OPTN/UNOS Living Donor Committee
Report to the Board of Directors
November 12-13, 2012
St. Louis, MO

Summary

I. Action Items for Board Consideration

- The Board of Directors is asked to approve a proposal to establish policy for the informed consent of living kidney donors and to modify existing related policy. New Policies 12.2 (Informed Consent of Living Kidney Donors) and 12.4 (Independent Donor Advocates) and modification of Policy 12.10 (Required Protocols for Kidney Recovery Hospitals) and Policy 12.7.10.1 (Vessel Recovery and Transplant). (Item 1, Page 2)

- The Board of Directors is asked to approve a proposal to establish policy for the medical evaluation of living kidney donors and to modify existing related policy. New Policies: 12.3.3 (Psychosocial Evaluation of the Living Kidney Donor), 12.3.4 (Medical Evaluation of the Kidney Living Donor); and modification of Policy 12.10 (Required Protocols for Kidney Recovery Hospitals). (Item 2, Page 12)

- The Board of Directors is asked to approve a proposal which would establish minimum requirements for living kidney donor follow-up and to modify existing related policy. New Policy 12.8.3.1 (Living Kidney Donor Reporting Requirements); and modification to Policies 7.2 (General Submission of Forms), 12.8.3 (Reporting Requirements) and Policy 12.10 (Required Protocols for Kidney Recovery Hospitals). (Item 3, Page 23)

- The Board of Directors is asked to approve a proposal to modify existing policy to require reporting of unexpected potential and proven disease transmission involving living organ donors. Modification of Policy 4.5 (Post-Transplant Reporting of Potential Transmission of Disease or Medical Conditions, Including Malignancies) and Policy 12.2 (Informed Consent of Living Donors). (Item 4, Page 35)

II. Other Significant Items

- Committee members are participating on a Joint Societies Work Group which is preparing policy recommendations for living liver donor consent, medical evaluation and follow-up policy development. (Item 5, Page 39)

- The Committee will propose new policy requirements for independent donor advocates during the spring 2013 public comment period. (Item 6, Page 39)

- The Committee is working with the SRTR to determine which living donor program metrics should be included in program specific reports. (Item 7, Page 39)

Report of the
OPTN/UNOS Living Donor Committee
to the Board of Directors

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Christie Thomas, MB, FRCP, FASN, FAHA, Chairperson
Sandra Taler, MD, Vice Chair

The following report is a summary of the Living Donor (LD) Committee's deliberations and discussions during its full Committee meetings held on April 2, 2012, August 14, 2012, September 10, 2012, and October 11, 2012.

1. **Proposal to Establish Requirements for the Informed Consent of Living Kidney Donors. New Policies 12.2 (Informed Consent of Living Kidney Donors) and 12.4 (Independent Donor Advocates) and modification of Policy 12.10 (Required Protocols for Kidney Recovery Hospitals) and Policy 12.7.10.1 (Vessel Recovery and Transplant).**

   On June 16, 2006, the Health Resources and Services Administration (HRSA) published a notice in the Federal Register in which the Secretary of Health and Human Services directed the Organ Procurement and Transplant Network (OPTN) to develop policies regarding living organ donors and organ donor recipients, including policies for the equitable allocation of living donor organs (in accordance with section 121.8 of the OPTN Final Rule). The notice directed the OPTN to develop such policies in the same manner, and with the same public comment process, that it does for policies on deceased organ donors and deceased organ donor recipients. The notice stipulated that noncompliance with such policies will subject OPTN members to the same consequences as noncompliance with OPTN policies regarding deceased donor transplantation.

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

   The Committee completed an assessment of all submitted protocols. This evaluation revealed wide variation in the living donor consent process throughout the country. Some transplant centers did not have formalized guidelines for living donor consent. To provide OPTN Members with a shared knowledge base, the Living Donor Committee used the 80/20 rule in evaluating submitted protocols. If eighty percent of programs had a particular element as part of their standardized consent processes, the Committee included that

element in the proposed guidelines. The Committee also reviewed and incorporated certain recommendations from a variety of sources, including the Advisory Committee on Organ Transplantation (ACOT), Centers for Medicare and Medicaid Services (CMS), and the State of North Carolina living donor statutes in the development of these guidelines.

Guidelines for the Consent of Living Donors were released for public comment between July 13, 2007 and August 11, 2007. The Guidelines included recommendations for donor candidate selection, Independent Donor Advocacy, donor evaluation, management, and follow-up.

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

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

During the September 2007 Board meeting, the Board approved *Guidance for the Informed Consent of Living Donors.* This resource has been available through the OPTN website since September 2007 and may be viewed at http://optn.transplant.hrsa.gov/resources/professionalresources.asp?index=7.

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

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

During this meeting, it was noted that early involvement of the societies in the OPTN policy development process, for the purpose of identifying the appropriate medical requirements and the appropriate level of specificity of such requirements, could be an important advance that might allow such policies to be developed in a timelier way with better initial acceptance by the transplant community.

It was determined that a Joint Societies Policy Steering Committee (comprised of members from the AST, ASTS, NATCO, OPTN/UNOS, and HRSA) would be given an opportunity to make recommendations on any OPTN policy under development that has the potential to prescribe medical care, including policies for the consent, medical evaluation, and follow-up of living kidney donors.

The Joint Societies Policy Steering Committee formed a Joint Societies Work Group (JSWG) consisting of appointed members of the represented societies to develop recommendations to include the informed consent living kidney donors. The charge of the

Joint Societies Work Group was to *"provide recommendations to the OTPN/UNOS regarding appropriate requirements for the medical evaluation (including the psychosocial evaluation) and informed consent of potential living kidney donors as well as post-donation follow-up and data submission*."

In response to its charge, the JSWG created three resources representing the consensus of its members, which included a position paper on the Informed Consent of Living Kidney Donors **(Exhibit A)**. These resource documents were approved by the Executive Committees of the parent societies and forwarded to UNOS and the Living Donor Committee for consideration in policy development.

A subcommittee of the Living Donor Committee reviewed the position paper on the Informed Consent of Living Kidney Donors. In general, the subcommittee agreed with the informed consent recommendations, but determined that some of the recommendations were too prescriptive, and should not be included in the proposal prepared for consideration by the full Committee. The Committee reviewed this proposal on July 20, 2011, and approved it for public comment.

The proposal was released for public comment between September 16, 2011, and January 12, 2012, and the proposal was generally supported by the general public, the regions, and other committees.

During the public comment period, UNOS staff from the Policy Department and Department of Evaluation and Quality reviewed the proposal and suggested a series of technical amendments to make some elements of the proposal easier to monitor and measure.

After the public comment period ended, two Living Donor Committee subcommittees considered the technical amendments and all public comment received on the proposal. A separate subcommittee took responsibility for drafting and approving responses to all public comment received on the proposal.

The Committee met on April 2, 2012, to review public comment and prepare a final draft of the proposal. The Committee approved sending the proposal to the Board of Directors for consideration during the June 2012 meeting. Vote 28-0-0

On June 18, 2012, representatives of the professional societies, HRSA, and OPTN/UNOS met by conference call. During this call the representatives of the professional societies objected to what they viewed as "substantive changes" in the three living donor proposals to be considered by the Board and a failure to follow procedures required under the Rockville document (**Exhibit B**). In response, the OPTN/UNOS President agreed to table Board consideration of the living donor proposals pending further discussion between JSWG and the LD committee.

The professional societies were asked to provide written lists of the "substantive changes" identified in the living donor policy proposals, which are available for review. (**Exhibit C**)

On July 6, 2012, the Committee leadership and members of the JSWG met by LiveMeeting to review and discuss the lists of "substantive changes" provided by the professional societies, and during this call the group reached consensus on how many of the "substantive changes" might be addressed.

On August 14, 2012, members of the JSWG and the full Living Donor Committee met by LiveMeeting to review the lists of "substantive changes" provided to the Committee. This LiveMeeting provided an opportunity for the JSWG to present their objections to the proposals and for Committee members and JSWG members to discuss each item.

The Committee held its biannual meeting on September 10, 2012. Dr. Stuart Flechner, Chair of the JSWG and Dr. John Roberts, OPTN/UNOS President, attended this meeting. During this meeting, committee members reviewed and reconsidered the "substantive changes" provided by the professional societies. The Committee supported removing all references to the Kidney Paired Donation pilot and agreed to add the phrase "on average" to the language describing the percentage of loss of kidney function at donation.

The Committee supported changing Policy 12.7.10.1 so the consent forms used for potential living donors would not need to indicate that vessels may be used for transplant. Instead, a recovery hospital will only need to obtain consent for vessel recovery in the rare cases when extra vessels will be obtained from the living donor.

