposal to Establish Minimum Requirements for Living Kidney Donor Follow-Up

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Living Donor Committee

Summary and Goals of the Proposal:

This proposal would require transplant programs to report required fields on the Living Donor Follow-Up (LDF) form at required post-operative reporting periods (6, 12, and 24 months). The OPTN currently relies on Living Donor Follow-Up (LDF) forms to collect data on the short-term health status of living donors. Data on living donors who donated in 2006 through 2009 demonstrate that many programs do not report meaningful living donor follow-up information at required reporting intervals. Consequently, to allow for meaningful analyses to objectively study the short-term effects of living donation, the transplant community must collectively improve patient information on the LDF form. The proposed minimum reporting requirements are based on recommendations from the Joint Society Work Group, which is composed of representatives from the American Society of Transplantation (AST), the American Society of Transplant Surgeons (ASTS), and the North American Transplant Coordinators Organization (NATCO) to the OPTN/UNOS Living Donor Committee.

Background and Significance of the Proposal:

One of the Committee's goals for the past several years has been to evaluate the existing living donor data and establish living donor performance metrics for transplant programs. The Committee began this work by comparing data on the Living Donor Registration (LDR) and Living Donor Follow-Up (LDF) forms to try to measure change in living donor health between donation and follow-up. Unfortunately, these metrics could not be calculated because the data submitted on LDF forms were too incomplete for analysis.

Specifically, the Committee is concerned with the number of living donors who are designated as "lost to follow-up" and those who do not have complete and timely follow-up information reported on LDF forms submitted at the time points required by OPTN policy. During an early review of such forms, the Committee noted that many forms were incomplete and many living donors were reported as "lost to follow up." To improve living donor data submission, the Committee recommended increasing options for reporting donor status on the LDF form to include the following:

(1) Living: Donor seen at transplant center;
(2) Living: Donor status updated by verbal or written communication between transplant center and donor;
(3) Living: Donor status updated by other health care facility;
(4) Living: Donor status updated by other source (example: 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 (if selected the transplant center is required to document their efforts to contact the donor).

In June, 2007, the OPTN/UNOS Board of Directors approved this change to the LDF forms that became effective March 31, 2008.

The Committee sponsored new bylaws which require transplant centers:

- To develop and once developed, comply with written protocols to address all phases of the living donation process. Specific protocols shall include the evaluation, preoperative, operative, post-operative care, and submission of required follow-up forms at six months, one-year, and two-year post donation.

- To disclose to prospective living donors that centers are required to develop a plan to collect the required follow-up information for each donor and submit LDF forms addressing the health information of each living donor at six months, one year, and two years after donation. Under the bylaws, transplant centers must have written protocols with a plan to collect follow-up information about each donor.

The Board approved these bylaws at its September 2007 meeting. ((ATTACHMENT I TO APPENDIX B OF UNOS BYLAWS, Designated Transplant Program Criteria XIII. Transplant Programs) that require Kidney (and Liver) Transplant Program that Perform Living Donor Kidney (or Liver) Transplants).

On July 22, 2008, the committee chair gave a presentation to the Membership and Professional Standards Committee (MPSC) on the current status of living donor follow-up. That presentation explained that the Committee's review of LDF forms revealed a large number of programs reported their donors as "lost to follow-up" when it is uncertain if reasonable measures were taken to contact donors. The committee's review determined that only completing two data elements (status and date of status) on the form enabled a center to meet requirements for completion of the form. The presentation concluded with a request to the MPSC to do the following:

- Determine a minimum threshold for categorizing living donors as "lost to follow-up" on LDF forms;

- Strengthen reporting requirements so that 6 month, one–year, and two-year LDF forms are submitted at appropriate times; and

- Commit to an annual review of the status of LD follow-up.

The MPSC agreed to study the issue through the formation of a joint work group 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.

- Require, as prescribed in existing policies, that LDF forms must be submitted at six months, one year, and two years after donation, and that the data submitted reports an accurate and up-to-date donor status.

