

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

**SUMMARY**

**I. Action Items for Board Consideration**

- The Board of Directors is asked to approve a change to the OPTN/UNOS Bylaws to require written notification (or disclosures) to living donors from recipient transplant programs (Item 1, Page 3)
- The Board of Directors is asked to approve the “Guidance for the Development of Program-Specific Living Kidney Donor Medical Evaluation Protocols.” (Item 2, Page 7)
- The Board of Directors is asked to approve modifications to (Communications of Donor History) Policy 4.1.1 to clarify that it applies only to deceased organ donors. (Item 3, Page 21)

**II. Other Significant Items**

- None

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

**Richmond, VA  
June 19-20, 2008**

**Robert S. Brown, Jr. MD, Chairman  
Andrew Klein, MD, Vice Chair**

*The following reports represents the OPTN/UNOS Living Donor Committee's recommendations for Changing the OPTN/UNOS Bylaws to Require Written Notification (or Disclosures) to Living Donors from Recipient Transplant Programs; the development of Guidance for the Development of Program-Specific Living Kidney Donor Medical Evaluation Protocols; and Revising Policy 4.0-Acquired Immune Deficiency Syndrome (AIDS), Human Pituitary Derived Growth Hormone (HPDGH), and Reporting of Potential Recipient Diseases Or Medical Conditions, Including Malignancies, of Donor Origin.*

1. **Proposal to Change the Bylaws to Require Written Notification (or Disclosures) to Living Donors from the Recipient Transplant Programs** (Proposed Modifications to Appendix-B, Section II, (F) "Patient Notification" of the OPTN Bylaws and Appendix B, Attachment I, XIII, D (13) of the UNOS Bylaws)

As one of its annual goals, the Living Donor Committee was asked to revise patient notification bylaws to include living donors, thus providing living donors with the same information and protections given to candidates on the national deceased donor transplant waiting list.

Under the proposed policy change, recipient transplant centers must provide written notification to living organ donors within ten business days following their donation date to include: the telephone number that is available for living donors to report concerns or grievances through the OPTN; disclosure that the recipient transplant center is required to submit Living Donor Follow-up (LDF) forms for a minimum of two years; and the plan for obtaining living donor data for completion of follow-up forms.

The Bylaws establish membership criteria for deceased donor transplantation programs as well as transplant programs that perform living donor transplants. Bylaws are intended to create a standardized level of quality among transplant programs.

Under existing Bylaws, transplant centers send written notification to transplant candidates when:

- a transplant evaluation has been completed, and a patient is not going to be placed on the waiting list;
- the candidate has been placed on the waiting list; and

- the candidate has been removed from the waiting list for reasons other than transplant or death.

This notification must be sent within 10 days and must include the telephone number that is available for patients and others to report grievances to the OPTN. In addition to these requirements, notification of listing letters must include the date of listing in the body of the letter.

The Committee supports notifying living donors about the UNOS Patient Services telephone number available for reporting concerns or grievances through the OPTN.

The Committee debated when the potential living donor or actual living donor should receive this notification. This debate included valuable insights from the living donors on the Committee. The Committee considered the recently approved Bylaws for the informed consent and medical evaluation of living donors. Under these new bylaws, each potential living donor will have the benefit of an Independent Donor Advocate who:

- (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.

With these safeguards in place, the Committee felt it was unlikely that potential living donors would have concerns or grievances to report during the medical evaluation and consent process. Living donors on the Committee commented that the pre-operative period is sometimes overwhelming. A potential donor who eventually becomes a living donor may not remember the mechanism for reporting concerns or grievances with the transplant center after the surgery. The Committee ultimately supported requiring written notification to living to living donors in the early post-operative period. The Committee recommended this notification be sent donors within 10 days following their donation to maintain consistency with existing bylaws.

Existing Bylaws and Policies stipulate that recipient transplant programs must submit Living Donor Follow-up forms addressing health information about each living donor at 6 months, one year, and two years post-donation. Each transplant center is also required to develop a protocol that includes a plan to collect follow-up information about each living donor.

Some living donors have contacted UNOS to report problems in receiving follow-up care from their transplant centers. Most of these complaints involve lack of responsiveness and inadequate services. In response to these living donor complaints, the Committee is recommending that recipient transplant centers also disclose their responsibilities for submitting follow-up forms on living donors in this notification letter.

The Committee acknowledges that, in some cases, the recipient transplant center may have no direct interaction with the living donor. Under existing bylaws and policies, all transplant centers must be OPTN/UNOS members and follow those rules and regulations. Since some living donors donate at non- OPTN/UNOS transplant centers, the recipient transplant center must bear the responsibility for living donor notification.

The proposal was released for public comment on February 8, 2008. Overall public comment supported the concept of providing living donors with the phone number available to report grievances to the OPTN, but revealed opposition to providing the notification ten days after donation. Instead, most public comment responses recommended providing the notification during the consent process for living donors. A summary of the public comment and Committee's responses are included in the briefing paper. **Exhibit A**

The Committee met on May 12, 2008, to review public comment. Based on that review, the Committee agreed to change the proposal to require centers to provide the phone number that is available for reporting grievances to the OPTN to potential living donors during the consent process. Based on this revised timeline for notification, the Committee recommended moving this requirement to the informed consent section of the living donor Bylaws. Committee vote: 18-0-0.

**\*\*\*RESOLVED, that the modifications to Bylaws, Appendix B, Attachment I, Section XIII, C (2) and (4), Designated Transplant Program Criteria set forth below, are hereby approved, effective pending distribution of notice.**

### **Designated Transplant Program Criteria**

#### **XIII. Transplant Programs.**

A.-D. 2) b. (iii). [No Change]

(iv) Informed Consent: Kidney 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; and

(5) disclosure by the transplant center that it is required, at a minimum, to submit Living Donor Follow-up forms addressing the health information on 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.

(6) the telephone number that is available for living donors to report concerns of grievances through the OPTN

[No further changes]

### **(3) Liver Transplantation – [No changes]**

#### **(4) Live Donor Liver Transplant Programs that Perform Living Donor Liver Transplants.**

a.-b. (iii) [No changes]

(iv) Informed Consent: Liver 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; and

(5) disclosure by the transplant center that it is required, at a minimum, to submit Living Donor Follow-up forms addressing the health information on 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.

(6) the telephone number that is available for living donors to report concerns of grievances through the OPTN

[No further changes]

2. **Guidance for the Development of Program-Specific Living Kidney Donor Medical Evaluation Protocols** – The Ad Hoc Living Donor Committee was formed in 2002 and identified “establishing minimum criteria for donor work-up” as a priority for its future work. This Committee developed a set of minimal guidelines for potential living kidney transplant recipient and donor evaluations, which included provisions for an independent donor team, psychiatric and social screening, and appropriate medical, radiologic, and anesthesia evaluation.

In January 2007, the OPTN/UNOS President sent a letter to all transplant programs that perform live donor transplants requesting copies of their informed consent, medical evaluation, and living donor follow-up protocols. The letter explained that federal regulation now required the Organ Procurement and Transplantation Network (OPTN) to develop policies for the equitable allocation of living donor organs. The Living Donor Committee planned to use these protocols to make recommendations to the Board of Directors regarding new living donor guidelines. These recommendations are intended to help individual institutions to develop living donor evaluation protocols that consistently meet the needs and interests of potential living donors. Additionally, institutions may choose to compare their protocol against this set of recommendations that reflect the consensus of expertise among medical professionals involved in living donor transplantation

Committee Members reviewed and assessed all submitted protocols. Their evaluation revealed wide variation in the medical evaluation of potential living kidney donors. Some centers did not have written guidelines for the medical evaluation of a living donor. Additionally, the Committee reviewed recommendations from the American Society of Transplantation (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 these guidelines.

Based on the information reviewed, the Committee developed a set of recommendations for the medical evaluation of living kidney donors. At its June 2007, meeting, the Committee approved sending the “Guidelines for the Medical Evaluation of Living Kidney Donors” for public comment. The Guidelines for the Medical Evaluation of Living Kidney Donors were released for a 30-day public comment beginning on July 13, 2007.

The Committee met by Live Meeting on August 14, 2007, to review public comment and to consider proposed modifications to the proposed Guidelines. Based on the comments received, the Committee agreed to make the Guidelines less prescriptive, and agreed to refer to the proposal as “Recommendations” rather than “Guidelines.” Final proposal language was drafted for consideration by the Board in September 2007.