The Committee approved a final version of the proposal for Board consideration. Vote 24-0-0

The briefing paper includes all public comment received on the proposal and reflects all changes to the proposal in response to public comment, technical amendments suggested by UNOS staff, and the "substantive changes" identified by the transplant professional societies or the JSWG. **(Exhibit D)**.

The Committee developed a "crosswalk" to illustrate the evolution of this policy proposal. The crosswalk compares the original recommendations from the JSWG, the original proposed policy language distributed for public comment, and the final proposed policy (post public comment and any content modified after the June 2012 Board meeting) to be considered by the Board of Directors **(Exhibit E)**.

The Resource Assessment and Impact Statement for this proposal is provided in **Exhibit F**.

The following proposal is recommended for consideration by the Board.

The proposed new policies 12.2 (Informed Consent of Living Kidney Donors) and 12.4 (Independent Donor Advocates) and modification to existing policy appear below. As proposed new policies, the entire text of the policies would typically be underlined. In addition to underlining, the policies would also contain double underlining and strikeouts to indicate changes based on public comment. Since the proposed policies would be difficult to read with extensive underlining and strikeouts, these proposed policies are being presented differently. For your convenience, proposed final policy language is presented without strikeouts and underlining. Proposed changes to the existing policy are indicated with strikeouts.

Additionally, please note that when this proposal was released for public comment (September 16, 2011 and January 12, 2012); it included a provision to remove existing Bylaw requirements for the consent of living kidney donors, which would be moved to policy under this proposal. As noted above, this proposal was originally planned for Board consideration in June 2012, but it was not presented to the Board at that time.

During the June 2012 Board meeting, the Board approved plain language revisions of the Bylaws which moved existing Bylaws for the consent of living kidney donors to policy 12.10. Consequently, it has been necessary to change this proposal so it modifies or eliminates elements of Policy 12.10 rather than the Bylaws (which no longer exist).

Proposed policy language with strikeouts and underlining is provided in the briefing paper **(Exhibit D)**.

**** RESOLVED, that new Policies 12.2 (Informed Consent of Living Kidney Donors) and 12.4 (Independent Donor Advocates) and modification of Policy 12.10 (Required Protocols for Kidney Recovery Hospitals) and Policy 12.7.10.1 (Vessel Recovery and Transplant), are hereby approved as set forth below, effective February 1, 2013:**

12.2 Informed Consent of Living Kidney Donors

Introduction:

Education is important to enable the potential donor to understand all aspects of the donation process, especially the risks and benefits.

The goal of informed consent is to ensure that a potential donor understands:

1) That he or she will undertake risk and will receive no medical benefit from the donor nephrectomy.

2) That there are both general risks of the operation as well as center specific risks.

Living Kidney Donor Consent

The recovery hospital must obtain informed consent from any potential living kidney donor which must include, but is not limited to, documentation in the donor chart of the following:

a. Written assurance by the potential donor that he or she is willing to donate, free from inducement and coercion, and has been informed that he or she may decline to donate at any time. Potential donors must be offered an opportunity to discontinue the donor consent or evaluation process and to do so in a way that is protected and confidential. The independent donor advocate (IDA) must be available to assist the potential donor during this process. (see Policy 12.4)

b. Instruction about all phases of the living donation process, which include consent, medical and psychosocial evaluations, pre and post operative care, and required post operative follow-up. (Policy 7.3.2) Teaching or instructional material can include any media (e.g., written, video, audio) or one-on-one or small group interaction. Teaching or instruction must be provided in a language in which the donor is able to engage in a meaningful dialogue with the transplant program staff.

c. Disclosure that the recovery hospital will take all reasonable precautions to provide confidentiality for the donor and recipient.

d. Disclosure that it is a federal crime for any person to knowingly acquire, obtain or otherwise transfer any human organ for valuable consideration (i.e., for anything of value such as cash, property, vacations).

e. Disclosure that the recovery hospitals must provide an Independent Donor Advocate (IDA).

f.

If the recovery hospital and the recipient hospital…	Then…	Including *all* the following information….
Are the same	The recovery hospital must provide the potential donor with both national and that hospital's program-specific transplant recipient outcomes from the most recent SRTR center-specific reports.	1. National 1-year patient graft survival 2. The hospital's 1-year patient and graft survival 3. Notification about all CMS outcome requirements not being met by the transplant hospital
Will not be the same and the recipient hospital is known	The recovery hospital must provide the potential donor with both national and the recipient hospital's program-specific transplant recipient outcomes from the most recent SRTR center-specific reports.	1. National 1-year patient and graft survival 2. The recipient hospital's 1-year patient and graft survival 3. Notification about all CMS outcome requirements not being met by the recipient hospital

g. Education about expected post-donation kidney function and how chronic kidney disease (CKD) and end-stage renal disease (ESRD) might potentially impact the donor in the future to include:

1) On average, donors will have some permanent loss of kidney function at donation.

2) Baseline risk or ESRD does not exceed that of members of the general population with the same demographic profile.

3) Donor risks must be interpreted in light of the known epidemiology of both CKD and ESRD. When CKD or ESRD occur, CKD generally develops in mid-life (40-50 years old) and ESRD generally develops after age 60. The medical evaluation of a young potential donor cannot predict lifetime risk of CKD or ESRD.

4) Donors may be at a higher risk for CKD if they sustain damage to the remaining kidney. The development of CKD and subsequent progression to ESRD may be more rapid with only one kidney.

5) Dialysis is required when reaching ESRD.

6) Current practice is to prioritize prior living kidney donors who become kidney transplant candidates. (Policy 12.9.3)

h. Disclosure of alternate procedures or courses of treatment for the recipient including deceased donor transplantation.

- The donor must be informed that a deceased donor kidney might become available for the recipient before the donor evaluation is completed or the living donor transplant occurs.

- The donor must be informed that any transplant candidate might have risk factors for increased morbidity or mortality that are not disclosed to the potential donor.

i. The disclosure that the donor will receive a thorough medical and psychosocial evaluation.

j. Inform the donor that health information obtained during their evaluation will be subject to the same regulations as all records and could reveal conditions that the transplant center must report to local, state or federal public health authorities.

k. Disclosure that recovery hospitals are required to report living donor follow-up information at the time intervals specified in Policy 12.8.3, and have the potential donor commit to post-operative follow-up testing coordinated by the living donor recovery hospital.

12.2.1 Living Kidney Donor Evaluation Consent

The recovery center must maintain documentation in the donor chart that it informed the potential donor of the following:

- That the potential donor must undergo a medical and psychosocial evaluation as required in Policy 12.3

- That the transplant hospital may refuse the potential donor. In such cases, potential donors must be informed that they could be

evaluated by another transplant program that may have different selection criteria.

- That the following are inherent risks associated with evaluation for living donation:

  i. allergic reactions to contrast,
  ii. discovery of reportable infections,
  iii. discovery of serious medical conditions,
  iv. discovery of adverse genetic findings unknown to the donor, and discovery of certain abnormalities that will require more testing at the donor's expense or create the need for unexpected decisions on the part of the transplant team.

- The following surgical, medical, psychosocial, and financial risks are associated with living kidney donation. This disclosure must state that these risks may be transient or permanent and include, but are not limited to the following:

  i) Potential Medical or Surgical Risks:

  - Death;
  - Scars, pain, fatigue, and other consequences typical of any surgical procedure;
  - Decreased kidney function;
  - Abdominal or bowel symptoms such as bloating and nausea and developing bowel obstruction;
  - Kidney failure and the need for dialysis or kidney transplant for the donor; and
  - Impact of obesity, hypertension, or other donor-specific medical condition on morbidity and mortality of the potential donor.

  ii) Potential Psychosocial Risks:

  - Problems with body image;
  - Post-surgery depression or anxiety;
  - Feelings of emotional distress or bereavement if the transplant recipient experiences any recurrent disease or in the event of the transplant recipient's death; and
  - Impact of donation on the donor's lifestyle.

iii) Potential Financial Impacts:

- Personal expenses of travel, housing, child care costs, and lost wages related to donation might not be reimbursed; however, resources might be available to defray some donation-related costs;
- Need for life-long follow-up at the donor's expense;
- Loss of employment or income;
- Negative impact on the ability to obtain future employment;
- Negative impact on the ability to obtain, maintain, or afford health, disability, and life insurance; and,
- Future health problems experienced by living donors following donation may not be covered by the recipient's insurance.