- Investigate any living donor transplant program that categorizes more than 10 percent of its donors as "lost to follow-up."

- State that the absence of additional funding specific to living donor follow-up is not an acceptable excuse for failing to complete the follow-up forms. Transplant centers should consider living donor follow-up as a mandatory component after transplantation.

- 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 in the future.

In addition and concurrent with the work done by the Living Donor Committee, in June 2007, the OPTN/UNOS Board approved a resolution from the Policy Oversight Committee in support of this effort stating that, "Resolved, that a joint OPTN committee be established to evaluate the use of living donor data." As a result, the Living Donor Data Task Force (LDDTF) was established in late 2007. The Task Force consisted of 19 members with varied expertise with living donation. Members were involved with:

- OPTN/UNOS Living Donor and Policy Oversight Committees, Kidney Paired Donation Working Group, and Board of Directors;

- ASTS and AST;

- Adult to Adult Living Donor Liver Transplantation Cohort Study (A2All), Renal and Lung Living Donors Evaluation Study (RELIVE), New York Center for Liver Transplantation, Living Donor Organ Network, the National Kidney Foundation; and

- Clinical Social Work/Psychology, patients, and donors.

The LDDTF was asked to take an objective look at the various needs for living donor follow-up data and to propose an appropriate approach for each need. Final recommendations for consideration by the Board of Directors included the following:

- As currently collected, the OPTN data are incomplete beyond the point when the discharge form is submitted (up to six weeks post donation, but much earlier for most donors) and therefore useless making conclusions about living donor safety or related research.

- There exists strong support for the following:

    a. Using the OPTN 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. Requiring 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. Developing a self-reporting mechanism for donors of a longer duration than that required of centers.

In addition to the aforementioned activities, for each of the past three years, the Committee sent each living kidney and liver donor transplant program an electronic letter containing data on the status of that program's living donor follow-up, which reported the following metrics:

- The percentage of LDF forms submitted and validated within three month of the expected date
- The percentage of LDF forms submitted and validated within six months of the expected date
- The percentage of programs with donors who have a validated one-year LDF form with a known patient status (alive or dead) at least 300 days post-donation (i.e., donors who are not categorized as "lost to follow-up")
- The percentage of living kidney 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

In November 2009, the Committee reported its continuing efforts towards improving Living Donor Follow-Up to the OPTN/UNOS Board. During the meeting, the Board resolved that the Committee should develop a policy proposal to establish a threshold for acceptable submission of living donor follow-up. During this same meeting, the Board directed the Committee to develop and disseminate a resource outlining best practices for the submission of living donor follow-up based on its review of high performing programs.

The Committee met in September 2010, and reviewed past, current, and planned future activities to improve living donor follow-up. The Committee considered trying to improve living donor follow-up by defining and proposing better enforcement of a "complete" LDF form. A complete one-year LDF form was defined as a form with: (i) a numerical serum creatinine for living kidney donor (or bilirubin for living liver donors) and (ii) a known patient status (alive or dead) at least 300 days post-donation. The Committee supported the collection of clinical data on living donors for a minimum of two years. However, the Committee understood that there was a lack of consensus on the value of clinical data on living donors during the early post-operative period and consequently anticipated there would be resistance or opposition to new requirements to obtain and report lab results for living donors for up to two years at that time.

After considering all factors, the Committee finalized a policy proposal to establish a threshold for the percentage of living donors that all programs must report with a valid status (alive or dead) at required post-operative intervals). The proposal established a 90% minimum threshold for such reporting. The Committee proposed the 90% threshold because it understood that despite centers' best efforts to educate living donors on the benefit and need to participate in post-operative follow-up, some donors might not agree to participate in required follow-up.

The *Proposal to Improve Reporting of Living Donor Status* was available for public comment between March 11 and June 10, 2011 and received overall support from the community. However, some regions, OPTN committees, members of the general public, and the National Kidney Foundation Living Donor Council commented that requiring centers to report only if their living donor was alive or dead was

insufficient and did nothing to help determine how organ donation could affect the future health of living donors.

