At-a-Glance

- **Proposal to Establish Requirements for the Medical Evaluation of Living Kidney Donors**

- **New Proposed Policy and Modification of the Bylaws:** 12.3 (Medical Evaluation of Living Donors); 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 establish policy requirements for the medical evaluation of living kidney donors. This proposal is in response to a directive from the Health Resources and Services Administration (HRSA), and based on recommendations from a Joint Societies Steering Committee composed of representatives of the American Society of Transplantation (AST); the American Society of Transplant Surgeons (ASTS) and the North American Transplant Coordinators Organization (NATCO) to the Living Donor Committee.

- **Affected Groups**
  Directors of Organ Procurement
  Lab Directors/Supervisors
  OPO Executive Directors
  OPO Medical Directors
  OPO Coordinators
  Transplant Administrators
  Transplant Data Coordinators
  Transplant 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, and the proposed policy would affect all potential living kidney donors, all living kidney donors, and their recipients.

- **Compliance with OPTN Strategic Goals and Final Rule**
  The proposed changes are consistent with the strategic plan goals to:
  - Optimize a safe environment for living donor transplantation through an improved living donor medical evaluation process.
  - Improve living kidney donation through development and enactment of policies to protect patient safety and preserve the public trust
  - Identify process and system improvements that best support critical network functions, and work to disseminate them to all members who could benefit

- **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 Requirements for the Medical Evaluation of Living Kidney Donors

New Proposed Policy and Modification of the Bylaws: 12.3 (Medical Evaluation of Living Donors); UNOS Bylaws, Appendix B, Attachment I, Section XIII (Transplant Programs) D (2) Kidney Transplant Programs that Perform Living Donor Kidney Transplants.

Living Donor Committee

Summary and Goals of the Proposal:

This proposal would establish policy requirements for the medical evaluation of living kidney donors. This proposal is in response to a directive from the Health Resources and Services Administration (HRSA), and based on recommendations from a Joint Societies Steering Committee composed of representatives of the American Society of Transplantation (AST); the American Society of Transplant Surgeons (ASTS) and the North American Transplant Coordinators Organization (NATCO) to the Living Donor Committee.

Background and Significance of the Proposal:

On June 16, 2006, the Health Resources and Services Administration (HRSA) published a notice in the Federal Register in which the Secretary of Health and Human Services directed the Organ Procurement and Transplant Network (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). The notice directed the OPTN to develop such policies in the same manner, and with the same public comment process, that is done for policies on deceased organ donors and deceased donor organ recipients. The notice stipulated that noncompliance with such policies will subject OPTN members to the same consequences as noncompliance with OPTN policies regarding deceased donor transplantation.

Based on this directive, the Committee began this new area of work by investigating current practices for the medical evaluation of living donors. In January 2007, the OPTN/UNOS President sent a letter to all living kidney and liver transplant programs requesting copies of their informed consent, medical evaluation, and living donor follow-up protocols. The letter explained that federal regulation now required the OPTN to develop policies regarding living donors and living donor organ recipients, and that the Committee planned to use these protocols to make recommendations to the OPTN/UNOS Board of Directors regarding new living donor guidelines. The recommendation would be used to develop guidelines to ensure that individual institution's living donor evaluation protocols consistently meet the needs and interests of potential living donors, and that they reflect the consensus of expertise among medical professionals involved in living donor transplantation.

The Committee reviewed and assessed all protocols submitted by transplant centers. The evaluation revealed wide variation in the medical evaluation of potential living kidney and liver donors. Some centers did not have written guidelines for the medical evaluation of a living donor. Additionally, the Committee reviewed recommendations from the AST and the Report of the Amsterdam Forum on the Care of the Live Kidney Donor, completed an extensive literature review, and completed a focused survey of 16 large transplant centers in the development of its donor evaluation guidelines.

Guidelines for the Medical Evaluation of Living Kidney Donors were released for public comment between July 13, 2007 and August 11, 2007. The Guidelines included recommendations for the psychosocial evaluation of living donors, relative and absolute contraindications to living donation, and suggestions for living donor follow-up.

Public response to the proposal was mixed. Some respondents supported the proposed standardization of the medical evaluation of living kidney donors. Others opined that the proposed guidelines were too prescriptive, dictated medical practice, and would lead to increased litigation. There was also concern with the word "guidelines" as it may not have the same connotation as guidelines in other areas of medicine.