12.4. Independent Donor Advocate

The living donor recovery hospital must provide an independent donor advocate (IDA) who is not involved with the potential recipient evaluation and is independent of the decision to transplant the potential recipient.

12.4.1 The IDA must assist the potential donor with the evaluation process and focus on their needs and questions. The IDA must be knowledgeable about risks and benefits associated with all phases of the donation process. IDA responsibilities include, but are not limited to the following:

- Promote the best interests of the potential living donor
- Advocate for the rights of the potential donor
- Assist the potential donor in obtaining and understanding information regarding the:

1) Consent process;
2) Evaluation process;
3) Surgical procedure;
4) Medical and psychosocial risks;
5) Benefit and need for follow-up.

12.7.10.1 Vessel recovery and transplant

A recovery hospital may only recover extra vessels for transplant if the living donor consents to the removal of extra vessels for transplant. ~~The consent forms used by the donor recovery transplant center must include language that indicates that vessels may be used for transplant.~~

12.10 Required Protocols for Kidney Recovery Hospitals

Kidney recovery hospitals must demonstrate that they have the following protocols:

(i) Living Donation Process Protocols: Kidney recovery hospitals must develop, and once developed must comply with written protocols to address all phases of the living donation process. Specific protocols shall include the ~~evaluation,~~ pre-operative, operative, post-operative care, and submission of required follow-up forms at 6 months, one-year, and two-years post donation.

Kidney recovery hospitals must document that all phases of the living donation process were performed in adherence to the hospital's protocol. This documentation must be maintained and made available upon request.

~~(ii) Independent Donor Advocate Protocols: Kidney transplant programs that perform living donor kidney transplants must develop, and once developed, must comply with written protocols for the duties and responsibilities of Independent Donor Advocate (IDA) that include, but are not limited to, the following elements:~~

~~(1) a description of the duties and primary responsibilities of the IDA to include procedures that ensure the IDA:~~

~~(a) promotes the best interests of the potential living donor;~~
~~(b) advocates the rights of the potential living donor; and~~
~~(c) assists the potential donor in obtaining and understanding information regarding the:~~

~~1. consent process;~~
~~2. evaluation process;~~
~~3. surgical procedure; and~~
~~4. benefit and need for follow-up.~~

(iii) Medical Evaluation Protocols: Kidney recovery hospitals must develop, and once developed, must comply with written protocols for the medical evaluation of the potential living donors that must include, but are not limited to, the following elements:

(1) a thorough medical evaluation by a physician and/or surgeon experienced in living donation to assess and minimize risks to the potential donor post-donation, which shall include a screen for any evidence of occult renal and infectious disease and medical co-morbidities, which may cause renal disease;
(2) a psychosocial evaluation of the potential living donor by a psychiatrist, psychologist, or social worker with experience in transplantation (criteria defined in Appendix B, Attachment I) to determine decision making capacity, screen for any pre-existing psychiatric illness, and evaluate any potential coercion;

(3) screening for evidence of transmissible diseases such as cancers and infections; and
(4) anatomic assessment of the suitability of the organ for transplant purposes.

~~(iv) Informed Consent Protocols: Kidney recovery hospitals must develop, and once developed, must comply with written protocols for the Informed Consent for the Donor Evaluation Process and for the Donor Nephrectomy, which include, at a minimum, the following elements:~~

~~(1) discussion of the potential risks of the procedure including the medical, psychological, and financial risks associated with being a living donor;~~
~~(2) assurance that all communication between the potential donor and the transplant center will remain confidential;~~
~~(3) discussion of the potential donor's right to opt out at any time during the donation process;~~
~~(4) discussion that the medical evaluation or donation may impact the potential donor's ability to obtain health, life, and disability insurance;~~
~~(5) disclosure by the kidney recovery hospital that it is required, at a minimum, to submit Living Donor Follow-up forms addressing the health information of each living donor at 6 months, one year, and two years post donation. The protocol must include a plan to collect the information about each donor; and~~
~~(6) the telephone number that is available for living donors to report concerns or grievances through the OPTN.~~
~~(7) documentation of disclosure by the kidney recovery hospital to potential donors that the sale or purchase of human organs is a federal crime and that it is unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation. This documentation must be maintained in the potential donor's official medical record.~~

2. **Proposal to Establish Requirements for the Medical Evaluation of Living Kidney Donors. New Policies: 12.3.3 (Psychosocial Evaluation of the Living Kidney Donor) and 12.3.4 (Medical Evaluation of the Kidney Living Donor); and modification of Policy 12.10 (Required Protocols for Kidney Recovery Hospitals)**.

On June 16, 2006, the Health Resources and Services Administration (HRSA) published a notice in the Federal Register in which the Secretary of Health and Human Services directed the Organ Procurement and Transplant Network (OPTN) to develop policies regarding living organ donors and living organ donor recipients, including policies for the equitable allocation of living donor organs, (in accordance with section 121.8 of the final rule). The notice directed the OPTN to develop such policies in the same manner, and with the same public comment process, that is done for policies on deceased organ donors and deceased donor organ recipients. The notice stipulated that noncompliance with such policies will subject OPTN members to the same consequences as noncompliance with OPTN policies regarding deceased donor transplantation.

Based on this directive, the Committee began this new area of work by investigating current practices for the medical evaluation of living donors. In January 2007, the OPTN/UNOS President sent a letter to all living kidney and liver transplant programs requesting copies of their informed consent, medical evaluation, and living donor follow-up

protocols. The letter explained that federal regulation now required the OPTN to develop policies regarding living donors and living donor organ recipients, and that the Committee planned to use these protocols to make recommendations to the OPTN/UNOS Board of Directors regarding new living donor guidelines. The recommendation would be used to develop guidelines to ensure that individual institution's living donor evaluation protocols consistently meet the needs and interests of potential living donors, and that they reflect the consensus of expertise among medical professionals involved in living donor transplantation.

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

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

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

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

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

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

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

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

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

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

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

During this meeting, it was noted that early involvement of the societies in the policy development process, for the purpose of identifying the appropriate medical requirements and the appropriate level of specificity of such requirements, could be an important advancement which would hopefully allow such policies to be developed in a more timely manner with better initial acceptance by the transplant community at large.

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

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

In response to its charge the JSWG created three resources representing the consensus of its members, including a position paper on the Medical and Psychosocial Evaluation of Living Kidney Donors **(Exhibit A)**. These resource documents were approved by the Executive Committees of the Parent Societies and forwarded to the Living Donor (LD) Committee for consideration in policy development. A subcommittee of the LD Committee reviewed the JSWG position paper on the Medical and Psychosocial Evaluation of Living Kidney Donors. In general, the subcommittee agreed with the recommendations for medical and psychosocial evaluation of living kidney donors, but did determine that some of the recommendations were too prescriptive. The Committee had particular difficulty

determining how to handle the relative contraindications against living kidney donation as recommended by the JSWG. The Committee preferred to include relative contraindications in the proposal but understood that relative contraindications could not be converted into specific rules, and without specific rules, the policies could not be enforceable.

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

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

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

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

The proposal was released for public comment between September 16, 2011, and January 12, 2012. During the public comment period, UNOS staff from the Policy Department and Department of Evaluation and Quality reviewed the proposal and suggested a series of technical amendments to make some elements of the proposal easier to monitor and measure.

After the public comment period ended, two Living Donor Committee subcommittees considered the technical amendments and all public comment received on the proposal. A separate Living Donor Committee subcommittee took responsibility for drafting and approving responses to all public comment received on the proposal.

The Committee met on April 2, 2012, to review public comment and consider a final draft of the medical evaluation proposal. The Committee approved sending the proposal to the Board of Directors for consideration at the next Board meeting. Vote 27-1-0

On June 18, 2012, representatives of the professional societies, HRSA, and OPTN/UNOS met by conference call. During this call the representatives of the professional societies objected to what they viewed as "substantive changes" in the three living donor proposals to be considered by the Board and a failure to follow procedures required under the Rockville document (**Exhibit B**). In response, the OPTN President agreed to table Board consideration of the living donor proposals pending further discussion between JSWG and the LD committee.

The professional societies were asked to provide written lists of the "substantive changes" identified in the living donor policy proposals, which are available for review. (**Exhibit C**)

On July 6, 2012, the Committee leadership and members of the JSWG met by LiveMeeting to review and discuss the lists of "substantive changes" provided by the professional societies, and during this call the group reached consensus on how many of the "substantive changes" might be addressed.

On August 14, 2012, members of the JSWG and the full Living Donor Committee met by LiveMeeting to review the lists of "substantive changes" provided to the Committee. This LiveMeeting provided an opportunity for the JSWG to present their objections to the proposals and for Committee members and JSWG members to discuss each item.