A document entitled “Recommendations for the Medical Evaluation of Living Kidney Donors” was presented to the Board at its September 18, 2007, meeting in Los Angeles. During that meeting, the Committee Chair agreed that the document could be renamed a “Resource Document” rather than “Recommendations.” After extensive discussion and due to a lack of consensus, the Board agreed to table this proposal until its next meeting in February 2008. In the interim, this Committee was charged to seek additional input from stakeholders including but not limited to the AST and ASTS. Within days after the Board meeting, OPTN/UNOS President, Tim Pruett, MD., sent notification to the AST and ASTS requesting each organization to provide specific comments to the Living Donor Committee, which could be considered at the Committee’s upcoming meeting.

At its October meeting, the Committee reviewed all comments received to date and further revised the Resource Document in preparation for re-release for public comment. The Resource Document was sent for a special 30-day public comment period on November 12, 2007

The Committee met by Live Meeting in December 18, 2007, to review public comments and made modifications to the proposed Resource Document. During that meeting, the Committee agreed to offer the professional transplant societies an additional opportunity to provide feedback. The AST and ASTS participated in a Live Meeting to review this proposal on a January 4, 2008. The Committee charged a small subset of its members to review the submitted comments, and to prepare a final version of the Resource Document for the next Board of Director's meeting on February 21, 2008.

On February 7, 2008, UNOS received a letter from HRSA recommending that the Board of Directors not approve the document in its current form and provided an Addendum which listed 16 specific concerns with the document. In response to the HRSA request, the Committee withdrew the proposal from the list of items for consideration by the Board. However, the Resource Document was discussed during the Board meeting, which included the review of a draft "professional" version of the Resource Document developed by the Committee Chair. The Board recommended that two versions of the Resource Document be developed to include a professional version and separate public version; and would be entitled Guidance for the Development of Program-Specific Living Kidney Donor Medical Evaluation Protocols in the future. The Board requested the Guidance Document be further modified and returned to the Board before or at its next meeting.

On May 7, 2008 HRSA provided comments on the Guidance Document resource which included adding an expiration date to the resource to ensure it remained updated and adding information explaining the importance of living donor follow-up. The Committee discussed the final draft of this resource at its meeting on May 12, 2008, and restated that the goal of this resource is to make sure, that as much as medically possible; the living donor is safe and is educated about their risk. Although not perfect to all Committee members, the majority agreed that it is a good resource based on common transplant center practice, data from transplant literature and from standards of evaluation for kidney evaluations used by nephrologists. The document will be reviewed annually and will be revised as appropriate when new data becomes available.

The Committee recommends the following proposal for consideration by the Board of Directors: 16-1-0

**\*\*\* RESOLVED, that Guidance for the Development of Program-Specific Living Kidney Donor Medical Evaluation Protocols, is hereby approved, effective June 20, 2008:**

Guidance for the Development of Program-Specific Living Kidney Donor Medical Evaluation Protocols

### **Summary and Goals**

On June 16, 2006, HRSA published a notice in the Federal Register in which the Secretary of HHS directed the OPTN to develop policies regarding living organ donors and organ donor 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. In response, the Board of Directors adopted changes to the Bylaws requiring transplant programs that perform living donor transplants to develop and follow written protocols that address all phases of the living donation process, including the evaluation, pre-operative, operative, and post-operative care, as well as the submission of data.<sup>1</sup>

To assist members, the Living Donor Committee developed a non-exhaustive set of elements to serve as a resource that could be used by transplant programs in developing their own program specific living donor kidney medical evaluation protocols, as required by the Bylaws. Since this resource is not considered OPTN or UNOS policy, it does not carry the monitoring or enforcement implications of policy. It is not an official guideline for clinical practice, and it is not intended to be clinically prescriptive or to define a standard of care. This resource will not be used to determine member compliance with policies or Bylaws; rather it is a resource being provided to the members for examples and amplification of the elements mentioned in the Bylaws. It is intended for members' voluntary use.

Both new and existing living donor transplant programs can use this guidance when developing medical evaluation protocols for their potential living donors. It is expected that a parallel document will be derived for the use of potential donors and the public.

## **I. Pre-evaluation Guidance**

While it must be recognized that each potential donor is unique, and no single evaluation protocol is applicable to all living donors, the potential living donor should be informed about the transplant center's evaluation protocol in its various phases. The donor evaluation includes psychosocial and medical components. These evaluations should help determine if an individual is a suitable donor. The psychosocial evaluation should determine the presence of psychosocial problems that might complicate donation (e.g., lack of social support to aid in their post operative recovery). The medical evaluation may uncover conditions that could significantly increase the risk of donation to the potential donor. The evaluation should also screen for diseases that the donor could transmit to the potential recipient, particularly in the presence of immunosuppression. Lastly, this evaluation should define the anatomy of the potential organ

<sup>1</sup> **Bylaws, Appendix B, Attachment I, Section XIII, C (2) and (4), Designated Transplant Program Criteria**

so the surgical team can assess the anatomical suitability of the organ and properly plan the surgery.

To the extent possible, the potential donor and the intended recipient should be made aware of the alternatives to living donor transplantation prior to beginning the donor evaluation. Both the potential donor and intended recipient should be informed of the donor and recipient outcomes of living donor transplantation nationally and at the particular institution.

It is important to inform the potential donor that he/she can stop the evaluation or donation process at any time. If a potential donor chooses to not proceed with the evaluation or donation process, the center may state that the donor did not meet the program's criteria for donation to help avoid difficult social situations.

### **Donor Risk**

Living kidney donation involves risk:

- Most of the risks and complications associated with the donor nephrectomy procedure occur in the peri-operative period, are relatively well known, and can include:
  - Risks associated with anesthesia
  - Surgical complications such as pain, infection, blood loss, and blood clots
  - Death - the risk of dying from living donor surgery is 0.04%.

Further study comparing the risk of ESRD in the general public to that in living kidney donors is needed. Since there has been no national systematic long-term data collection on the risks associated with living organ donation, the risk of renal dysfunction for the living kidney donor is not well known. However, recent data does reveal:

- The risk of end stage kidney disease, and the need for dialysis or to receive a kidney transplant is between 0.10 to 0.52%;
- This risk may be higher if the prospective donor is African American;
- Of the 81,960 living kidney donors since 1987, 36 (0.04%) have been listed for transplant, not including ESRD without transplant or ESRD without dialysis;
- Between January, 1996 and February, 2007, 146 previous living donors have been on the kidney waiting list; and
- For those living donors whom the date of donation is known (121), the median time from donation to listing is 20 years.

The concern about the long-term risk of donation has to be balanced against the benefit of transplantation for the recipient.

It is clear that those patients who remain on dialysis have an increased risk of death as compared to patients who are transplanted. Furthermore, there is strong evidence that the longer a transplant candidate remains on dialysis, the greater the risk of graft loss and mortality after transplantation.

The potential donor and the medical team should discuss these risks and whether the risk of nephrectomy to the living donor is warranted in comparison to the benefit the recipient receives from transplantation.

### **Risks of Donor Evaluation**

Some risk is associated with medical screening and may include:

- Contrast materials used in abdominal imaging may cause mild to severe allergic reaction;
- Both risks and benefits may result from medical testing. The evaluation may lead to the early discovery of infections or malignancies unknown to the potential donor;
- Positive test results for some infections must be reported by law to health agencies;
- HLA testing could reveal the true identity of family relationships, and create issues that the donor or other family members may not wish exposed; and
- Testing may bring unexpected decisions for the donor and medical team as well as the need for additional testing and treatments that may be the financial responsibility of the donor or donor's insurance.

Physician knowledge and experience are important components in this process, and the involved professionals' medical judgment will always need to direct the course of the evaluation. The health care team should be judicious in the choice of screening tests and circumspect in the interpretation of the positive findings.

### **Decision Regarding Donation**

The final decision regarding whether the donor can donate an organ is based upon:

- the medical test results;
- the donor's psychosocial evaluation;
- the relationship of the donor to the prospective recipient and;
- assessment of risk based upon current medical knowledge.

The donor should make the decision to donate with concurrence of the independent donor advocate and the medical team.

If a decision to donate is made, the recipient should be consulted to determine if transplantation should proceed. Under these circumstances, both the donor and recipient should be informed of the risks of both procedures given the specifics of the donor and recipient circumstances (e.g. severity of recipient illness, donor anatomy, etc).

Prospective living donors may be willing to undergo varying degrees of personal risk to provide an organ needed by a transplant candidate, and this difference needs to be taken into consideration.

Transplant candidates may be willing to undergo varying degrees of communicable disease and organ quality risk from acceptance of the prospective living donor's gift of his or her organ.

## **II. Evaluation Guidance**

This document presents a list of tests and procedures that may be necessary to assess the medical and psychosocial suitability of the donor.

To date, there have been no randomized controlled trials to determine the testing required in the evaluation of a living kidney donors. The process described here is representative of general medical practice for the assessment of living donors at existing practices at US transplant programs.