The Committee met by LiveMeeting on August 14, 2007 to review public comment and to consider modification of the proposed guidelines. Based on public comment, the Committee agreed to make the guidelines less prescriptive and agreed to refer to the proposal as "recommendations" rather than "guidelines". The committee revised the proposal and voted to send the revised proposal to the Board for consideration.

During the September 2007 Board meeting, there was an extensive discussion of the proposed recommendations for the medical evaluation of living kidney donors. The Board commended the Living Donor Committee for its excellent work in preparing recommendations for the medical evaluation of living kidney donors and approved some but not all sections of the proposed recommendations. The Board directed that the recommendations should be further revised, resubmitted for public comment, and presented to the Board in the future date for final adoption.

A modified proposal now titled: Resource Document for the Development of Program-Specific Living Kidney Donor Medical Evaluation Protocols was released for public comment between November 12, 2007 and December 21, 2007.

Once again, there was mixed public reaction to the proposal. Many supported the proposal as an important step forward in the care of potential living kidney donors, while other expressed concerns that the proposal was still overly prescriptive and would force transplant programs to perform all the testing recommended in the proposal or potentially face legal liability.

During its May 2008 meeting, the Committee reviewed public comment and prepared a final set of recommendations titled: Guidance for the Development of Program-Specific Living Kidney Donor Medical Evaluation Protocols, which was subsequently approved by the Executive Committeee. This resource has been available through the OPTN website since May 2008.

As an informational item, the Committee has also developed a parallel resource for the medical evaluation of living liver donors, which was distributed for public comment and appoved by the OPTN/UNOS Board. This resource, titled: Guidance for the Medical Evaluation of Potential Living Liver Donors has been available through the OPTN website since November 2009.

In December 2009, HRSA informed the OPTN that although helpful, the voluntary recommendations for the medical evaluation of living donors developed to date were not sufficient and policies were still required.

In April 2010, representatives of the ATS, ASTS, NATCO, OPTN/UNOS and HRSA met to discuss and develop a new process for incorporating clinical input into developing OPTN policies with the potential to direct or prescribe medical care. The need for such a process had been identified during the course of the OPTN's prior attempts to develop policies that are more specific and detailed regarding OPTN and UNOS member requirements for the consent, medical evaluation and follow-up of living donors.

During this meeting, it was noted 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, could be an important advancement which would hopefully allow such policies to be developed in a more timely manner with better initial acceptance by the transplant community at large.

It was determined that a Joint Society Policy Steering Group (comprised of members from the AST, ASTS, NATCO, OPTN/UNOS and HRSA) would be provided an opportunity to make recommendations on any OPTN policy under development that has the potential to prescribe medical care, and would make its first recommendations on OPTN policies in development for the medical evaluation of living kidney donors.

The Joint Society Policy Steering Group formed a Joint Societies Work Group (JSWG) consisting of appointed members of the represented societies to develop recommendations for the medical evaluation of living kidney donors. The charge of the Joint Societies Work Group was to *"provide recommendations to the OTPN/UNOS regarding appropriate requirements for the medical evaluation (including the psychosocial evaluation) and informed consent of potential living kidney donors as well as post-donation follow-up and data submission*."

In response to its charge the JSWG created three resources representing the consensus of its members, including a position paper on the Medical and Psychosocial Evaluation of Living Kidney Donors **(Exhibit A)**. These resource documents were approved by the Executive Committees of the Parent Societies and forwarded to the Living Donor (LD) Committee for consideration in policy developent. A subcommittee of the LD Committee reviewed the JSWG position paper on the Medical and Psychsocial Evaluation of Living Kidney Donors. In general, the subcommittee agreed with the recommendations for medical and psychosocial evaluation of living kidney donors, but did determine that some of the recommendations were too prescriptive. The Committee had particular difficulty determining how to handle the relative contraindications against living kidney donation as recommended by the JSWG. The Committee preferred to include relative contraindications in the proposal but understood that relative contraindications could not be coverted into specific rules, and without specific rules, the policies would not be enforceable.