During this same public comment period, the American Society of Transplant Surgeons (ASTS) responded with opposition to the proposal. They commented that the OPTN/UNOS had established a Joint Societies Work Group (JSWG) consisting of members from ASTS, AST, NATCO, and OPTN/UNOS to develop consensus policies on the consent, evaluation, and follow-up of the living kidney donor. Since streamlined recommendations for the follow-up for the living donor are a prominent part of the consensus document, ASTS suggested that the OPTN wait until this document was vetted through the societies prior to adopting any preliminary changes.

The ASTS comments referenced a newly formed group, the Joint Societies Steering Committee, which was established by HRSA and the OPTN contractor to determine a new process for incorporating clinical input into developing OPTN policies that have the potential to direct or prescribe medical care. The need for such a process had been identified during the course of attempts to develop policies that are more specific and detailed regarding OPTN member requirements in the area of living donor protections. It was anticipated that early involvement of the societies in the policy development process, for the purpose of identifying the appropriate medical requirements and the appropriate level of specificity of such requirements, would be an important advance.

The Joint Societies Steering Committee formed a JSWG consisting of appointed members of the represented Societies with a charge to *"…provide recommendations to OPTN/UNOS regarding appropriate requirements for the medical evaluation (including psycho-social evaluation) and informed consent of potential living kidney donors as well as post-donation follow-up and data submission."*

The JSWG created documents that represent the consensus reached by its members, which included (1) a Guidance Document for Informed Consent of Living Kidney Donors; (2) a position paper on the Medical and Psychosocial Evaluation of the Living Kidney Donor; and (3) Recommendations for Donor Follow-Up and Data Submission **(Exhibit A)**.

The Committee reviewed the aforementioned recommendations on donor follow-up and data submission. The following language (in italics) is taken directly from recommendations by the JSWG.

> *Living kidney donor transplantation is an essential part of kidney transplant practice, and that this activity can only go forward if potential donors have full faith and confidence that their transplant professionals and transplant centers are looking out for their best interests and well being. To provide this degree of confidence the workgroup believes these guidelines represent the best available information for transplant centers to help potential donors make the decision to donate in an informed fashion, and to maximize donor safety.*
>
> *The future of individuals who donate organs for transplantation is, by nature, unpredictable. Despite comprehensive and exhaustive living donor evaluative protocols, prognosticating the long-term outcome for an individual donor is difficult. Conclusions surrounding the safety of living organ donation are primarily based upon single-center homogeneous patient populations or incomplete non-validated large data sets. While 2-year follow-up of living donors should not be expected to yield definitive data regarding the long-term safety of organ donation, the provision of limited data at defined time points provides value. For example, finding abnormal*

kidney function at one of these time points would be relatively rare but of great importance to both the donor and the transplant community.

An individual's presentation to a transplant center with an interest in living donation should be recognized as the initial stages of a contract between two parties. The patient enters with the promise of an altruistic, selfless, and potentially life-saving gift of an organ for transplantation. The center promotes the safety of living donation and a genuine interest in the health of that individual beyond the date of donation. The parties together express an implicit trust in one another. As with all contracts, however imperfect, efforts must be made to ensure not only the expectations of both parties but also the spirit of the intentions that brought the two together. Mandatory follow-up at 6 months, 1 year and 2 years following surgery is the transplant community's responsibility to maintaining the public's trust and demonstrating a sincere interest in that contract we share with current and future living donors. With statements of its need at the initial encounter with a potential donor and a concentrated effort at bringing the parties together at these 3 time points, the donor is more likely to appreciate the significance of ongoing contact with the health care system beyond year 2 and continue regular, yearly, preventive health care visits and to become their own health care advocate. Regular contact with the centers also allows the donor programs to become familiar with issues that develop after donation providing an opportunity to proactively modify education or procedures to manage these situations.