This list should be viewed as suggestive and opinions will vary. The list will require modification over time as improved screening tests become available. At all times, the transplant program should assess the risk of the screening procedures versus the benefit of the information derived.

### **Psychosocial Evaluation**

The Bylaws state that this evaluation be performed by a psychiatrist, psychologist or social worker with experience in transplantation. The psychosocial evaluation should:

- Review psychosocial issues that might complicate the living donor's recovery and identify potential risks for poor psychosocial outcome;

- Attempt to identify factors that warrant educational or therapeutic intervention prior to donation, and provide the necessary referrals for further psychological or psychiatric evaluation if current or prior psychiatric disorders are suspected;
- Determine if the potential donor understands the short- and long-term medical risks associated with living donation as currently understood with the information available;
- Allow the transplant program to explore the reason(s) for volunteering to donate, to determine that the decision is free of coercion;
- Determine the potential donor is able to make an informed decision and has 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 needed;
- Review the financial circumstances of the potential donor (employment, insurance coverage, etc) and determine that the potential donor understands the possible financial implications of living donation and including the availability of financial resources where applicable;
- Inform the donor that he/she may experience problems in obtaining future disability and health 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.

To protect the potential donor, the most sensitive questions should be asked at the end of the psychosocial evaluation, which prevents recording responses to very sensitive questions in the medical record of inappropriate candidates.

## **DONOR MEDICAL EVALUATION**

The OPTN/UNOS Bylaws state that a thorough medical evaluation 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 of the kidneys.

This document is scheduled to expire by 12/31/2010. After this date, users are encouraged to contact the OPTN to confirm that this document remains in effect. The OPT/UNOS Living Donor Committee, in consultation with experts, will at the appropriate time, review and update the guidance in this document.

## **Components of the Medical Evaluation**

### **1. General History:**

- Evaluate for significant medical conditions such as hypertension, diabetes, lung disease, heart disease, gastrointestinal disease, autoimmune disease, neurologic disease, genitourinary disease, history of cancer, history of infections, hematologic disorders, and bleeding/clotting disorders.
- Smoking, alcohol and drug use/abuse, including intravenous drug use/abuse and other high risk behavior.
- Active and past medications (nephrotoxic, chronic use of pain medications and NSAIDS, other)
- Allergies
- Family history (coronary artery disease, cancer, other)
  - Kidney Specific Personal History
    - Kidney disease, proteinuria
    - Kidney injury
    - Diabetes
    - Chronic infection
    - Nephrolithiasis
    - Recurrent urinary tract infections
    - Gout or other arthritis
    - Gestational diabetes
  - Kidney Specific Family History:
    - Kidney disease
    - Diabetes
    - Hypertension
    - Reflux

**2. Social History:** although a full psychosocial evaluation will be carried out, an evaluation should be part of the medical evaluation to include special emphasis on:

- Employment, health insurance status, living arrangements, social stability
- Psychiatric illness, depression, suicide attempts

### **3. Physical Exam:**

- Height, weight, BMI
- Examination of all major organ systems

#### **4. Kidney-specific:**

- Blood pressure (Measure after sitting for 5 minutes, take twice at the same visit, obtain 2 different assessments of blood pressure on different days). 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.
- Vascular evaluation (abdominal, femoral, carotid bruits, etc),
- Microscopic evaluation.

#### **5. General Laboratory Tests:**

- CBC with platelet count
- Prothrombin Time/Partial Thromboelastin Time
- Comprehensive panel (electrolytes, transaminase levels, albumin, calcium, phosphorus, alkaline phosphatase, bilirubin)
- HCG quantitative pregnancy test for women < 55 years old
- Age and gender appropriate cancer screening tests. The transplant program may choose to follow the screening recommendations from the American Cancer Society.
- Chest X-Ray
- Electrocardiogram (ECG)
- Evaluation for coronary artery disease, as suggested by the American College of Physicians
- Pulmonary function tests for smokers, as suggested by the American College of Anesthesiology and American Lung Association

#### **6. Kidney-specific Tests:**

- Urinalysis; microscopy as indicated
- Urine culture if clinically indicated
- Measurement of protein excretion
- Measurement of glomerular filtration rate by 24 hour urine collection or equivalent testing.
- Screening for Polycystic Kidney Disease as indicated by family history. If the prospective donor is over age 30, this is usually accomplished with an ultrasound. In those under age 30, genetic testing remains the gold standard.
- Uric acid
- GTT in relatives of diabetics as indicated

#### **7. Immunological testing:**

- ABO blood group typing
- Human Leukocyte Antigen (HLA) typing
- Cross match

## **8. Metabolic Focused Testing:**

- Fasting blood glucose
- Fasting cholesterol levels (Cholesterol, Triglycerides, HDL Cholesterol, LDL Cholesterol) with Fasting Lipid Profile if cholesterol/triglycerides are elevated.
- Uric acid (High uric acid levels are associated with the metabolic syndrome and independently with reduced kidney function)
- If the risk of diabetes is higher than the general population by presence of a first degree relative with diabetes or the presence of metabolic syndrome characteristics, but the prospective donor does not meet the definition of diabetes, they should be counseled that they are at an increased risk to develop diabetes and perhaps kidney disease.

The goal of these tests is to determine the number of elements of the metabolic syndrome present: Donor may be at increased risk of kidney disease if  $\geq 3$  risk actors (central obesity, high blood pressure BP  $>130/85$ , fasting blood glucose  $\geq 100$ mg/dl, triglyceride levels  $> 150$ mg/dl, HDL  $< 40$  for a man and  $<50$ mg/dl for a woman).

## **9. Anatomic Assessment:**

This assessment is used to determine which kidney is most anatomically suitable for transplantation (typically dependent upon the number of arteries going to the kidneys) and whether the kidneys are of equal size or have masses, cysts, or stones. The donor should preferably keep the kidney with the fewest issues. Based on these findings, the surgeon will determine 1) the suitability of the organ, and 2) any additional risks associated with anatomical variants. The radiologic imaging may reveal serendipitous findings that will need to be investigated. These finding 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, MR angiogram or angiogram, used singly or in combination. .

## **10. 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 typically includes testing for the following:

- CMV (Cytomegalovirus)
- EBV (Epstein Barr Virus) – VCA or EBNA antibody test may be performed if the recipient is EBV seronegative
- HIV 1,2 (Human Immunodeficiency Virus)
- HTLV I (Human T-cell Lymphotropic Virus) antibody testing
- HBsAg (Hepatitis B surface antigen)
- HBcAB (Hepatitis B core antibody)
- HBSAB (Hepatitis B surface antibody)
- HCV (Hepatitis C Virus)

- RPR (Rapid Plasma Reagin Test for syphilis)
- Tuberculosis

Other diseases may be tested for depending on program preference and donor risk profile:

- 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.

### **11. Cancer screening:**

The screening tests follow the practices advised by the American Cancer Society. Screenings to be performed depending upon gender, age, or family history include:

- Cervical Cancer
- Breast Cancer
- Prostate Cancer
- Colon Cancer
- Skin Cancer

Lung cancer screening is not currently recommended by the American Cancer Society, but could be considered in the older patient with a strong smoking history.

## **POSSIBLE EXCLUSION CRITERIA**

**A variety of criteria may make an individual unsuitable for living donation. Some of these may include:**

- Age < 18 years, or mentally incapable to make an informed decision,
- Uncontrollable hypertension, history of hypertension with evidence of end stage organ damage, history of hypertension in a Caucasian younger than age 50 or greater than age 50 on more than one anti-hypertensive medication, or hypertension in a non-Caucasian. High blood pressure is associated with a more significant effect on progression of kidney disease in the non-Caucasian population, or in patients taking more than one anti-hypertensive medication.
- Diabetes
- Significant history of thrombosis or embolism
- Bleeding disorders
- Uncontrollable psychiatric illness
- Morbid obesity
- Clinically significant Coronary and/or Peripheral Vascular Artery Disease
- Symptomatic Valvular Disease

- Chronic lung disease with impairment of oxygenation or ventilation
- Recent malignancy, or cancers with long times to recurrence (e.g., breast cancer)
- History of melanoma
- History of metastatic cancer
- Bilateral or recurrent nephrolithiasis
- Significant urologic abnormalities of donor kidney
- Creatinine clearance  $< 80$  ml/min/1.73m<sup>2</sup>, or projected GFR with removal of one kidney at 80 years old of  $< 40$  cc/min/1.73m<sup>2</sup> (based upon Thiel in Living Donor Kidney Transplantation, editors Gaston and Wadstrom, 2005)
- Proteinuria (protein in the urine)  $> 300$  mg/24 hours, excluding postural proteinuria
- Human Immunodeficiency Virus infection
- Hepatitis C Virus infection
- Active Hepatitis B Virus infection

### **OPTN/UNOS LIVING DONOR FOLLOW-UP**

The organ recipient's transplant center is required to submit to OPTN/UNOS information on the status of each living donor for a minimum of two years. Any information received is used determine if living donors experience short term health complications and how living donation may impact quality of life. Follow up information submitted by transplant centers is the only method currently available to obtain information on living donors.