The Committee opined that although the relative contraindications recommended by the JSWG are not appropriate for inclusion in policy, it is important information that living donor transplant programs should be considering in the medical evaluation of living kidney donors. (**Exhibit A**) includes appendices (I-V) which provide rationale for the relative contraindications involving hypertension, nephrolithiasis, the metabolic syndrome, microalbuminuria, and glucose tolerance testing). The Committee requested that the list of recommended relative contraindications be included as background information in this proposal as follows:

A Kidney Recovery Hospital should consider excluding all donors who meet any of the following criteria:

- Hypertension in a Caucasian younger than age 50
- Hypertension in a Caucasian greater than age 50 on more than one anti-hypertensive medication
- Hypertension in a racial or ethnic groups at elevated risk at any age
- Impaired fasting glucose with other features of the metabolic syndrome in a donor younger than age 50
- Significant history of thrombosis or embolism
- Bleeding disorders
- BMI greater than 35
- Clinically significant cardiovascular disease
- Clinically significant pulmonary disease
- Microalbuminuria greater than 30 mg per day
- Proteinuria (protein in the urine) greater than 300 mg/24 hours, excluding postural proteinuria
- Creatinine clearance or isotopic GFR greater than 1 standard deviations below the mean for age and gender
- History of cancer, including metastatic

The Committee approved this proposal for public comment when it met by teleconference on July 20, 2011.

Collaboration:

The proposal is based on recommendations from a Joint Societies Steering Committee composed of representatives of the AST, ASTS and NATCO to the LD Committee. The OPTN/UNOS Disease Transmission Advisory Committee and Operations and Safety Committee were asked to review and provide feedback during development of the proposal.

Alternatives considered:

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

Strengths and weaknesses:

The proposal would lead to the standardization of the medical evaluation of living kidney donors. A weakness of the proposal is that it would not create standardization of the medical evaluation of all types of living donors.

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 medical evaluation of the potential living donor.

Under this proposal, an existing policy 12.3.1 (ABO Identification) will be renumbered to become policy 12.3.2.1, so the new proposed requirement to ABO type a living donor will precede the existing requirement to ABO type with two samples taken at different times, and sent to the same or different laboratories.

Supporting Evidence and/or Modeling:

***Table 1*. Living Kidney Donors in the US**
January 1, 2005 – December 31, 2010

	Transplanted Living Donor Kidneys
Year of Donation	
2005	6,570
2006	6,434
2007	6,043
2008	5,968
2009	6,387
2010	6,275

Based on OPTN data as of July 8, 2011
Data subject to change base on future data submission or correction

Expected Impact on Living Donors or Living Donation:

A standardized medical evaluation process could improve the confidence of living donors in the safety of living donation. Over time, analysis of the living kidney donor medical evaluation process could contribute to better outcomes. Overall, a standardized medical evaluation process should improve the transparency of the living donation process.

Expected Impact on Specific Patient Populations:

There should be no impact on the candidate pool. However, the proposal has the potential to affect all living kidney donors. In 2010, there were 6275 living donors.

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

HHS Program Goals	*Strategic Plan Goals*
Patient Safety	The OPTN will promote safe, high-quality care for transplant candidates, transplant recipients, and living donors
Best Use	To achieve the best use of donated organs, the OPTN will refine policies by incorporating objective, measurable criteria related to concepts of donor risk/quality and recipient benefit
Operational Effectiveness	The OPTN will identify process and system improvements that best support critical network functions, and work to disseminate them to all members who could benefit

Plan for Evaluating the Proposal:

The Committee will request biannual blinded reports on the number of centers found out of compliance through UNOS Living Donor Program Audits.

Additional Data Collection:

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

Expected Implementation Plan:

If this policy proposal is ultimately approved by the Board of Directors, living donor recovery centers would be required to follow new policies for the medical evaluation of living kidney donors. UNOS Living Donor Programs Auditors will evaluate center compliance. The proposal will 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 and OPOs	Policy notice delivered through e-newsletter and stored in member archive	30 days after the board of directors votes to approve the policy change

Article in the UNOS Update	Update readers	Print copy delivered by US mail	The earliest possible issue following board approval of the policy change
System Notice	Relevant staff at transplant centers and OPOs	Email	30 days prior to implementation and again at implementation
Mention in e-newsletter in Policy-related category	Relevant staff at transplant centers and OPOs	E-mail and access to member archive website	Publish in e-newsletter the month the policy change is implemented and in the e-newsletter issue the following month.
Blurb on TX administrators listserv	Transplant Administrators	Electronic list serv Post	implementation of policy change

Monitoring and Evaluation:

Develop, implement and comply with a process for the medical evaluation of living kidney donors. Document that the process was performed in adherence to OPTN policy requirements and make this documentation available upon request.