The Committee held its biannual meeting on September 10, 2012. Dr. Stuart Flechner, Chair of the JSWG and Dr. John Roberts, OPTN/UNOS President attended this meeting. During this meeting, committee members reviewed and reconsidered the "substantive changes" provided by the professional societies. For this medical evaluation proposal, the Committee supported modification of the tuberculosis screening requirement, using the American Cancer Society for center specific screening protocols, and adding the word "both" to the exclusion criteria for age and mental capacity.

The Committee approved a final version of the proposal for Board consideration. Vote 24-0-0

The Disease Transmission Advisory Committee has prepared a resource titled: *Guidance for Identifying Risk Factors for Mycobacterium tuberculosis (MTB) During Evaluation of Potential Living Donors* to assist programs with determining which potential living donor may need tuberculosis screening.

The briefing paper includes all public comment received on the proposal and reflects all changes to the proposal in response to public comment, technical amendments suggested by UNOS staff, and the "substantive changes" identified by the professional societies or JSWG. **(Exhibit G)**.

The Committee developed a "crosswalk" to illustrate the evolution of this policy proposal. The crosswalk compares the original recommendations from the JSWG, the original proposed policy language distributed for public comment, and the final proposed policy (post public comment and any content modified after the June 2012 Board meeting) to be considered by the Board of Directors **(Exhibit E)**.

The Resource Assessment and Impact Statement for this proposal is provided in **Exhibit H**.

The proposed new policies 12.3.3 (Psychosocial Evaluation of the Living Kidney Donor) and 12.3.4 (Medical Evaluation of the Living Kidney Donor) and modification to related policy appear below. As proposed new policies, the entire text of the policies would typically be underlined. In addition to underlining, the policies would contain double underlining and strikeouts to indicate changes based on public comment. Since the proposed policies would be difficult to read with extensive underlining and strikeouts, these proposed policies are being presented differently. For your convenience, proposed final policy language is presented without strikeouts and underlining. Proposed changes to existing are indicated with strikeouts.

Additionally, please note that when this proposal was released for public comment (September 16, 2011 and January 13, 2012); it included a provision to remove existing Bylaw requirements for the medical evaluation of living kidney donors, which would be moved to policy under this proposal. At noted above, this proposal was originally planned for Board consideration in June 2012, but it was not presented to the Board at that time.

During the June 2012 Board meeting, the Board approved revisions of the Bylaws which moved existing Bylaws requirements for the medical evaluation of living kidney donors to policy 12.10. Consequently, it has been necessary to change this proposal so it modifies or eliminates elements of Policy 12.10 rather than the Bylaws (which no longer exist).

Proposed policy language with strikeouts and underlining is provided in the briefing paper **(Exhibit G)**.

** **RESOLVED, that new Policies 12.3.3 (Psychosocial Evaluation of the Living Kidney Donor) and 12.3.4 (Medical Evaluation of the Living Kidney Donor) and modifications of Policy 12.10 (Required Protocols for Kidney Recovery), are hereby approved as set forth below, effective February 1, 2013:**

12.3.3 Psychosocial Evaluation of the Living Kidney Donor

This psychosocial evaluation must be performed by a psychiatrist, psychologist, and/or clinical social worker. Documentation of the psychosocial evaluation must be maintained in the donor record. The psychosocial evaluation must include the following components:

- Assess for any psychosocial (including mental health) issues that might complicate the living donor's recovery and identify potential risks for poor psychosocial outcome;

- Assess for the presence of high-risk behaviors as defined by the US Public Health Service (PHS) that have the potential to increase the risk of disease transmission to the recipient;

- Assess history of smoking, alcohol, and drug use/abuse and dependency;

- Identify factors that warrant educational or therapeutic intervention prior to final donation decision;

- Determine that the potential donor understands the short and long-term medical and psychosocial risks associated with living donation, for both donor and recipient;

- Assess whether the decision to donate is free of inducement, coercion, and other undue pressure; by exploring the reason(s) for volunteering to donate and the nature of the relationship (if any) to the transplant candidate;

- Assess the potential donor's ability to make an informed decision and the ability to cope with the major surgery and related stress. This includes the potential donor having a realistic plan for donation and recovery, with social, emotional and financial support available as recommended; and

- Review the occupation, employment status, health insurance status, living arrangements, and social support of the potential donor and determine if the potential donor understands the potential financial implications of living donation.

12.3.4 Medical Evaluation of the Living Kidney Donor

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

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

Documentation of the Medical Evaluation must be maintained in the donor record. The Medical Evaluation must include the following components:

A) General History:

- Evaluate for a personal history of significant medical conditions which include but are not limited to hypertension, diabetes, genetic renal diseases, lung disease, heart disease, gastrointestinal disease, autoimmune disease, neurologic disease, genitourinary disease, hematologic disorders, bleeding or clotting disorders, history of cancer and history of infections.

- Evaluate for Kidney Specific Personal History:

  Kidney disease, proteinuria, hematuria
  Kidney injury
  Diabetes including gestational diabetes
  Nephrolithiasis
  Recurrent urinary tract infections

- Active and past medications with special consideration for known nephrotoxic medications
- Allergies
- Evaluation for coronary artery disease

B) Family history of coronary artery disease and cancer

C) Kidney Specific Family History:

- Kidney disease
- Diabetes
- Hypertension
- Kidney Cancer

D) Social History:

The medical evaluation must determine:

- Occupation, employment status, health insurance status, living arrangements, and social support
- Smoking, alcohol and drug use/abuse
- High risk behavior as defined by the US PHS
- Psychiatric illness, depression, suicide attempts

E) Physical Exam:

- Height, weight, BMI
- Examination of all major organ systems
- Blood pressure
    - Taken on at least two different occasions; or
    - Perform 24-hour or overnight blood pressure monitoring

F) General Laboratory Tests:

- Complete Blood Count (CBC) with platelet count
- Blood Type and Screen
- Prothrombin Time (PT)
- International Normalized Ratio (INR) or Partial Thromboplastin Time (PTT)
- Metabolic testing (to include electrolytes, BUN, creatinine, transaminase levels, albumin, calcium, phosphorus, alkaline phosphatase, bilirubin)
- HCG quantitative pregnancy test for premenopausal women without surgical sterilization
- Chest X-Ray
- Electrocardiogram (ECG)

G) Other Metabolic Testing:

- Fasting blood glucose

- Fasting lipid profile (Cholesterol, Triglycerides, HDL Cholesterol, and LDL Cholesterol)
- Glucose Tolerance Test and/or Glycosylated Hemoglobin in first degree relatives of diabetics and in high risk individuals

H) Kidney-Specific Tests:

- Urinalysis; Urine microscopy
- Urine culture if clinically indicated
- Measurement of urinary protein and albumin excretion
- Measurement of glomerular filtration rate by isotopic methods or a creatinine clearance calculated from a 24-hour urine collection.
- Centers must establish a protocol and follow their protocol for screening for Polycystic Kidney Disease or other inherited renal disease as guided by family history
- Patients with a history of nephrolithiasis or nephrolithiasis (>3mm) identified on radiographic imaging-must have a 24 hour urine stone panel measuring calcium, oxalate, uric acid, citric acid, creatinine and sodium excretion

I) Anatomic Assessment:

An assessment to determine whether the kidneys are of equal size or have masses, cysts, or stones or other anatomical defects and to determine which kidney is more anatomically suitable for transplantation.

- The choice of test for radiologic imaging may be determined based upon the local radiological expertise and surgical preference, and may include CT angiogram or MR angiogram.

J) Screening for transmissible diseases:

Infectious disease testing must include:

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

For tuberculosis (TB), living donor recovery centers must determine if the potential donor is at increased risk for this infection, and if so testing must include:

- Screening for latent TB using either intradermal PPD or Interferon Gamma Release Assay (IGRA)

For the following infectious diseases, transplant centers must determine if the potential donor is from an endemic area, and if so testing must include:

- Strongyloides
- Trypanosoma cruzi
- West Nile

K) Cancer screening:

Centers must develop protocols consistent with the American Cancer Society (ACS), and once developed follow their own protocols for screening:

- Cervical Cancer
- Breast Cancer
- Prostate Cancer
- Colon Cancer
- Skin Cancer
- Lung cancer

L) Exclusion Criteria

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

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

- Both age less than 18 years and mentally incapable of making an informed decision
- Uncontrollable hypertension or history of hypertension with evidence of end stage organ damage
- HIV
- Diabetes
- Active malignancy, or incompletely treated malignancy
- High suspicion of donor coercion
- High suspicion of illegal financial exchange between donor and recipient
- Evidence of acute symptomatic infection (until resolved)
- Diagnosable psychiatric conditions requiring treatment before donation, including any evidence of suicidality

12.10 Required Protocols for Kidney Recovery Hospitals

Kidney recovery hospitals must demonstrate that they have the following protocols:

(i) Living Donation Process Protocols: Kidney recovery hospitals must develop, and once developed must comply with written protocols to address all phases of the living donation process. Specific protocols shall include the evaluation, ~~pre-operative, operative, post-operative care~~, and submission of required follow-up forms at 6 months, one-year, and two-years post donation.