### **MEDICAL EVALUATION AFTER LIVING DONATION**

Following kidney donation, donors should remain informed about their health and have the basic evaluations performed as listed below:

- Blood pressure
- Height, weight and waist circumference
- An age appropriate physical exam

Laboratory studies may include:

- Urinalysis
- Urine albumin:creatinine ratio
- Serum creatinine
- Fasting blood glucose
- Lipid profile

All living kidney donors are encouraged to maintain lifestyle choices that will protect their overall health and in particular kidney health. Like all adults, kidney donors should be advised to establish a health evaluation schedule as recommended by the American

College of Physicians. These evaluations may be the financial responsibility of the donor.

### III. References:

1. Delmonico F; Council of the Transplantation Society. A report of the Amsterdam Forum on the care of the live kidney donor: data and medical guidelines. *Transplantation* 2005;79(6 Suppl):S53-66.
2. Davis CL, Delmonico FL. Living donor kidney transplantation: a review of the current practices for the live donor. *J Am Soc Nephrol* 2005;16(7):2098-2110.
3. Fleisher LA et al ACC/AHA 2007 guidelines on peri-operative cardiovascular evaluation and care for non-cardiac surgery: Executive summary. *J Am Col Cardiol* 2007; 17:1708-1730
4. Qaseem A et al. Risk assessment for and strategies to reduce peri-operative pulmonary complications for patients undergoing noncardiothoracic surgery: A guideline from the American College of Physicians. *Ann Intern Med* 2006;144:575-580.
5. Abdul-Ghani, MA et al. What is the best predictor of future type-2 diabetes? *Diabetes Care* 2007;30:1544-1548.
6. Wilson PWF et al. Prediction of incident diabetes mellitus in middle-aged adults. The Framingham Offspring Study. *Arch Intern Med* 2007;167:1068-1074.
7. Smith RA et al. Cancer screening in the United States 2007: A review of current guidelines, practices and prospectives. *CA Cancer J Clin* 2007;57:90-104.
8. Pei Y. Diagnostic approach in autosomal dominant polycystic kidney disease. *Clin J Am Soc Nephrol* 2006; 1:1108-1114.
9. Rathmann W, Haastert B, Icks A, Giani G, Roseman JM. Ten year change in serum uric acid and its relation to changes in other metabolic risk factors in young black and white adults: the CARDIA study. *Eur J Epidemiol* 2007;22(7):439-445.
10. Siu YP, Leung KT, Tong MK, Kwan TH. Use of allopurinol in slowing the progression of renal disease through its ability to lower serum uric acid level. *Am J Kidney Dis* 2006;47(1):51-59.
11. Suliman ME, Johnson RJ, Garcia-Lopez E, Qureshi AR, Molinaei H, Carrero JJ, Heimbürger O, Barany P, Axelsson J, Lindholm B, Stenvinkel P. J-shaped mortality relationship for uric acid in CKD. *Am J Kidney Dis* 2006;48(5):761-767.
12. Talaat KM, el-Sheikh AR. The effect of mild hyperuricemia on urinary transforming growth factor Beta and the progression of chronic kidney disease. *Am J Nephrol* 2007;27(5):435-440.
13. Lee JE, Choi SY, Huh W, Kim YG, Kim DJ, Oh HY. Metabolic syndrome, C-reactive protein and chronic kidney disease in nondiabetic, nonhypertensive adults. *Am J Hypertens* 2007;20(11):11889-1194.
14. Rashidi A, Ghanbarian A, Azizi F. Are patients who have metabolic syndrome without diabetes at risk for developing chronic kidney disease?

Evidence based on data from a large cohort screening population. *Clin J Am Soc Nephrol* 2007;2(5):976-983.

15. Kronborg J, Jenssen T, Njolstad I, Toft I, Eriksen BO. Metabolic risk factors associated with serum creatinine in non-diabetic population. *Eur J Epidemiol* 2007;22(10):707-713.

16. Infante M, Lutman Fr, Cavuto S, Brambilla G, Chiesa G, Passera E, Angeli E, Chiarenza M, Aranzulla G, Cariboni U, Alloisio M, Incarebone M, TEstori A, Destro A, Cappuzzo F, Roncalli M, Santoro A, Ravasi G; for the DANTE Study Group. Lung cancer screening with spiral CT baseline results of the randomized DANTE trial. *Lung Cancer* 2007 “Oct 11.

17. Mishra P, Younossi ZM. Abdominal Ultrasound for Diagnosis of Nonalcoholic Fatty Liver Disease (NAFLD). *Am J Gastroenterol.* 2007 Dec;102(12):2716-7.

18. Grattagliano I, Portincasa P, Palmieri VO, Palasciano G. Managing nonalcoholic fatty liver disease: recommendations for family physicians. *Can Fam Physician.* 2007 May;53(5):857-63. Review

19. Rogers NM, Peh CA, Faull R, Pannell M, Cooper J, Russ GR. Transmission of toxoplasmosis in two renal allograft recipients receiving an organ from the same donor. *Transpl Infect Dis.* 2007 Jul 1.

20. Schneider V, Lévesque LE, Zhang B, Hutchinson T, Brophy JM. Association of selective and conventional nonsteroidal antiinflammatory drugs with acute renal failure: A population-based, nested case-control analysis. *Am J Epidemiol.* 2006 Nov 1;164(9):881-9. Epub 2006 Sep 27.

21. Al-Azzam SI, Abu-Dahoud EY, El-Khatib HA, Dawoud TH, Al-Husein BA. Etiologies of chronic renal failure in Jordanian population. *J Nephrol.* 2007 May-Jun;20(3):336-9.

22. Gooch K, Culleton BF, Manns BJ, Zhang J, Alfonso H, Tonelli M, Frank C, Klarenbach S, Hemmelgarn BR. NSAID use and progression of chronic kidney disease. *Am J Med.* 2007 Mar;120(3):280.e1-7.

23. Hernández-Hernández E, Alberú J, González-Michaca L, Bobadilla-del Valle M, Correa-Rotter R, Sifuentes-Osornio J. Screening for tuberculosis in the study of the living renal donor in a developing country. *Transplantation.* 2006 Jan 27;81(2):290-2.

24. Green M, Avery RK, Preskasaitis J eds, “Guidelines for the Prevention and Management of Infectious Complications of Solid Organ Transplantation” *Am J Transpl* 2004: 4(Suppl. 10).

25. Dew MA, Jacobs CL, Jowsey SG, Hanto R, Miller C, Delmonico FL; Guidelines for the psychosocial evaluation of living unrelated kidney donors in the United States. *Am J Transpl* 2007 May;7(5):1047-54.

26. Ramcharan T, Matas AJ: Long-term (20-37 years) follow-up of living kidney donors. *Am J Transplant* 2:959-964., 2002

27. Fehrman-Ekholm I, Elinder CG, Stenbeck M, Tyden G, Groth CG: Kidney donors live longer. *Transplantation* 64:976-978., 1997

28. Narkun-Burgess DM, Nolan CR, Norman JE, Page WF, Miller PL, Meyer TW: Forty- five year follow-up after uninephrectomy. *Kidney Int* 43:1110-1115., 1993

29. Najarian JS, Chavers BM, McHugh LE, Matas AJ: 20 years or more of follow-up of living kidney donors. *Lancet* 340:807-810., 1992
30. Fehrman-Ekholm I, Duner F, Brink B, Tyden G, Elinder CG: No evidence of accelerated loss of kidney function in living kidney donors: results from a cross-sectional follow-up. *Transplantation* 72:444-449, 2001
31. Goldfarb DA, Matin SF, Braun WE, Schreiber MJ, Mastroianni B, Papajcik D, Rolin HA, Flechner S, Goormastic M, Novick AC: Renal outcome 25 years after donor nephrectomy. *J Urol* 166:2043-2047., 2001
32. Kasiske BL, Ma JZ, Louis TA, Swan SK: Long-term effects of reduced renal mass in humans. *Kidney Int* 48:814-819., 1995
33. Ellison MD, McBride MA, Taranto SE, Delmonico FL, Kauffman HM: Living kidney donors in need of kidney transplants: a report from the organ procurement and transplantation network. *Transplantation* 74:1349-1351., 2002
34. Fehrman-Ekholm I, Thiel GT: *Long-term risks after kidney donation*. London and New York, Taylor & Francis, 2005
35. Hartmann A, Fauchald P, Westlie L, Brekke IB, Holdaas H: The risk of living kidney donation. *Nephrol Dial Transplant* 18:871-873, 2003
36. Organ Procurement and Transplant Network. as of February 2005
37. Davis C, Ojo AO: Living Donor Risks. *Amercian Transplant Congress*, 2005

### 3. **Proposal to Require Transplant Centers to Inform Potential Recipients about Known High Risk Donor Behavior**

The Committee reviewed this proposal at its May 12, 2008, meeting. The Committee supports informing transplant candidates if their potential deceased donor has a history of high risk behavior, but also opined that donor risk should be based on state of the art risk assessment rather than outdated CDC criteria. The Committee was unanimous in recommending revision of CDC high risk criteria.