The UNOS Department of Evaluation and Quality will request a corrective action if the 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:

The proposed changes to policy 12.3 would be entirely new policy requirements that typically would be presented with underlining. Since the proposed changes would be difficult to read with underlining, the proposed changes are being presented differently. For your convenience, the proposed new policies are presented here without underlining. Strikeouts are used to indicate what language would be removed from the bylaws. Underlining is used to indicate existing policy.

The position paper on the Medical and Psychosocial Evaluation of Living Kidney Donors **(Exhibit A)** includes appendices (I-V) which provide rationale for the measurement or evaluation of blood pressure, urinary protein, creatinine clearance, risk of nephrolithiasis, glucose tolerance testing, and diabetes.

12.3 Medical Evaluation of Living Kidney Donors

Introduction

These policies address the minimum required tests and procedures to assess the medical and psychosocial suitability of a living donor.

12.3.1 Psychosocial Evaluation of the Living Kidney Donor

This evaluation must be performed by a psychiatrist, psychologist, clinical social worker, clinical nurse specialist or advanced practice nurse with experience in transplantation and must:

- Review psychosocial (including mental health) issues that might complicate the living donor's recovery and identify potential risks for poor psychosocial outcome;
- Assess for the presence of high-risk behaviors in the donor that have the potential to increase the risk of disease transmission to the recipient;
- Assess history of substance use, abuse, and dependency;
- Attempt to identify factors that warrant educational or therapeutic intervention prior to final donation decision;
- Determine if the potential donor understands the short and long-term medical and psychosocial risks associated with living donation, for both donor and recipient, as currently understood with the information available;
- Explore the reason(s) for volunteering to donate, and the nature of the relationship (if any) to the transplant candidate to determine that the decision is free of inducement or coercion and other undue pressure;
- Assess the potential donor's ability to make an informed decision and the ability to cope with the major surgery and related stress. This includes a realistic plan for donation and recovery, with social, emotional and financial support available as recommended;
- Review the financial circumstances of the potential donor (employment, insurance coverage, etc) and determine if the potential donor understands the possible financial implications of living donation;
- Inform the donor that he/she may experience problems maintaining or obtaining disability, health, and life insurance following donation; and
- Inform the donor that health information obtained during their evaluation will be subject to the same regulations as regular medical records and may not be additionally protected.

12.3.2 Medical Evaluation of the Living Donor

The medical evaluation must be performed by a physician or surgeon experienced in living donation. The goal of the medical evaluation is to:

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

The Medical Evaluation must include the following components:

General History:

- Evaluate for significant medical conditions such as hypertension, diabetes, genetic renal diseases, lung disease, heart disease, gastrointestinal disease, autoimmune disease, neurologic disease, genitourinary disease, hematologic disorders, bleeding or clotting disorders, history of cancer and history of infections.
- Kidney Specific Personal History:
  - Kidney disease, proteinuria, hematuria
  - Kidney injury
  - Diabetes including gestational diabetes
  - Nephrolithiasis
  - Recurrent urinary tract infections
- Active and past medications (nephrotoxic, chronic use of pain medications and NSAIDS, other)
- Allergies
- Evaluation for coronary artery disease

Family history of coronary artery disease and cancer

Kidney Specific Family History:
Kidney disease
Diabetes
Hypertension
Kidney Cancer

Social History:

The medical evaluation must place special emphasis on:

- Employment, health insurance status, living arrangements, social stability
- Smoking, alcohol and drug use/abuse and other high risk behavior
- Psychiatric illness, depression, suicide attempts

Physical Exam:

- Height, weight, BMI
- Examination of all major organ systems
- Blood pressure must be taken on at least two different occasions. It may however be preferable to perform a 24-hour blood pressure monitor as cohort studies show improved accuracy for determining the correct blood pressure category with 24-hour monitoring

General Laboratory Tests:

- CBC with platelet count
- Type and Screen (see policy 12.3.2.1)
- Prothrombin Time/Partial Thromboplastin Time
- Metabolic panel (electrolytes, BUN, creatinine, transaminase levels, albumin, calcium, phosphorus, alkaline phosphatase, bilirubin)
- HCG quantitative pregnancy test for premenopausal women without surgical sterilization
- Chest X-Ray
- Electrocardiogram (ECG)

Metabolic Focused Testing:

- Fasting blood glucose
- Fasting cholesterol levels (Cholesterol, Triglycerides, HDL Cholesterol, and LDL Cholesterol) with Fasting Lipid Profile if cholesterol/triglycerides are elevated.