~~Kidney recovery hospitals must document that all phases of the living donation process were performed in adherence to the hospital's protocol. This documentation must be maintained and made available upon request.~~

(ii) Independent Donor Advocate Protocols: Kidney transplant programs that perform living donor kidney transplants must develop, and once developed, must comply with written protocols for the duties and responsibilities of Independent Donor Advocate (IDA) that include, but are not limited to, the following elements:

(1) a description of the duties and primary responsibilities of the IDA to include procedures that ensure the IDA:

(a) promotes the best interests of the potential living donor;
(b) advocates the rights of the potential living donor; and
(c) assists the potential donor in obtaining and understanding information regarding the:

1. consent process;
~~2. evaluation process;~~
~~3. surgical procedure; and~~
4. benefit and need for follow-up.

~~(iii) Medical Evaluation Protocols: Kidney recovery hospitals must develop, and once developed, must comply with written protocols for the medical evaluation of the potential living donors that must include, but are not limited to, the following elements:~~

~~(1) a thorough medical evaluation by a physician and/or surgeon experienced in living donation to assess and minimize risks to the potential donor post-donation, which shall include a screen for any evidence of occult renal and infectious disease and medical co-morbidities, which may cause renal disease;~~
~~(2) a psychosocial evaluation of the potential living donor by a psychiatrist, psychologist, or social worker with experience in transplantation (criteria defined in Appendix B, Attachment I) to determine decision making capacity, screen for any pre-existing psychiatric illness, and evaluate any potential coercion;~~
~~(3) screening for evidence of transmissible diseases such as cancers and infections; and~~
~~(4) anatomic assessment of the suitability of the organ for transplant purposes.~~

(iv) Informed Consent Protocols: Kidney recovery hospitals must develop, and once developed, must comply with written protocols for the Informed Consent for the Donor Evaluation Process and for the Donor Nephrectomy, which include, at a minimum, the following elements:

(1) discussion of the potential risks of the procedure including the medical, psychological, and financial risks associated with being a living donor;

(2) assurance that all communication between the potential donor and the transplant center will remain confidential;
(3) discussion of the potential donor's right to opt out at any time during the donation process;
(4) discussion that the medical evaluation or donation may impact the potential donor's ability to obtain health, life, and disability insurance;
(5) disclosure by the kidney recovery hospital that it is required, at a minimum, to submit Living Donor Follow-up forms addressing the health information of each living donor at 6 months, one-year, and two-year post donation. The protocol must include a plan to collect the information about each donor; and
(6) the telephone number that is available for living donors to report concerns or grievances through the OPTN.
(7) documentation of disclosure by the kidney recovery hospital to potential donors that the sale or purchase of human organs is a federal crime and that it is unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation. This documentation must be maintained in the potential donor's official medical record.

3. **Proposal to Establish Minimum Requirements for Living Kidney Donor Follow-up and to Modify Existing Related Policy. New Policy 12.8.3.1 (Living Kidney Donor Reporting Requirements); and Modification to Policies 7.2 (General Submission of Forms), 12.8.3 (Reporting Requirements) and 12.10 (Required Protocols for Kidney Recovery Hospitals).**

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

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

(1) Living: Donor seen at transplant center;
(2) Living: Donor status updated by verbal or written communication between transplant center and donor;
(3) Living: Donor status updated by other health care facility;
(4) Living: Donor status updated by other source (example: recipient)
(5) Living: Donor contacted, declined follow up with transplant center;
(6) Dead;
(7) Lost: No attempt to contact donor; and
(8) Lost: Unable to contact donor (if selected the transplant center is required to document their efforts to contact the donor).

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

The Committee sponsored new bylaws which require transplant centers:

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

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

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

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

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

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

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

The MPSC agreed to study the issue through the formation of a joint work group with the Living Donor Committee. Final recommendations of the workgroup were issued in January 2009 and included the following:

- Enforce a minimum standard for submission of complete LDF forms.

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

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

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

- Support educational efforts to improve living donor follow-up data submission.

- Support the concept that completion of LDF forms and categorizing donors "as lost to follow-up" will become a metric for evaluating living donor programs in the future.

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

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

- ASTS and AST;

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

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

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

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

- There exists strong support for the following:

    a. Using the OPTN data supplemented by data from the Social Security Death Master File (SSDMF) and the National Death Index (NDI) as the mechanism for tracking short- and long-term deaths.
    b. Requiring center reporting and completion of data through a limited time interval (discharge through 6-12 months), with the duration depending on whether funding is made available to the centers.
    c. Developing a self-reporting mechanism for donors of a longer duration than that required of centers.

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

- The percentage of LDF forms submitted and validated within three month of the expected date

- The percentage of LDF forms submitted and validated within six months of the expected date

- The percentage of programs with donors who have a validated one-year LDF form with a known patient status (alive or dead) at least 300 days post-donation (i.e., donors who are not categorized as "lost to follow-up")

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

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

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

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

The *Proposal to Improve Reporting of Living Donor Status* was available for public comment between March 11 and June 10, 2011 and received overall support from the community. However, some regions, OPTN committees, members of the general public, and the National Kidney Foundation Living Donor Council commented that requiring centers to report only if their living donor was alive or dead was insufficient and did nothing to help determine how organ donation could affect the future health of living donors.

During this same public comment period, the American Society of Transplant Surgeons (ASTS) responded with opposition to the proposal. They commented that the OPTN/UNOS had established a Joint Societies Work Group (JSWG) consisting of members from ASTS,

AST, NATCO, and OPTN/UNOS to develop consensus policies on the consent, evaluation, and follow-up of the living kidney donor. Since streamlined recommendations for the follow-up for the living donor are a prominent part of the consensus document, ASTS suggested that the OPTN wait until this document was vetted through the societies prior to adopting any preliminary changes.

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

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

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

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

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

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

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

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

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

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

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

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

The resource titled, "Guidance for Developing and Implementing Procedures to Collect Post-Donation Follow-Up Data from Living Donors" is intended to help programs review, discuss, and generate ideas on how best to develop or improve their own strategies to promote optimal follow-up of living donors. Transplant programs should consider these recommendations as suggestions and consider the extent to which each suggestion may or may not be applicable or feasible given their own institutional setting and operational constraints.

Living donor transplant centers can use this resource as a "toolbox" when developing or modifying their living donor follow-up protocols. The toolbox may be useful for LDF data collection specifically, as well as for general issues of maintaining contact with donors after donation, and is available on the OPTN website at http://optn.transplant.hrsa.gov/resources/professionalresources.asp?index=7

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

The proposal was released for public comment between September 16, 2011, and January 12, 2012.

The Committee met on September 19, 2011, and reviewed the proposal and previewed a presentation on the proposal for use at upcoming regional meetings. During this meeting a HRSA representative questioned why the JSWG recommendation to collect information on the loss of insurance related to donation was not included in the proposal sent for public comment. The insurance question was not included in the proposal because it is not addressed on the Living Donor Follow-up (LDF) form and the Committee understood the form could not be easily modified. The HRSA representative instructed that the question could and should be part of required follow-up reporting and that the LDF form could be updated to capture this information.

After the public comment period ended, two Living Donor Committee subcommittees considered all public comment received on the proposal. A separate subcommittee took responsibility for drafting and approving responses to all public comment received on the proposal.

The Committee met on April 2, 2012, to review public comment and consider a final proposed draft of the living kidney donor follow-up proposal.

The Committee was evenly split on whether the 90% threshold should remain or should be lowered. The Committee did not support only requiring centers to documents their attempts to obtain follow-up, and opined it would not be possible to define an "adequate attempt" for follow-up in policy.

Other committee members felt the 90% threshold was too high and any threshold should be implemented in a staggered fashion. Some members commented that establishing follow-up policy will force centers to allocate staff and/or resources to remain compliant. Some

members commented that requiring follow-up was a fundamental change for transplant programs which would require new personnel and or new processes and would require time to implement.