The Committee was very concerned that the policy could be applied to living donors. The Committee acknowledges that OPO's are seldom involved in living donation, and that current language may imply that it applies to deceased donors. However, other Committees and some regions also questioned if the policy would apply to living donors.

Living Donor confidentiality is of paramount importance to the Committee. As the policy is currently stated, a potential living donor might not be offered an opportunity to opt out of the donation process rather than have his or her high risk status disclosed. The Living Committee recommends revising this policy to specify that it only applies to deceased organ donors.

The Committee recommends the following modifications to clarify that the policy only applies to deceased donors. 18-1-0

\*\*\* **RESOLVED, that the modification to Policy 4.1.1 (Communication of Donor History), set forth below, is hereby approved, effective pending distribution of notice.**

**4.0 ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS), HUMAN PITUITARY DERIVED GROWTH HORMONE (HPDGH), AND REPORTING OF POTENTIAL RECIPIENT DISEASES OR MEDICAL CONDITIONS, INCLUDING MALIGNANCIES, OF DONOR ORIGIN**

**4.1 [No Changes]**

**4.1.1 Communication of Donor History.** The Host OPO will obtain a history on each potential deceased donor in an attempt to determine whether the potential donor is in a "high risk" group, as defined by the Centers for Disease Control and Prevention (CDC). If the donor meets the criteria below,<sup>1</sup> the Host OPO must communicate this information regarding donor history to all institutions receiving organs from the donor.

Behavior/History Criteria

- i) Men who have had sex with another man in the preceding 5 years.
- ii) Persons who report nonmedical intravenous, intramuscular, or subcutaneous injection of drugs in the preceding 5 years.
- iii) Persons with hemophilia or related clotting disorders who have received human derived clotting factor concentrates.
- iv) Men and women who have engaged in sex in exchange for money or drugs in the preceding 5 years.
- v) Persons who have had sex in the preceding 12 months with any person described in terms i-iv above or with a person known or suspected to have HIV infection.
- vi) Persons who have been exposed in the preceding 12 months to known or suspected HIV-infected blood through percutaneous inoculation or through contact with an open wound, nonintact skin, or mucous membrane.
- vii) Inmates of correctional systems (This exclusion is to address issues such as difficulties with informed consent and increased prevalence of HIV in this population).

Pediatric Donor Criteria

- viii) Children meeting any of the criteria listed above for adults.

- ix) Children born to mothers with HIV infection or mothers who meet the behavioral or laboratory criteria for adult donors (regardless of their HIV status) unless they are greater than 18 months of age, have not been breast fed within the last 12 months and the child's antibody tests, physical examination, and review of medical records do not indicate evidence of HIV infection.
- x) Children less than or equal to 18 months of age who are born to mothers with or at risk for HIV infection or who have been breast fed within the past 12 months.

#### Laboratory and Other Medical Criteria

- xi) Persons who cannot be tested for HIV infection because of refusal, inadequate blood samples (e.g., hemodilution that could result in false-negative tests), or another other reasons.
- xii) Persons with a repeatedly reactive screening assay for HIV-1 or HIV-2 antibody regardless of the results of supplemental assays.
- xiii) Persons whose history, physical examination, or medical records reveal other evidence of HIV infection or high-risk behavior, such as a diagnosis of AIDS, unexplained weight loss, night sweats, blue or purple spots on the skin or mucous membranes typical of Kaposi's sarcoma, unexplained lymphadenopathy lasting greater than 1 month, unexplained temperature greater than 100.5 F (38.6 C) for greater than 10 days, unexplained persistent cough and shortness of breath, opportunistic infections, unexplained persistent diarrhea, male to male sexual contact, sexually transmitted diseases, or needle tracks or other signs of parenteral drug abuse.

If the transplant center receives information from the Host OPO that the deceased donor meets any of the above criteria, the transplant center must inform the potential recipient prior to implantation. The transplant center shall maintain documentation of the potential recipient's informed consent to receive an organ from the donor who meets any of the above criteria. In the event that the potential recipient is not able to provide informed consent, the legal next of kin, designated healthcare representative, or appropriate surrogate may provide consent on this matter.

Briefing Paper

As one of its annual goals, the Living Donor Committee was asked to revise patient notification bylaws to include living donors, thus providing living donors with the same information and protections given to candidates on the national deceased donor transplant waiting list. Under the proposed policy change, recipient transplant centers must provide written notification to living organ donors within ten business days following their donation date to include: the telephone number that is available for living donors to report concerns or grievances through the OPTN; disclosure that the recipient transplant center is required to submit Living Donor Follow-up (LDF) forms for a minimum of two years; and the plan for obtaining living donor data for completion of follow-up forms.

The Bylaws establish membership criteria for deceased donor transplantation programs as well as transplant programs that perform living donor transplants. Bylaws are intended to create a standardized level of quality among transplant programs.

Under existing Bylaws, transplant centers send written notification to transplant candidates when:

- a transplant evaluation has been completed and a patient is not going to be placed on the waiting list;
- the candidate has been placed on the waiting list; and
- the candidate has been removed from the waiting list for reasons other than transplant or death.

This notification must be sent within 10 days and must include the telephone number that is available for patients and others to report grievances to the OPTN. In addition to these requirements, notification of listing letters must include the date of listing in the body of the letter.

The Committee supports notifying living donors about the UNOS Patient Services telephone number available for reporting concerns or grievances through the OPTN.

The Committee debated when the potential living donor or actual living donor should receive this notification. This debate included valuable insights from the living donors on the Committee. The Committee considered the recently approved Bylaws for the informed consent and medical evaluation of living donors. Under these new bylaws, each potential living donor will have the benefit of an Independent Donor Advocate who:

- (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.

With these safeguards in place, the Committee felt it was unlikely that potential living donors would have concerns or grievances to report during the medical evaluation and consent process. Living donors on the Committee commented that the pre-operative period is sometimes overwhelming. A potential donor who eventually becomes a living donor may not remember the mechanism for reporting concerns or grievances with the transplant center after the surgery. The Committee ultimately supported requiring written notification to living to living donors in the early post-operative period. The Committee recommended this notification be sent donors within 10 days following their donation to maintain consistency with existing bylaws.

Existing Bylaws and Policies stipulate that recipient transplant programs must submit Living Donor Follow-up forms addressing health information about each living donor at 6 months, one year, and two years post-donation. Each transplant center is also required to develop a protocol that includes a plan to collect follow-up information about each living donor.

Some living donors have contacted UNOS to report problems in receiving follow-up care from their transplant centers. Most of these complaints involve lack of responsiveness and inadequate services. In response to these living donor complaints, the Committee is recommending that recipient transplant centers also disclose their responsibilities for submitting follow-up forms on living donors in this notification letter.

The Committee acknowledges that, in some cases, the recipient transplant center may have no direct interaction with the living donor. Under existing bylaws and policies, all transplant centers must be OPTN/UNOS members and follow those rules and regulations. Since some living donors donate at non- OPTN/UNOS transplant centers, the recipient transplant center must bear the responsibility for living donor notification.

The proposal was released for public comment on February 8, 2008.

Overall public comment supported the concept of providing living donors with the phone number available to report grievances to the OPTN, but revealed opposition to providing the notification ten days after donation. Instead, most public comment responses recommended providing the notification during the consent process for living donors. A summary of the public comment and Committee's responses follow.