*Elements of the metabolic syndrome
Central obesity (BMI or abdominal circumference criteria),
BP >130/85
Fasting blood glucose ≥ 100mg/dl,
Fasting triglyceride levels > 150mg/dl,
HDL < 40 for a man and <50mg/dl for a woman.

Kidney-Specific Tests:

- Urinalysis; Urine microscopy
- Urine culture if clinically indicated
- Measurement of urinary protein and albumin excretion. A random protein/creatinine ratio and/or an albumin/creatinine ratio is sufficient as a screening test for proteinuria and albuminuria. Urine albumin excretion as reported over time or per gram creatinine is the most reliable measurement for future kidney and cardiovascular disease risk. If values are borderline then a repeat screen or a 24-hour urine should be performed
- Measurement of creatinine clearance by glomerular filtration rate or by 24-hour urine collection or isotopic methods. Estimation equations to assess GFR are inadequate in candidates with normal or near normal renal function. If measured creatinine clearance

is close to the minimum acceptable age and gender specific value, a repeat measurement should be considered
- Screening for Polycystic Kidney Disease or other inherited renal disease as guided by family history
- Patients with a history of nephrolithiasis or renal stones identified on radiographic imaging should have a 24 hr urine stone panel including calcium, oxalate, uric acid, citric acid, creatinine and sodium
- Glucose Tolerance Test and/or Glycated Hemoglobin in first degree relatives of diabetics and in at risk groups

Anatomic Assessment:

This assessment is used to determine whether the kidneys are of equal size or have masses, cysts, or stones or other anatomical defects and to determine which kidney is more anatomically suitable for transplantation. The radiologic imaging may reveal serendipitous findings that may need to be investigated. These findings may be related, or unrelated to the organ of interest.

- The test of choice will depend upon the local radiological expertise and surgical preference, but may include CT angiogram or MR angiogram.

Screening for transmissible diseases:

This screening is used to identify the risk of passing an infection or disease to a recipient. This screening may also identify a condition that may require donor treatment or may increase the risk of donation. Infectious disease testing must include:

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

Screening for transmissible diseases must be repeated if there is significant time between evaluation and the eventual donor nephrectomy, especially in donors considered as having increased risk for disease transmission per the US PHS guidelines[1]. Transplant centers should consider additional testing based on donor risk profile such as:

[1] The "Exclusionary Criteria" in Rogers MF, Simonds RJ, Lawton KE, et al. Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissues and Organs. CDC MMWR

- Strongyloides for donors from endemic areas
- Trypanosoma cruzi for donors from endemic areas
- West Nile for endemic areas
- Toxoplasmosis: Transmission is low if recipients are treated with trimethoprim-sulfamethoxazole

Cancer screening:

Age and sex appropriate cancer screening tests.
Screenings to be performed depending upon gender, age, or family history include:

- Cervical Cancer
- Breast Cancer
- Prostate Cancer
- Colon Cancer
- Skin Cancer
- Lung cancer screen for the older patient with a strong smoking history

EXCLUSION CRITERIA

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

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

- Age less than 18 years and mentally incapable of making an informed decision
- Uncontrollable Hypertension or history of hypertension with evidence of end organ damage
- Diabetes
- Active malignancy, or incompletely treated malignancy
- Evidence of donor coercion
- Evidence of NOTA violation (illegal financial exchange between donor and recipient)
- Persistent infections or infections with drug resistant organisms
- Untreated psychiatric conditions, including suicide risk

~~**12.3.1**~~ **12.3.2.1 ABO Identification.** The member transplant hospital must ABO type, and subtype if appropriate, each living donor on two separate occasions prior to the donation. Two separate occasions are defined as two ABO samples taken at different times, and sent to the same or different laboratories

---

Recommendations and Reports. 1994; May 20/43 (RR-8):1-17.
http://www.cdc.gov/mmwr/preview/mmwrhtml/00031670.htm

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.