After extensive discussion and several straw votes to consider and rule out possible options, the Committee approved modifying the proposal to provide a staggered minimum threshold for follow-up with pre-determined dates for increases in the threshold as follows:

12.8.3.1 Living Kidney Donor Reporting Requirements

Transplant centers that recover living kidney donor organs must report accurate, complete and timely follow-up data on the LDF form for at least:

- 70% of their living kidney donors who donate between September 1, 2012, and August 31, 2013;
- 80% of their living kidney donors who donate between September 1, 2013, and August 31, 2014; and
- 90% of their living kidney donors who donate beginning September 1, 2014.

Living donor follow-up data within 60 days of the six-month, one-year, and two-year anniversary of donation is considered timely. The completed data on the LDF at a minimum must include:

- Donor Status
  - Patient status
  - Cause of death, if applicable and known
  - Working for income, and if not working, reason for not working
  - Loss of insurance (health, disability, life) related to donation

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

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

The Committee approved sending the modified proposal to the Board for consideration. 23-0-0

On June 18, 2012, representatives of the professional societies, HRSA, and OPTN/UNOS met by conference call. During this call the representatives of the professional societies objected to what they viewed as “substantive changes” in the three living donor proposals to be considered by the Board and a failure to follow procedures required under the Rockville document (**Exhibit B**). In response, the OPTN/UNOS President agreed to table Board consideration of the living donor proposals pending further discussion between JSWG and the LD committee.

The professional societies were asked to provide written lists of the “substantive changes” identified in the living donor policy proposals, which are available for review. (**Exhibit C**)

On July 6, 2012, the Committee leadership and members of the JSWG met by LiveMeeting to review and discuss the lists of “substantive changes” provided by the professional societies, and during this call the group reached consensus on how many of the “substantive changes” might be addressed.

On August 14, 2012, members of the JSWG and the full Living Donor Committee met by LiveMeeting to review the lists of “substantive changes” provided to the Committee. This LiveMeeting provided an opportunity for the JSWG to present their objections to the proposals and for Committee members and JSWG members to discuss each item.

The Committee held its biannual meeting on September 10, 2012. Dr. Stuart Flechner, Chair of the JSWG and Dr. John Roberts, OPTN President attended this meeting. During this meeting, committee members reviewed and reconsidered the “substantive changes” provided by the professional societies. For this donor follow-up proposal, the Committee ultimately supported having different and lower thresholds for donor status and clinical information versus laboratory data.

The Committee supported sending this proposal for Board consideration. Vote 23-1-0

The UNOS Policy and Research Departments reviewed the proposed new policy language and offered recommendations which would clarify the proposed policy language and better define how and when the follow-up rates would be calculated. The Committee met by LiveMeeting on October 11, 2012, to review and approve the modified policy language. Vote 21-0-0

The briefing paper includes all public comment received on the proposal and reflects all changes to the proposal in response to public comment, technical amendments suggested by UNOS staff, and any elements modified in response to objections by the transplant professional societies or the JSWG. **(Exhibit I)**.

The Committee developed a “crosswalk” to illustrate the evolution of this policy proposal. The crosswalk compares the original recommendations from the JSWG, the original proposed policy language distributed for public comment, and the final proposed policy (post public comment and modified after the June 2012 Board meeting) to be considered by the Board of Directors **(Exhibit E)**.

It may be helpful for living donor programs to understand the anticipated timeline for this policy proposal. If the policy proposal is approved by the Board in November 2012, the policy would be expected to take effect on February 1, 2013. As proposed, the new reporting requirement would apply only to living kidney donors who donate beginning February 1, 2013. For these donors, living donor recovery hospitals would first be required to report under the new requirements for living donor follow-up beginning in August 2013 (when the six month LDF forms are due for donors who donated after February 1, 2013). The first cohort of donors to be reviewed will include donors who donate between implementation (February 2013) and August 2013. The six month LDFs for the last donor in this cohort will be due in March 2014. Centers must submit 100% of their forms within 6 months of their due date (Policy 7.81), so no center could be out of policy for failing to report required follow-up elements prior to **August 2014**.

The Resource Assessment and Impact Statement for this proposal is provided in **Exhibit J**.

The proposed new policies 12.8.1 (Living Donor Reporting Requirements) and modification to related policy appear below.

Please note that when this proposal was released for public comment (September 16, 2011 and January 12, 2012); it included a provision to remove existing Bylaw requirements for the kidney donors follow-up, which would be moved to policy under this proposal. At noted above, this proposal was originally planned for Board consideration in June 2012, but it was not presented to the Board at that time.

During the June 2012 Board meeting, the Board approved revisions of the Bylaws which moved existing Bylaws requirements for living donor follow-up to policy 12.10. Consequently, it has been necessary to change this proposal so it modifies or eliminates elements of Policy 12.10 rather than the Bylaws (which no longer exist).

For the convenience of the reader, new policy language is underlined and revised language is ~~stricken through~~. Changes that have been made post public comment appear in double underlines

****RESOLVED, that new Policies 12.8.3.1 (Living Kidney Donor Reporting Requirements) and modification of Policies 7.2 (General Submission of Forms), 12.8.3 (Reporting Requirements) and 12.10 (Required Protocols for Kidney Recovery Hospitals), are hereby approved as set forth below, effective February 1, 2013:**

7.2 General Submission of Forms

The Transplant Candidate Registration, Deceased Donor Registration, ~~Living Donor Follow-up,~~ Recipient Histocompatibility, Donor Histocompatibility, and Recipient Malignancy Forms must be submitted to the OPTN within 30 days of the form generation date. The Living Donor Follow-up Form must be submitted to the OPTN with 60 days of the form generation date.

12.8.3 Reporting Requirements

Transplant centers that recover living donor organs must complete the LDR form when the donor is discharged from the hospital or within six weeks following the transplant date, whichever is first. Living Donor Registration Forms (LDR) must be submitted to the OPTN within 60 days of the form generation date. ~~Transplant centers that recover living donor organs must complete the LDR form when the donor is discharged from the hospital or within six weeks following the transplant date, whichever is first. Transplant centers that recover living donor organs must submit LDF forms for each living donor at six months, one year and two years from the date of donation~~

12.8.3.1

Transplant centers that recover living donor organs must submit Living Donor Follow-up (LDF) forms for each living donor at six months, one year, and two years from the date of donation.

The transplant center must report accurate, complete, and timely follow-up data for Donor Status and Clinical Information using the LDF form for at least:

- 60% of their living kidney donors who donate between February 1, 2013 and December 31, 2013
- 70% of their living kidney donors who donate between January 1, 2014 and December 31, 2014
- 80% of their living kidney donors who donate after December 31, 2014.

The transplant center must report accurate, complete, and timely follow-up Kidney Laboratory Data using the LDF form for at least:

- 50% of their living kidney donors who donate between February 1, 2013 and December 31, 2013
- 60% of their living kidney donors who donate between January 1, 2014 and December 31, 2014
- 70% of their living kidney donors who donate after December 31, 2014.

- Donor Status and Clinical Information
    - Patient status
    - Cause of death, if applicable and known
    - Working for income, and if not working, reason for not working
    - Loss of medical (health, life) insurance due to donation
    - Has the donor been readmitted since last LDF form was submitted?
    - Kidney complications
    - Maintenance dialysis
    - Donor developed hypertension requiring medication
    - Diabetes
- Kidney Laboratory Data
    - Serum creatinine
    - Urine protein

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

Follow-up rates will be calculated separately, and at least annually, for the submission of the six-month, one-year, and two-year LDF forms

12.10 Required Protocols for Kidney Recovery Hospitals

Kidney recovery hospitals must demonstrate that they have the following protocols:
(i) Living Donation Process Protocols: Kidney recovery hospitals must develop, and once developed must comply with written protocols to address all phases of the living donation process. Specific protocols shall include the evaluation, pre-operative, operative, post-operative care, ~~and submission of required follow-up forms at 6 months, one-year, and two-years post donation~~.

Kidney recovery hospitals must document that all phases of the living donation process were performed in adherence to the hospital's protocol. This documentation must be maintained and made available upon request.