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## SUMMARY OF PUBLIC COMMENTS

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### LIVING DONOR COMMITTEE - PROPOSAL TO CHANGE THE OPTN/UNOS BYLAWS TO REQUIRE WRITTEN NOTIFICATION (OR DISCLOSURES) TO LIVING DONORS FROM THE RECIPIENT TRANSPLANT PROGRAMS

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As of 4/30/2008, 48 responses have been submitted to UNOS regarding this policy proposal. Of these, 35 (72.92%) supported the proposal, 11 (22.92%) opposed the proposal, and 2 (4.17%) had no opinion. Of the 46 who responded with an opinion, 35 (76.09%) supported the proposal and 11 (23.91%) opposed the proposal. Comments on the proposal received to date are as follows:

#### **I: Individuals Comments:**

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#### COMMENT 1:

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*vote: Oppose*

*Date Posted: 05/05/2008*

eS5SU4 akiyguclak, [url=<http://levotxmroijs.com/>]levotxmroijs[url],  
[link=<http://lkkdaxnaohih.com/>]lkkdaxnaohih[link], <http://junfekbfceejx.com/>

***Committee Response: Unable to respond.***

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#### COMMENT 2:

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*vote: Oppose*

*Date Posted: 02/08/2008*

I feel that this information should be provided prior to donation. Potential donors may have legitimate concerns and have a right to know the grievance process whether they are able to donate or not.

***Committee Response: Comment indicates support for the intent of this proposal, but disagree with timing of notification.***

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**COMMENT 3:**

---

*vote: Oppose*

*Date Posted: 02/08/2008*

I support providing this information to donors, but it is appropriately shared at the evaluation rather than after the donation (recipients are provided this upon listing, not after transplant.) Otherwise will miss those who are only evaluated.

***Committee Response: Comment indicates support for the intent of this proposal, but disagree with timing of notification.***

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**COMMENT 4:**

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*vote: Oppose*

*Date Posted: 05/04/2008*

i3HgfF mqkrgjpkdlcq, [url=<http://bdvteejopjc.com/>]/bdvteejopjc[/url],  
[link=<http://bqztymjiajgo.com/>]/bqztymjiajgo[/link], <http://fmiykohmtwml.com/>

***Committee Response: Unable to respond.***

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**COMMENT 5:**

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*vote: Oppose*

*Date Posted: 04/25/2008*

qg4AcQ ilhjgbmkkhxc, [url=<http://gcpipjgljswm.com/>]/gcpipjgljswm[/url],  
[link=<http://npmvklqkrqlx.com/>]/npmvklqkrqlx[/link], <http://wnbpfvjfafa.com/>

***Committee Response: Unable to respond.***

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**COMMENT 6:**

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*vote: Oppose*

*Date Posted: 04/16/2008*

SEE ATTACHMENT

***Committee Response: Attachment not available for response.***

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**COMMENT 7:**

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*vote: Oppose*

*Date Posted: 04/30/2008*

see attachment

***Committee Response: Unable to open attachment and provide response.***

 Read Comment

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**COMMENT 8:**

---

*vote: Oppose*

*Date Posted: 04/24/2008*

This disclosure should be done during the consent of the donor, not after the fact.

***Committee Response: Comment indicates support for the intent of this proposal, but disagreement with timing of the notification.***

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**COMMENT 9:**

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*vote: Oppose*

*Date Posted: 04/29/2008*

YOU ARE REGULATING US TO DEATH. WE NOW SPEND MORE TIME TRYING TO KEEP UP WITH UNOS & CMS REGS. THEN WE DO CARING FOR PATIENTS.

***Committee Response:***

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**COMMENT 10:**

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*vote: Support*

*Date Posted: 02/17/2008*

all transplant patients and living donors must be protected by having needed information at the right time. The pre op period is overwhelming and needed information is simply discarded as the brain struggles to cope with the implications of the surgery. I support written notification or disclosures to living donors within ten days of surgery as a safeguard to their long term health.

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**COMMENT 11:**

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*vote: Support*

*Date Posted: 02/08/2008*

Following my donation, I had many concerns and problems and I had absolutley no where to go. As soon as the kidney was taken from me- everyone was done with me. Not a single care was given to my post op care or state.

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**COMMENT 12:**

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*vote: Support*

*Date Posted: 02/09/2008*

I do support the above change in the bylaws and feel that more long term medical follow up on living donors needs to be considered. Patrick M. Buddle M.D.

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**COMMENT 13:**

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*vote: Support*

*Date Posted: 02/08/2008*

I don't oppose this - but why wait until after the donation? Shouldn't this information be shared with the potential LD as part of their Informed consent process prior to donation?

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**COMMENT 14:**

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*vote: Support*

*Date Posted: 02/08/2008*

I propse that living donors who are medically excluded also receive written notification within 10 business days the telephone number to report concerns or grievances.

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**COMMENT 15:**

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*vote: Support*

*Date Posted: 02/10/2008*

I whole-heartedly support the Living Donor Committee proposal; esp. when it comes to follow-up care for the living donor. My personal experience as a living organ donor was positive; however the follow-up care was poor (there was none).

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**COMMENT 16:**

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*vote: Support*

*Date Posted: 02/08/2008*

My transplant center does do a 2 year follow up of me(donor June 2006). I am coming up on my two years in June. Now I would like to have access to research studies on problems and outcomes of living donors long term.

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**COMMENT 17:**

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*vote: Support*

*Date Posted: 02/20/2008*

Seems they should have access to any and all information related to their decision to donate.

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**COMMENT 18:**

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*vote: Support*

*Date Posted: 04/15/2008*

There needs to be a way to get the feedback to a program, how will grievances be dealt with?

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**COMMENT 19:**

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*vote: Support*

*Date Posted: 04/25/2008*

Transplant programs should be required to retain documentation of compliance with this policy.

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### REGIONAL COMMENT SUMMARY

**PROPOSAL 3: Proposal to Change the OPTN/UNOS Bylaws to Require Written Notification (or Disclosures) to Living Donors from the Recipient Transplant Hospitals.**

The goal of this proposal is to provide living donors with the same information and protections given to candidates on the national transplant waitlist. Under the proposed change, recipient transplant centers must provide written notification to living organ donors within ten business days following their donation date to include the following:

- telephone number that is available for living donors to report concerns or grievances through the OPTN
- disclosure that the recipient transplant center is required to submit Living Donor Follow-up (LDF) forms to the OPTN for a minimum of two years
- plan for obtaining living donor data for completion of follow-up forms

**DATE THIS DOCUMENT MODIFIED: 5/7/08**

Region	Meeting Date	Motion to Approve as Written	Approved as Amended (see below)	Did Not Consider
1	3/31/2008	0 yes, 13 no, 1 abstention		
2	04/18/2007	4 yes, 17 no, 0 abstentions	19 yes, 0 no, 0 abstentions	
3	5/2/2008	4 yes, 12 no, 1 abstention		
4	5/2/2008	8 yes, 10 no, 1 abstention		
5	5/1/2008		25 yes, 0 no, 0 abstentions	
6	3/7/2008	34 yes, 5 no, 0 abstentions		
7	3/18/2008	0 yes, 17 no, 0 abstentions	16 yes, 0 no, 1 abstention	
8	4/25/2008	18 yes, 2 no, 0 abstentions		
9	3/26/2008	4 yes, 10 no, 5 abstentions		
10	3/28/2008	0 yes, 16 no, 0 abstentions		
11	3/20/2008	4 yes, 10 no, 0 abstentions		

Region 1: The region opposed the proposal for the following reasons:

- CMS requires that most of this information be provided before the donation date
- Opposed to arbitrary timeframes

- Living liver donors are often not at home to receive the letter ten days after the donation date
- There is no way of knowing for sure that the living donor received the information

One member commented that OPTN/UNOS cannot be an advocate for the living donor and a telephone number should be included for an advocate such as the NKF or Living Donors *Online!*

The members suggested that the information required in this proposal be provided before the donation date (perhaps during the consent process) and during the first post-op visit.

***The Committee debated when the potential living donor or actual living donor should receive this notification. This debate included valuable insights from the living donors on the Committee. The Committee considered the recently approved OPTN/UNOS bylaws for the informed consent and donor medical evaluation of living donors. Under these new bylaws, each potential living donor will have the benefit of an Independent Donor Advocate who:***

- (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.***

***With these safeguards in place, the Committee felt it was unlikely that potential living donors would have concerns or grievances to report to the OPTN during the medical evaluation and consent process. Living donors on the Committee commented that the pre-operative period is sometimes overwhelming. A potential donor who eventually becomes a living donor may not remember the mechanism for reporting concerns or grievances with the transplant center after the surgery. The Committee ultimately supported requiring a written notification be sent to living donors in the early post-operative period.***

Region 2: The region did not support the proposal as written. There was concern about providing the information post-transplant. The Members agreed that this information should be required during the donor evaluation. In addition, there was support for changing the language to read “no later than 10 business days following their donation date. This language would allow centers to provide the information pre-donation.