Data collection at these time points must be pertinent, attainable, and related to the donation process, and not overly burdensome on the donor or the transplant center that provides such reports. These elements include:

1. *Alive/Dead (Cause if known)*
2. *Hospital readmissions for donor related complications (wound, SBO, etc.)*
3. *Need for dialysis (Yes/No)*
4. *Development of post-donation diagnoses: hypertension, diabetes, cancer, other*
5. *Loss of income or livelihood due to donation*
6. *Loss of medical (health, life) insurance due to donation*
7. *Lab work - serum creatinine and urine protein in kidney donors*

Although requests for more data or increased length of follow-up are desirable, the listings above should be an expected minimum on all donors following surgery at 6 months, 1 year, and 2 years. Transplant centers must demonstrate a documented effort of obtaining such data as an obligation to operate as a living donor transplant center.

In response to the new recommendations from the JSWG, the Living Donor Committee determined that it should delay action on the living donor follow-up policy proposal that would have required centers only to report the status (alive or dead) for at least 90% of their donors.

Instead, the Committee determined that it should propose new minimum requirements for living kidney donor follow-up based on the recommendations of the JSWG. The Committee decided that centers should need to report the JSWG's recommended follow–up data elements for at least 90% of living kidney donors. In this proposal, the required follow-up data elements recommended by the Joint Society have been slightly modified to match the language and order of elements that appear on the LDF form. Also, to date, the JSWG has provided follow-up recommendations only for living kidney donors.

Consequently, this proposal is limited to minimum requirements for living kidney donor follow-up. The Committee will address minimum requirements for living liver donor follow-up at some future date.

It may be helpful for living donor programs to understand the anticipated timeline for this policy proposal. If this proposal receives favorable public comment, it would not be considered by the OPTN/UNOS Board before June 2012. If the policy proposal is approved by the Board in June 2012, the policy would be expected to take effect in September 2012. As proposed, the new reporting requirement would apply only to living kidney donors who donate beginning in September 2012. For these donors, living donor recovery hospitals would first be required to report under the new requirements for living donor follow-up beginning in March 2013 (when the six month LDF forms are due for donors who donated in September 2012). The first cohort of donors to be reviewed will include donors who donate between implementation (September 2012) and March 2013. The six month LDFs for the last donor in this cohort will be due in September 2013. Centers must submit 100% of their forms within 6 months of their due date (Policy 7.81), so no center could be out of policy for not reporting required follow-up elements before **March 2014**.

As previously mentioned, during its November 2009 meeting, the Board directed the Committee to develop and disseminate a resource outlining best practices for the submission of living donor follow-up based on its review of high performing programs. The Committee has completed work on this resource, and it was offered to each living donor program in March 2011.

The resource, titled, "Guidance for Developing and Implementing Procedures to Collect Post-Donation Follow-Up Data from Living Donors" is intended to help programs 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.

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, and is available on the OPTN website @ http://optn.transplant.hrsa.gov/resources/professionalresources.asp?index=7

The Committee met by teleconference on July 20, 2011 and voted to approve this proposal for public comment.

Collaboration:

The proposal is based on recommendations from a Joint Societies Steering Committee composed of representatives of the ASTS, AST, and NATCO to the Living Donor Committee.

Alternatives considered:

The Committee considered if some components of the recommendations from the JSWG for living kidney donor follow-up reporting could also be applied to living liver donors so that group of donors could also be addressed in the proposal. The Committee ultimately decided that policy for living liver donor follow-up would best be addressed at some future date in a separate proposal.

Strengths and weaknesses:

The proposal would lead to the standardization of requirements for living kidney donor follow-up. A weakness of the proposal is that it would not create standardized requirement for living liver donor follow-up.