(ii) Independent Donor Advocate Protocols: Kidney transplant programs that perform living donor kidney transplants must develop, and once developed, must comply with written protocols for the duties and responsibilities of Independent Donor Advocate (IDA) that include, but are not limited to, the following elements:

(1) a description of the duties and primary responsibilities of the IDA to include procedures that ensure the IDA:

(a) promotes the best interests of the potential living donor;
(b) advocates the rights of the potential living donor; and
(c) assists the potential donor in obtaining and understanding information regarding the:

1. consent process;
2. evaluation process;
3. surgical procedure; and
~~4. benefit and need for follow-up.~~

(iii) Medical Evaluation Protocols: Kidney recovery hospitals must develop, and once developed, must comply with written protocols for the medical evaluation of the potential living donors that must include, but are not limited to, the following elements:

(1) a thorough medical evaluation by a physician and/or surgeon experienced in living donation to assess and minimize risks to the potential donor post-donation, which shall include a screen for any evidence of occult renal and infectious disease and medical co-morbidities, which may cause renal disease;
(2) a psychosocial evaluation of the potential living donor by a psychiatrist, psychologist, or social worker with experience in transplantation (criteria defined in Appendix B, Attachment I) to determine decision making capacity, screen for any pre-existing psychiatric illness, and evaluate any potential coercion;
(3) screening for evidence of transmissible diseases such as cancers and infections; and
(4) anatomic assessment of the suitability of the organ for transplant purposes.

(iv) Informed Consent Protocols: Kidney recovery hospitals must develop, and once developed, must comply with written protocols for the Informed Consent for the Donor Evaluation Process and for the Donor Nephrectomy, which include, at a minimum, the following elements:

(1) discussion of the potential risks of the procedure including the medical, psychological, and financial risks associated with being a living donor;
(2) assurance that all communication between the potential donor and the transplant center will remain confidential;
(3) discussion of the potential donor's right to opt out at any time during the donation process;
(4) discussion that the medical evaluation or donation may impact the potential donor's ability to obtain health, life, and disability insurance;
(5) disclosure by the kidney recovery hospital that it is required, at a minimum, to submit Living Donor Follow-up forms addressing the health information of each living donor at 6

months, one-year, and two-years post donation. The protocol must include a plan to collect the information about each donor; and
(6) the telephone number that is available for living donors to report concerns or grievances through the OPTN.
(7) documentation of disclosure by the kidney recovery hospital to potential donors that the sale or purchase of human organs is a federal crime and that it is unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation. This documentation must be maintained in the potential donor's official medical record.

4. Proposal to Require Reporting of Unexpected Potential and Proven Disease Transmission Involving Living Organ Donors. Modification of Policy 4.5 (Post-Transplant Reporting of Potential Transmission of Disease or Medical Conditions, Including Malignancies) and Policy 12.2 (Informed Consent of Living Donors).

In November 2010, the Board approved revisions to Policies 2.0 (Minimum Procurement Standards for an Organ Procurement Organization (OPO) and 4.0 (Identification of Transmissible Diseases in Organ Recipients). The revisions included rules for communication and reporting of all unexpected suspected potential or proven transmissions, including infections or malignancies. Many deceased donor events are reported when recipient illness develops and the donor is suspected as a source. Additionally, new deceased donor information such as final culture results received after donation or a tumor found post-recovery are required reporting as a suspected transmission.

There has been confusion about whether the 2010 policy revisions included living donor organs or whether they only applied to deceased donor organs. These policy revisions were intended to include living donor events, but did not specifically state this intent. Consequently, after these revised policies took effect, the Committee questioned if policy should be updated to clearly require the reporting of unexpected potential or proven transmissions involving living organ donors.

In the case of living donation, an unexpected transmission would be a condition that was not known or not detected prior to the recovery and transplant of a living donor organ. An expected or proven transmission would be a condition known prior to transplant. A CMV positive donor donating to a CMV negative recipient who is prophylaxed to prevent development of the illness would be an example of an expected disease transmission.

Current Policy 12.8.4 (Submission of Living Donor Death and Organ Failure Data) requires the reporting of living donor deaths, loss of native organ function, and the loss or redirection of any living donor organ through the Improving Patient Safety Portal (for two years post donation). The Committee first considered modifying this policy to also require reporting any unexpected potential or proven living donor- derived disease transmission, including infections or malignancies for two years post donation.

The Committee consulted the Disease Transmission Advisory Committee (DTAC) for input on this proposal. DTAC recommended an alternate policy approach that would not require new policy but would modify existing policy 4.5 (Post-Transplant Reporting of Potential Transmission of Disease or Medical Conditions Including Malignancies) to require reporting any unexpected suspected or proven living donor- derived disease transmission, including infections or malignancies.

The Disease Transmission Advisory Committee has prepared a resource titled: *Guidance for Reporting Potential Deceased and Living Donor-Derived Disease Transmission Events (PDTE)* to assist programs with determining which disease conditions are relevant and thus require reporting.

The proposal was sent for public comment between March 16 and June 15, 2012. After public comment, a Living Donor Committee subcommittee reviewed and prepared responses to all comments, which are available in the briefing paper **(Exhibit K)**.

The Committee met on September 10, 2012, to review public comment and approve final proposed policy language. Based on the strong public support for the proposal, the Committee approved sending the proposal for Board consideration without modification. Vote 22-0-0

The Resource Assessment and Impact Statement for this proposal is provided in **Exhibit L**.

For the convenience of the reader, new policy language is underlined and revised language is ~~stricken through~~. Changes that have been made post public comment appear in double underlines.

****RESOLVED, that modifications of Policies 4.5 (Post-Transplant Reporting of Potential Transmission of Disease or Medical Condition, Including Malignancies) and 12.2 (Informed Consent of Living Donors), are hereby approved as set forth below, effective February 1, 2013:**

4.5 POST-TRANSPLANT REPORTING OF POTENTIAL TRANSMISSION OF DISEASE OR MEDICAL CONDITIONS, INCLUDING MALIGNANCIES. In order to promote prompt notification of potential risk of disease transmission through organ transplantation, all events involving unexpected potential or proven transmission of a medical condition, including infections and malignancies, discovered after procurement of a deceased donor organ or recovery and transplant of a living donor organ must be reported to the OPTN Improving Patient Safety ~~System~~℠ Portal.

- When an organ recipient is suspected to have, is confirmed positive for, or has died from a potential transmissible disease or medical condition for which there is substantial concern that it could be of donor origin, then the transplant program must notify the Living Donor Recovery Center (for living donor recipients) or Host OPO (for deceased donor recipients) by phone and provide available documentation to the Living Donor Recovery Center or Host OPO as soon as possible, but, at the latest, within ~~and not to exceed~~ 24 hours of ~~this~~ their knowledge~~/concern~~ of the event. The transplant center that suspects potential transmission should not wait for all medical documentation that may eventually be available, but must inform:

    - the Living Donor Recovery Center or Host OPO and
    - the OPTN Improving Patient Safety ~~System~~ Portal.

    ~~to transfer knowledge/concern as soon as possible to~~
    - ~~all other centers that received organs from the same donor.~~

- If ~~When~~ a Host OPO learns ~~of~~ new information regarding a deceased donor, (~~i.e.~~ including but not limited to final culture results, information from autopsy report~~, etc.~~) as part of its donor follow-up (See Policy 2.2.5) that indicates risk of potential transmission of disease or malignancy, then the Host OPO must report the donor result through the OPTN Improving Patient Safety ~~System~~SM Portal.

- If a Recovery Center learns new information regarding a living donor, during the first two years post donation, (including but not limited to new or follow-up testing results, donor death or autopsy reports) that indicates risk of potential transmission of disease or malignancy, then the Recovery C~~c~~enter:

    - may need to report the new information to local, state or federal public health authorities;
    - must disclose to the living donor that a potential disease transmission or malignancy must be reported to the recipient transplant center and the OPTN Improving Patient Safety Portal;
    - must notify the recipient transplant center; and
    - must report the potential transmission through the OPTN Improving Patient Safety Portal.

4.5.1 Living Donor Recovery Center and Host OPO Responsibilities. The Living Donor Recovery Center or Host OPO shall be responsible for:

i. Communication of test results and diagnosis from a suspected donor and/or affected recipient(s) that may be pertinent to acute patient care as soon as practicable, not to exceed 24 hours, to any transplant program(s) Patient Safety Contact and tissue bank(s) that received an organ(s) or tissue from the donor who is the subject of the investigation. This includes results of all tests that were not available at the time of procurement or recovery (i.e. cultures, final pathology, etc) or subsequently performed after recovery and documenting that this information is shared with all recipient centers and tissue banks.

ii. Notification of the event to the OPTN Improving Patient Safety ~~System~~SM Portal as soon as possible, not to exceed 24 hours.

iii. Follow-up Communication of Potential Disease Transmission

•For deceased donors, completion and submission of the Potential Disease Transmission Report Form (a form that will be sent to the Host OPO after OPTN contractor receives the electronic notification from the OPTN Improving Patient Safety ~~System~~ Portal) to OPTN Patient Safety Staff within 24 hours of reporting the event through the Improving Patient Safety ~~System~~SM Portal to identify:

o The specific Patient Safety Contact at the recipient transplant program(s) and tissue bank(s) personnel that were notified of the potential transmission;

o Disposition of all organs, tissues and vessels; and

- Any preliminary information available regarding any remaining donor samples for additional testing, notification to state or local health department as appropriate for nationally notifiable infectious diseases, and whether an autopsy was performed on the donor.