***The Committee debated when the potential living donor or actual living donor should receive this notification. This debate included valuable insights from the living donors on the Committee. The Committee considered the recently approved OPTN/UNOS***

*bylaws for the informed consent and donor medical evaluation of living donors. Under these new bylaws, each potential living donor will have the benefit of an Independent Donor Advocate who:*

- (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.**

*With these safeguards in place, the Committee felt it was unlikely that potential living donors would have concerns or grievances to report to the OPTN during the medical evaluation and consent process. Living donors on the Committee commented that the pre-operative period is sometimes overwhelming. A potential donor who eventually becomes a living donor may not remember the mechanism for reporting concerns or grievances with the transplant center after the surgery. The Committee ultimately supported requiring a written notification be sent to living donors in the early post-operative period.*

Region 3: The region did not support this proposal. During the discussion of this proposal the following concerns were raised:

- This proposal would add a third layer to the consent process since the Conditions of Participation requires consent at evaluation and then consent at transplant.

*The CMS CoP do not provide the telephone number that is available for living donors to report concerns or grievances through the OPTN;*

- What does the 10 day period accomplish?

*The 10 day period was selected to mirror existing policy.*

*The OPTN/UNOS bylaws establish membership criteria for deceased donor transplantation programs as well as transplant programs that perform living donor transplants. Bylaws are intended to create a standardized level of quality among transplant programs.*

*Under existing OPTN/UNOS bylaws, transplant centers send written notification when:*

- *a transplant evaluation has been completed and the patient is not going to be placed on the waiting list;*

- *the candidate has been placed on the waiting list; and*
- *a candidate has been removed from the waiting list for reasons other than transplant or death.*

*This notification must be sent within 10 days and must include the telephone number that is available for patients and others to report grievances to the OPTN. In addition to these requirements, notification of listing letters must include the date of listing in the body of the letter.*

Region 4: Several members supported the proposal but felt that the notification letter should be sent 10 business days prior to the donation date, not 10 business days following the donation date. In addition, the region would like for UNOS to establish guidelines on how it responds to grievances (the process that is followed) received through the patient hotline and distribute for public comment. It is unclear to members what process is followed and many cannot support this proposal until it is outlined in policy.

*The Committee debated when the potential living donor or actual living donor should receive this notification. This debate included valuable insights from the living donors on the Committee. The Committee considered the recently approved OPTN/UNOS bylaws for the informed consent and donor medical evaluation of living donors. Under these new bylaws, each potential living donor will have the benefit of an Independent Donor Advocate who:*

- (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.*

*With these safeguards in place, the Committee felt it was unlikely that potential living donors would have concerns or grievances to report to the OPTN during the medical evaluation and consent process. Living donors on the Committee commented that the pre-operative period is sometimes overwhelming. A potential donor who eventually becomes a living donor may not remember the mechanism for reporting concerns or grievances with the transplant center after the surgery. The Committee ultimately supported requiring a written notification be sent to living donors in the early post-operative period.*

Region 5: The region amended the proposal to state that the notification letter should be sent during the evaluation phase NOT post donation.

*The Committee debated when the potential living donor or actual living donor should receive this notification. This debate included valuable insights from the living donors on the Committee. The Committee considered the recently approved OPTN/UNOS bylaws for the informed consent and donor medical evaluation of living donors. Under these new bylaws, each potential living donor will have the benefit of an Independent Donor Advocate who:*

- (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.*

*With these safeguards in place, the Committee felt it was unlikely that potential living donors would have concerns or grievances to report to the OPTN during the medical evaluation and consent process. Living donors on the Committee commented that the pre-operative period is sometimes overwhelming. A potential donor who eventually becomes a living donor may not remember the mechanism for reporting concerns or grievances with the transplant center after the surgery. The Committee ultimately supported requiring a written notification be sent to living donors in the early post-operative period.*

Region 6: During the discussion there were some Members who were concerned about the timing of the notice. These Members thought that the potential donor should receive this notification at the start of the evaluation rather than after donation.

*The Committee debated when the potential living donor or actual living donor should receive this notification. This debate included valuable insights from the living donors on the Committee. The Committee considered the recently approved OPTN/UNOS bylaws for the informed consent and donor medical evaluation of living donors. Under these new bylaws, each potential living donor will have the benefit of an Independent Donor Advocate who:*

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- (c) assists the potential donor in obtaining and understanding information regarding the:*
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Region 7: Region 7 supported the concept of this proposal but felt that the letter should be sent to any potential living donor with the information included in the original proposal during the evaluation phase. They made this change for the following reasons:

- Consistence with recipient evaluation protocols.
- Each potential living donor should be provided the same information as potential recipients. The fact that a transplant has or has not occurred should not factor into them receiving the information.
- To ensuring that living donors are aware of the follow-up and the option to report grievances via the OPTN the information needs to be provided at a time when they are able to focus solely on information and not their current medical status.

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*supported requiring a written notification be sent to living donors in the early post-operative period.*

They were also comments made about the follow-up being the responsibility of the recipient transplant centers especially for pediatric transplant centers who may never see an adult donor in their hospital either for donation evaluation, donation procedure, or follow-up.

*The Committee acknowledges that, in some cases, the recipient transplant center may have no direct interaction with the living donor. Under existing bylaws and policies, all transplant centers must be OPTN/UNOS members and follow its rules and regulations. Since some living donors donate their organ at non- OPTN/UNOS transplant centers, the recipient transplant center must bear the responsibility for living donor notification.*

Region 8: Although the region supported this proposal, there was concern about providing the information post-transplant. Many of the Members agreed that this information should be required during the donor evaluation. In addition, there was support for changing the language to read “no later than 10 business days following their donation date. This language would allow centers to provide the information pre-donation.

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*supported requiring a written notification be sent to living donors in the early post-operative period.*

Region 9: The region did not support the proposal as written and was concerned about sending a letter to living donors post-op. Many were of the opinion that the letter should be sent prior to the donation date and that ii and iii below are not necessary to include in the letter, only the telephone number available to report concerns or grievances through the OPTN.

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(ii) disclosure that the recipient transplant center is required to submit Living Donor Follow-up (LDF) forms to the OPTN for a minimum of two years; and

(iii) the plan for obtaining living donor data for completion of follow-up forms.

*Existing OPTN/UNOS bylaws already mandate that recipient transplant programs must disclose their responsibility to submit Living Donor Follow-up forms addressing the health information on each living donor at 6 months, one-year, and two-years post donation; and disclose their plan to collect the information about each donor.*

*Some living donors have contacted UNOS to report problems in receiving follow-up care from their transplant centers. Most of these complaints involve lack of responsiveness and inadequate services. In response to these living donor complaints the Living Donor Committee is recommending that recipient transplant centers also disclose their responsibilities for submitting follow-up forms on living donors in this notification letter.*

Region 10: Although the region supported that living donors should be provided this information they felt strongly that this policy change would add expense to the transplant center without gain. They felt that this information should be provided through the previously established system for ensuring that the donor's rights were protected, the Independent Donor Advocate. They also were concerned since they felt, at this time, the patient community does not understand the appropriate use of the 800 UNOS number and that without working the "kinks" out of this system before it was introduced to the living donor community we may be only increase their level of frustration.

Region 11: The region felt that this was not necessary since a CMS requirement already addresses this.

*The CMS CoP do not provide the telephone number that is available for living donors to report concerns or grievances through the OPTN*

**Committee Comment**

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**Ad Hoc International Relations Committee**

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No comment.

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**Communications Committee**

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No comment received

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**Ethics Committee**

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No comment received

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**Executive Committee**

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No comment received

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**Finance Committee**

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No comment received

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**Histocompatibility Committee**

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Support with no comment.

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**Kidney Transplantation Committee**

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The Kidney Transplantation Committee reviewed this proposal during its March 2008 meeting. Many on the Committee expressed that this information would also be useful to donors prior to donation as a part of informed consent.

15 in favor, 0 opposed, 0 abstentions

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**Liver and Intestinal Organ Transplantation Committee**

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No comment received

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**Living Donor Committee**

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N/A

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**Membership and Professional Standards Committee**

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The MPSC was not meeting during the period of public comment so it considered this proposal using the Committee Management System. The issue was posted for review from February 11, 2008 until March 13, 2008 and 13 members reviewed it and submitted individual comments.

The MPSC members who reviewed the proposal voted 8 For, 5 Against, 0 Abstentions.