Description of intended and unintended consequences:

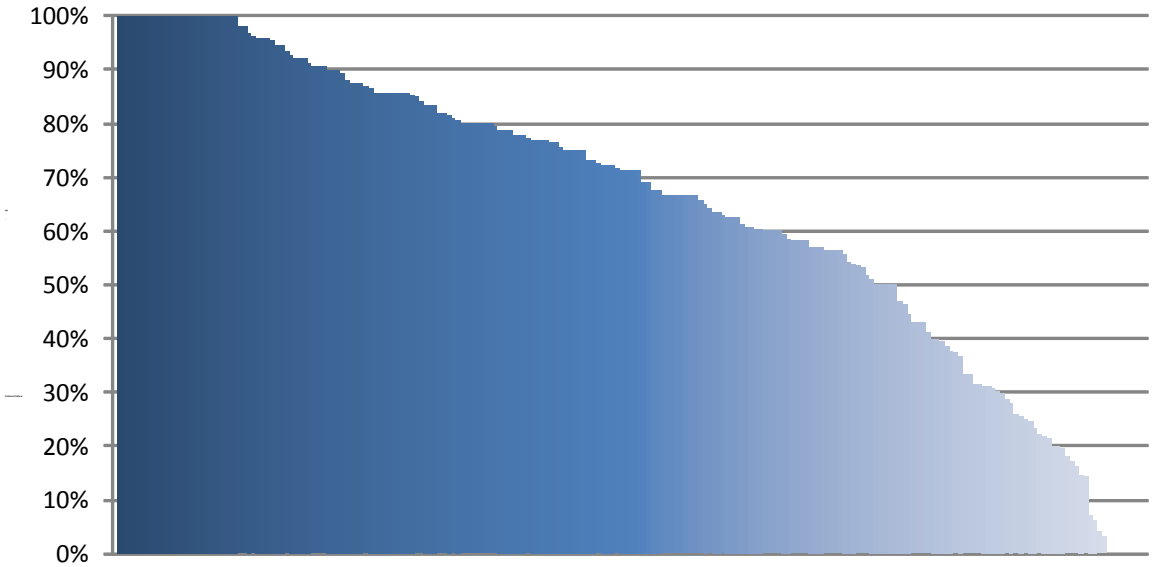
The proposal creates the need to eliminate existing OPTN bylaws and UNOS bylaws, specifically, the requirement that kidney recovery hospitals must develop, and once developed, must comply with written protocols for the submission of required follow-up forms at 6 months, one-year, and two-years post donation. Under this proposal, this bylaw requirement would be superseded by new policy requirements for collecting specific living donor follow-up at required reporting intervals.

Supporting Evidence and/or Modeling:

Transplant center compliance with OPTN policies regarding submission of 1 year LDF forms is high, at 98.9% for kidney donors and 99.5% for liver donors for those who donated between July 1, 2008 - June 30, 2009. Despite these high rates of compliance with OPTN policy for forms submission, by one year post-donation, some donors are listed as lost to follow-up or do not have an up-to-date patient status (alive or dead) or clinical lab values included in their follow-up forms.

For those who donated between July 1, 2008 - June 30, 2009, only 63.5% of kidney donors had a valid status (alive or dead; not lost to follow-up) on their one-year LDF form with a patient status date within two months of the donation anniversary (see Figure 1 for data by program), and only 38.2% had a valid serum creatinine lab value on their form.

Figure 1. Percent of living kidney donors who have a validated 1 year LDF form with a known patient status (alive or dead) dated within 2 months of the donation anniversary, by program.



Note: Each bar represents 1 program. Includes living kidney donors who donated between 7/1/08 and 6/30/09. 26 programs achieved 100% follow-up (left side of the graph), and 8 programs had 0% follow-up (blank area on right side of graph).

Expected Impact on Living Donors or Living Donation:

Requiring transplant programs that recover living donor organs to report accurate and current follow-up information for at least 90% of their donors at the required reporting intervals should result in more complete and useful data on living donors.

Expected Impact on Specific Patient Populations:

There should be no direct impact on the candidate pool. However, the proposal has the potential to affect all living kidney donors. In 2010, there were 6275 living kidney donors. At least 90% of the donors at each program will need to be followed at the program or have their required follow-up reported back to the program for submission on the LDF form. If donors are already being followed by the transplant program at the 90% level, this policy will have no impact on that program's donors.