- For all donors, ~~If requested by~~ the Ad Hoc Disease Transmission Advisory Committee~~,~~ may request submission of a Potential Disease Transmission Donor Follow-Up Report (a form that will be sent ~~to the Host OPO~~ by OPTN contractor staff) 45 days after the initial reporting date; OPTN Patient Safety Staff may request additional information related to the donor beyond 45 days, including pending test results depending on the potentially transmitted disease or condition.

iv. Management of the review, in partnership with OPTN Patient Safety Staff, to determine whether the organ donor was diagnosed with a potentially transmissible disease or condition;

4.5.2 Transplant Program Responsibilities. Any transplant program treating recipient(s) that received organ(s) from a donor who is the subject of a potential disease transmission report is responsible for:

i. Responding to Host OPO, Living Donor Recovery Center, or OPTN Patient Safety Staff requests for information regarding recipient(s) in a timely fashion and communicating updated information regarding recipient condition, test results, diagnosis, and plans for treatment and follow-up.

ii. Submitting copies of any pertinent test results (including cultures, serologies, imaging studies, autopsy results, etc.) to OPTN Patient Safety Staff.

iii. Notifying recipient(s) involved in cases of confirmed transmissions and documenting this notification in the recipient medical record as required in Policy 4.3.

iv. If requested by the Ad Hoc Disease Transmission Advisory Committee, submission of a Potential Disease Transmission Recipient Follow-Up Report (a form that will be sent to the transplant program by OPTN staff) within 45 days of the initial reporting date.

OPTN Patient Safety Staff may request additional information related to the recipient beyond 45 days, (including pending test results, long term follow-up testing, and/or screening results, etc.) depending on the potentially transmitted disease or condition in an effort to determine the probability of donor-derived disease transmission.

12.2 Informed Consent of Living Donors

…

L. Disclosure that any infectious disease or malignancy pertinent to acute recipient care discovered during the potential donor's first two years of post-operative follow-up care:

- will be disclosed to the donor;
- may need to be reported to local, state or federal public health authorities;

- will be disclosed to their recipient's transplant center; and
- will be reported through the OPTN Improving Patient Safety Portal.

5. **Joint Societies Work Group** - Committee members are participating on a Joint Societies Work Group which is preparing policy recommendation for living liver donor consent, medical evaluation and follow-up policy development. This work group began meeting in August 2012, and is expected to provide final policy recommendations for review by the leadership of the transplant professional societies by mid November 2012. Final policy recommendations will be provided to HRSA and the Living Donor Committee before the end of this year. After receiving the final recommendations the Committee will prepare living liver donor consent, medical evaluation and follow-up policy proposals for spring 2013 public comment.

6. **Independent Donor Advocate Policy Update** - In September, 2007, the OPTN/UNOS Board approved new Bylaw requirements for living liver donor and living kidney donor programs which established minimum mandatory elements for the living donor evaluation, consent, and follow-up. One of the elements required living donor programs to develop, and once developed, comply with written protocols for the duties and responsibilities of the independent donor advocate (IDA:

   (1) to promote the best interests of the potential living donor;
   (2) to advocate the rights of the potential living donor; and
   (3) to assist the potential living donor in obtaining and understanding information regarding the:

   (a) consent process;
   (b) evaluation process;
   (c) surgical procedure; and
   (d) benefit and need for follow-up.

   In June 2012, the OPTN/UNOS Board approved revision of the Bylaws that moved these IDA requirements to Policy 12. 10. The Committee is planning to update existing IDA policy to address independent donor advocate teams and to provide guidance on IDA and IDA Team responsibilities.

7. **Living Donor Program Specific Reports** - During the Committee's September 10, 2012 meeting, a representative of the SRTR reported that the SRTR is under contractual obligation to begin reporting living donor programs metrics, and asked for the Committee's assistance in determining which metrics should be publicized.

LIVING DONOR COMMITTEE		
	MONTH/YEAR	April 2012
	DAY	2
		In Person
NAME	**POSITION**	
Connie Davis MD	Chair	X
Amy Waterman PhD	Vice Chair	X
Denise Morin RN, MSN	Regional 1 Rep.	X
Diane James, RN, MSN	Regional 2 Rep.	X
Linda Chen, MD	Regional 3 Rep.	X
Steven Potter MD, FACS	Regional 4 Rep.	X
Fuad S Shihab, MD	Regional 5 Rep.	X
Jordana Gaumond M.D.	Regional 6 Rep.	X
Sandra Taler, MD	Regional 7 Rep.	X
Christie Thomas MB, FRCP, FASN, FAHA	Regional 8 Rep.	X
Carlos Marroquin MD	Regional 9 Rep.	X
Todd Pesavento MD	Regional 10 Rep.	X
Richard Stravitz MD	Regional 11 Rep.	X
Tonya Bradford PhD	At Large	X
William Freeman, MD, MPH	At Large	X
Mary Amanda Dew PhD	At Large	X
Cynthia Forland PhD	At Large	X
Margaret Frueh RN, MS	At Large	X
Cherie Hayostek MD	At Large	N/A
Chris Freise MD	At Large	X
Chris Jernigan	At Large	X
Tiffany Furuya	At Large	X
Susan Light MD	At Large	X
Krystal McLear	At Large	X
Donald Olenick Esq.	At Large	X
Bradley Kornfeld JD	At Large	X
Matthew Cooper, MD	At Large	X
James Montano	At Large	N/A
Rebecca Morrow, PhD	At Large	X
Vicky Young PhD	At Large	X
Raelene Skerda, RPh BPharm	Ex. Officio	X

Bernard Kozlovsky MD, MS	Ex Officio	X
Chris McLaughlin	Ex Officio	X
Michelle Desler MS	Visiting Board Member	X
Bertram Kasiske MD	SRTR	X
Jennifer Wainright PhD	UNOS Research	X
Diana Marsh	DEQ	By Phone
Ronnie Brown	UNOS	X
James Alcorn	Director Policy	X
Lee Bolton	Committee Liaison	X

Living Donor Committee	MONTH/YEAR	August 2012	September 2012	October 2012
	DAY	14	10	11
		Live Meeting	In Person	Live Meeting
NAME	POSITION			
Christie Thomas MD	Chair	X	X	X
Sandra Taler, MD	Vice Chair	X	X	X
Denise Morin RN, MSN	Regional 1 Rep.	X	X	X
Diane James, RN, MSN	Regional 2 Rep.	X	X	X
Linda Chen, MD	Regional 3 Rep.	X	X	X
Matthias Kapturczak	Regional 4 Rep.	X	X	
Fuad S Shihab, MD	Regional 5 Rep.	X	X	X
Christian Kuhr, MD	Regional 6 Rep.			
Krista Lentine, MD	Regional 8 Rep.	X	X	X
Carlos Marroquin MD	Regional 9 Rep.	X	X	X
Todd Pesavento MD	Regional 10 Rep.	X	X	
Vinaya Rao, MD	Regional 11 Rep.	X	X	X
Tonya Bradford PhD	At Large	X	X	X
William Freeman, MD, MPH	At Large	X	X	X
Mary Amanda Dew PhD	At Large	X	X	X
Regina Gill	At Large	X	X	X
George Bowen	At Large	X	X	
Daniel Ranch, MD	At Large	X	X	
Chris Freise MD	At Large	X	X	
Chris Jernigan	At Large	X	X	X
Tiffany Furuya	At Large	X	X	X
Susan Light MD	At Large	X	X	X
Krystal McLear	At Large			
Donald Olenick Esq.	At Large	X	X	X
Bradley Kornfeld JD	At Large	X	X	X
Rebecca Morrow, PhD	At Large	X	X	X
Chris McLaughlin	HRSA, ex offico	X	X	
Bertram Kasiske MD	SRTR		X	X
Matthew Cooper, MD	Board Member	X	X	
Jennifer Wainright PhD	UNOS Research	X	X	X
Diana Marsh	DEQ		By Phone	
Elizabeth Miller	DEQ		X	X
Ronnie Brown	UNOS		X	
James Alcorn	Director UNOS Policy		X	
Angela Allen, PhD	Director UNOS Instructional Innovations		X	
Lee Bolton	Committee Liaison	X	X	X