Individual Member Comments:

- This information is in the consent for evaluation, discharge instructions, and other educational material. Sending a letter after surgery is over kill.
- Donors should be notified of this at the time of the evaluation (just as recipients are), and not mailed to them within 10 days of the surgery. This allows for a uniform practice (more likely to have compliance, and also more easy to monitor for compliance). This also allows for notification of donors who are evaluated but ultimately do not go on to donate (some of them may wish to have this access to the grievance number also.)
- Strongly disagree. This information needs to be given to donors before the donation, not as a "by the way" after the fact. I think it serves no purpose.
- Prospective living donors should have the same avenues available to report concerns (and receive the same notification) as individuals who proceed to living donation. This would make the process analogous to that for prospective recipients, as not all prospective recipients proceed to transplant, yet all are notified of avenues available for reporting concerns. Simply because it's unlikely this information will be used does not mean it should be withheld until a more convenient time, regardless of new safeguards such as the Independent Donor Advocate. What if the Donor Advocate is the source of concern? After donation disclosures regarding the obligations of transplant centers that relate to the donor, and the donor's privacy, are ill timed. All disclosures should be provided during the consent process, otherwise an informed consent cannot be obtained.

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- Passing on the UNOS Patient Services phone number and that this is done within 10 days.
- (1) Why 10 days? Many surgeons see post-op patient 2-3 weeks after surgery. Why not pass along any information at that visit, when the opportunity to address patient concerns face-to-face has occurred. Is the 10-day period anything but arbitrary?

*Under existing OPTN/UNOS bylaws, transplant centers send written notification when:*

- *a transplant evaluation has been completed and the patient is not going to be placed on the waiting list;*
- *the candidate has been placed on the waiting list; and*
- *a candidate has been removed from the waiting list for reasons other than transplant or death.*

*This notification must be sent within 10 days and must include the telephone number that is available for patients and others to report grievances to the OPTN. In addition to these requirements, notification of listing letters must include the date of listing in the body of the letter.*

*The Living Donor Committee was charged to revise the patient notification bylaws to include living donors. The Committee supports notifying living donors about the UNOS Patient Services telephone number available for reporting concerns or grievances through the OPTN. The Committee is recommending the notification be sent to living donors within 10 days following their donation to maintain consistency with existing bylaws.*

- (2) Most importantly: after major surgery, our emphasis should be on counseling the patient about what is a normal and expected post-operative course and getting the patient back to baseline health, not inviting them to litigation and grievance. UNOS fielding their concerns re: recovery, medical care, personal attention, analgesia, and outcomes strikes me as an uninvolved third party that is completely ill equipped to sort out the extent and validity of any complaint. I am appalled by the lack of trust in our system of qualified surgeons and the care we deliver to organ donors. Every hospital has a Patient Bill of Rights and system in place to address patient concerns.

This is the logical regress for patients with complaints that are not satisfactorily addressed by the treating physician and transplant team.

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**Minority Affairs committee**

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The committee determined that there was no minority impact from the proposed policy.

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**Operations committee**

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No Comment

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**OPO committee**

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The OPO Committee chose not to discuss this proposal.

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**Organ Availability committee**

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The Committee discussed this proposal on their April 14th conference call and is in full support (13-0-0). The Committee offers the following considerations:

- This is a redundant policy, and, in addition, the patients are already receiving too much to read
- It is recommended that the phone number be made available before the transplant to address grievances
- It is too much material to give a letter both before and after the transplant, rather have the letter mailed up to two weeks of the planned donation or fold it into the pre-op information because patients have too much they need to remember after the transplant
- The wording should be changed to “10 days after discharge from the hospital” acknowledging that some donors may still be in the hospital at 10 days still receiving treatment. Change “donation date” to ten days post-hospital stay as follows:
  - Appendix B: OPTN Bylaws
    - F. (1) Patient Notification
      - (2) Recipient transplant programs must provide written documentation to living organ donors within ten days post-hospital stay to include the following....

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*With these safeguards in place, the Committee felt it was unlikely that potential living donors would have concerns or grievances to report to the OPTN during the medical evaluation and consent process. Living donors on the Committee commented that the pre-operative period is sometimes overwhelming. A potential donor who eventually becomes a living donor may not remember the mechanism for reporting concerns or grievances with the transplant center after the surgery. The Committee ultimately supported requiring a written notification be sent to living donors in the early post-operative period.*

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#### **Pancreas Transplantation committee**

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The Pancreas Committee considered this proposal during its March 14, 2008 meeting. The Pancreas Committee voted to support this proposal. (14-Support, 0-Oppose, 0-Abstain)

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#### **Patient Affairs committee**

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The Committee supported the written notification requirements proposed by the Living Donor Committee with a vote of 14:0:1 with the following modifications: 1. The written notification should be provided during the consent process since knowledge of such information could possibly influence the decision to serve as a living donor; 2. Such written notification should be provided by the center on a separate (downloadable) letter with UNOS letterhead. (This latter suggestion resulted from a similar discussion regarding the patient notification requirement within the bylaws which led to many patients mistakenly calling the UNOS patient services line to reach their transplant center.)

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#### **Pediatric Transplantation committee**

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The Committee noted that while on the surface this appears to benefit patient safety, there appears to be little direction regarding how the collection of living donor data is to be

managed. Adult living donors for pediatric recipients and paired exchanges were raised as examples where follow-up can be challenging. The proposal does not outline any requirements for follow-up in centers, most likely because it is unclear who pays for this extended care. Members noted that follow-up care for living donors is generally left to clinical judgment. Follow-up care is not paid for beyond a limited number of post-operative tests. As a result, members suggested that it will be difficult for centers to collect this data, leaving many as potentially non-compliant with policy.

***Existing OPTN/UNOS bylaws already mandate that recipient transplant programs must disclose their responsibility to submit Living Donor Follow-up forms addressing the health information on each living donor at 6 months, one-year, and two-years post donation; and disclose their plan to collect the information about each donor.***

The timing of sending contact information for living donors to report concerns or grievances to the OPTN was also questioned. Living donors are usually not feeling well and not focused on such information immediately after surgery. Members felt strongly that this information should be discussed and dispersed prior to donation.

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***With these safeguards in place, the Committee felt it was unlikely that potential living donors would have concerns or grievances to report to the OPTN during the medical evaluation and consent process. Living donors on the Committee commented that the pre-operative period is sometimes overwhelming. A potential donor who eventually becomes a living donor may not remember the mechanism for reporting concerns or grievances with the transplant center after the surgery. The Committee ultimately supported requiring a written notification be sent to living donors in the early post-operative period.***

Due to these substantial concerns, the Committee was uncomfortable with supporting this proposal. Members suggested that as written, it may not achieve the Living Donor

Committee's desired goals and ultimately may create paperwork without changing outcomes. As a result, the Committee voted unanimously to oppose the proposal as written (Committee vote: 16-0-0).

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### Policy Oversight committee

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W. Kenneth Washburn, M.D. reviewed this proposal from the Living Donor Committee, which would require that recipient transplant programs must provide written notification to living organ donors within ten business days following their donation date to include:

- The telephone number that is available for living donors to report concerns or grievances through the OPTN;
- Disclosure that the recipient transplant center is required to submit Living Donor Follow-up (LDF) forms to the OPTN for a minimum of two years; and
- The plan for obtaining living donor data for completion of follow-up forms.

The Committee reiterated its previous comments that the notification should be provided to potential living donors earlier in the process, perhaps when consent for evaluation is obtained. This is consistent with many individual and regional comments on the proposal. This would also be consistent with the requirement that that transplant candidates must be notified within ten business days of the patient's being placed on the waiting list (i.e., pre-rather than post-transplant). The information could be provided after donation as well. The Committee also suggested that the notifications procedure and contact information should be placed on the OPTN and UNOS websites.

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### Thoracic Organ Transplantation committee

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The Committee did not support this proposal: 18-Opposed; 0-Support; 0-Abstention. The Committee supported the concept, but did not support the timing of the information delivery. The information should be delivered to the living donor once his/her candidacy for donation is established.

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- (iv) *benefit and need for follow-up.*

*With these safeguards in place, the Committee felt it was unlikely that potential living donors would have concerns or grievances to report to the OPTN during the medical evaluation and consent process. Living donors on the Committee commented that the pre-operative period is sometimes overwhelming. A potential donor who eventually becomes a living donor may not remember the mechanism for reporting concerns or grievances with the transplant center after the surgery. The Committee ultimately supported requiring a written notification be sent to living donors in the early post-operative period.*

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#### **Transplant Administrators committee**

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The TAC recommends changing the language to read “recipient transplant centers must provide written notification to living organ donors no later than ten business days following their donation date to include the following:” with the understanding that most centers will put this information in the evaluation or consent document rather than in a document sent after the transplant.

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### **Transplant Coordinators committee**

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The TCC opposed this proposal by a vote of 0-13-0.

The TCC felt that the 10 day time frame would not be effective for living donors and would create a situation where transplant centers may fail to meet policy.

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