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

The policy proposal will promote patient safety through improving short term follow-up reporting for living kidney donors leading to evidence-based information about the safety of living kidney donation.

Plan for Evaluating the Proposal:

- ***What questions or hypotheses are guiding the evaluation of the proposal?***
  Will overall living donor follow-up reporting improve if programs are required to report accurate and current follow-up information on 90% of living kidney donors at the required reporting intervals?

- ***Policy Performance Measures:***
  The Committee will monitor the aggregate and center-specific percentage of living kidney donors for whom the required follow-up elements have been reported.

- ***Time Line for Evaluation:***
  On an annual basis, the Committee will monitor the percentage of living kidney donors for whom the required follow-up elements have been reported.

Additional Data Collection:

The proposal does not require changes to the OPTN data collection system.

Expected Implementation Plan:

Living donor recovery hospitals will continue to report living donor follow-up at six months, 1 year, and 2 years from the date of donation. The proposal does not require programming in UNet^{SM}.

Communication and Education Plan:

Communication Activities			
Type of Communication	**Audience(s)**	**Deliver Method(s)**	**Timeframe**
Policy Notice	Relevant staff at transplant centers (emphasis on living donor programs)	e-newsletter/member archive	30 days after the board votes to approve the policy change.
System notice	Relevant staff at transplant centers (emphasis on living donor programs)	e-mail	30 days before policy is implemented and again on the day of implementation.
Blurb in e-newsletter	All relevant staff at transplant centers.	e-newsletter and accessing URL of member archive	March issue of the e-newsletter
Article in the UNOS Update	Update readers	Print copy by U.S. Mail	The earliest possible issue following board approval of the policy change.
Blurb on TX administrators listserv.	Transplant Administrators	Electronic list serv	Post implementation of policy change.

Monitoring and Evaluation:

During onsite reviews, Department of Evaluation and Quality (DEQ) site surveyors will review a sample of a center's follow-up forms for 6 months, 1 year and 2 years. Site surveyors will verify information submitted on the form with medical record documentation. Site surveyors will review compliance with OPTN policies.

The DEQ will request a corrective action if the transplant center's documentation does not comply with the requirements of this policy and forward the survey results to the OPTN/UNOS Membership and Professional Standards Committee.

Policy or Bylaw Proposal:

12.8.3 Living Donor Registration Forms (LDR) must be submitted to the OPTN within 60 days of the form generation date. Transplant centers that recover living donor organs must complete the LDR form when the donor is discharged from the hospital or within six weeks following the transplant date, whichever is first. Transplant centers that recover living donor organs must submit LDF forms for each living donor at six months, one year and two years from the date of donation. [No Change]

12.8.3.1

Transplant centers that recover living donor organs must report accurate and timely follow-up data on the LDF form for at least 90% of their living kidney donors at the required reporting intervals, which at a minimum must include:

- **Donor Status**
  - Patient status
  - Cause of death, if applicable and known
  - Working for income, and if not working, reason for not working

- **Kidney Clinical Information**
  - Serum creatinine
  - Urine protein
  - Maintenance dialysis
  - Donor developed hypertension requiring medication
  - Diabetes

- **Complications**
  - Has the donor been readmitted since last LDF form was submitted?
  - Kidney complications

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

ATTACHMENT I
TO APPENDIX B OF UNOS BYLAWS
Designated Transplant Program Criteria

(2) Kidney Transplant Programs that Perform Living Donor Kidney Recovery: Kidney transplant programs that perform living donor kidney recovery ("kidney recovery hospital") must demonstrate the following:

a. Personnel and Resources Kidney recovery hospitals must demonstrate the following regarding personnel and resources:

(i) That the 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 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 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 recovery hospitals must demonstrate that they have the following protocols:

(i) Living Donation Process: 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.~~

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 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 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 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 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 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.