

**OPTN/UNOS Living Donor Committee  
Report to the Board of Directors  
November 13-14, 2014  
St. Louis, MO**

**Mary Amanda Dew, PhD, Chair  
Krista Lentine, MD, PhD, Vice Chair**

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**OPTN/UNOS Living Donor Committee  
Report to the Board of Directors  
November 12-13, 2014  
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**Mary Amanda Dew, PhD, Chair  
Krista Lentine, MD, PhD, Vice Chair**

*This report reflects the work of the OPTN/UNOS Living Donor Committee between April 2014 and September 2014.*

**Action Items**

**1. Proposal to Require Reporting of Aborted Living Donor Organ Recovery Procedures**

*Public Comment:* [March 14 – June 13, 2014](#)

The OPTN relies on the UNet<sup>SM</sup> Improving Patient Safety Portal for notification of patient safety concerns and living donor adverse events. Under this proposal, an aborted living donor organ recovery procedure would become a new category of living donor adverse events that recovery hospitals would need to report through the UNet<sup>SM</sup> Improving Patient Safety Portal. Additionally, the proposal would clarify current living donor adverse event reporting requirements by eliminating some redundant sections of policy.

The Committee considered and addressed all public comment received on this proposal which is provided in the briefing paper **Exhibit A**. After careful review, the Committee voted in support of sending the proposal for consideration by the Board of Directors (17-Yes, 0-No, 0-Abstain).

**RESOLVED, that the new or modified Policies 18.5.C (Submission of Living Donor Death and Organ Failure), 18.5.D (Reporting of Non-Transplanted Living Donor Organs), 18.5.E (Reporting of Living Donor Organs Not Transplanted in the Intended Recipient), and 18.6 (Reporting of Living Donor Adverse Events) as set in Exhibit A, are hereby approved effective February 1, 2015.**

**2. Proposal to Modify Existing or Establish New Requirements for the Informed Consent of Living Donors**

*Public Comment:* [March 14 – June 13, 2014](#)

This proposal would modify existing or establish new policy requirements for the informed consent of living donors. This proposal is in response to a directive from the Health Resources and Services Administration (HRSA) to develop such policy, and it is based on recommendations from a Joint Societies Steering Committee, composed of representatives of the American Society of Transplantation (AST), the American Society of Transplant Surgeons (ASTS), and the North American Transplant Coordinators Organization (NATCO), to the Living Donor Committee. Policy to standardize the informed consent of living kidney donors has already been established. This proposal would modify some elements of existing policy for the informed consent of living kidney donors and establish new requirements for living liver, lung, intestine, and pancreas organ donors.

The Committee considered and addressed all public comment received on this proposal that is provided in the briefing paper **Exhibit B**. Additional responses to the National Catholic Bioethics Center and the National Catholic Partnership on Disability are provided as informational items **Exhibit C and Exhibit D**. After modifying the original proposed policy

language, the Committee voted in support of sending the proposal for consideration by the Board of Directors (17-Yes, 0-No, 0-Abstain).

**RESOLVED, that the following new or modified Policies 14.2.A (ILDA Requirements for Kidney Recovery Hospitals), 14.2.B (Protocols for Kidney Recovery Hospitals), 14.3 (Informed Consent Requirements), as set forth in Exhibit B are effective February 1, 2015.**

**3. Proposal to Modify Existing or Establish New Requirements for the Psychosocial and Medical Evaluation of Living Donors**

*Public Comment:* [March 14 – June 13, 2014](#)

This proposal would modify existing or establish new policy requirements for the psychosocial and medical evaluation of living donors. This proposal is in response to a directive from the Health Resources and Services Administration (HRSA) to develop such policy, and it is based on recommendations from a Joint Societies Steering Committee, composed of representatives of the American Society of Transplantation (AST), the American Society of Transplant Surgeons (ASTS), and the North American Transplant Coordinators Organization (NATCO), to the Living Donor Committee. Policy to standardize the informed consent of living kidney donors has already been established. This proposal would modify some elements of existing policy for the psychosocial and medical evaluation of living kidney donors and establish new requirements for living liver, lung, intestine, and pancreas organ donors.

The Committee considered and addressed all public comment received on this proposal that is provided in the briefing paper **Exhibit E**. Additional responses to the National Catholic Bioethics Center and the National Catholic Partnership on Disability are provided as informational items **Exhibit C and Exhibit D**. After modifying the original proposed policy language, the Committee voted in support of sending the proposal for consideration by the Board of Directors (17-Yes, 0-No, 0-Abstain).

**RESOLVED, that the following new or modified Policies 14.1 (Required Protocols for Recovery Hospitals), 14.5 (Psychosocial Evaluations Requirements for Living Donors), 14.4 (Medical Evaluation Requirements for Living Donors), 14.6 (Registration and Blood Type Verification of Living Donors Before Donation), 14.7.A (Prospective Crossmatching Prior to Kidney Placement), 14.7.B (Placement of Non-directed Living Donor Kidneys), 14.7.C (Transplant Hospital Acceptance or Living Donor Organs), 14.8 (Packaging, Labeling, and Transporting of Living Donor Organs, Vessels, and Tissue Typing Materials) as set forth in Exhibit C are effective February 1, 2015.**

## **Committee Projects**

**4. Clarify the Status of Domino Donors**

*Public Comment:* *January 2015 (Estimated)*

*Board Consideration:* *November 2015 (Estimated)*

There are inconsistent practices regarding whether domino donors are considered as living donors or recipients for policy requirements and compliance. Current OPTN policy addresses the allocation of domino donor hearts, but does not address domino liver donation. The need to develop policy addressing domino liver donation has become more apparent and important as proposed new policies for living liver informed consent, medical evaluation, and follow-up are in effect or may soon be in effect.

Over the past several months, the Living Donor Committee in consultation with representatives from the Thoracic, Operations and Safety and Liver Committees and UNOS staff worked to draft proposed policy language for domino donation. During this process, the Living Donor Committee consulted surgeons and medical staff from hospitals experienced with domino liver donation.

At this point, the Living Donor Committee is seeking feedback from other Committees that may want to provide early feedback on the proposed policy language before it distributed for public comment. The proposed policy language was provided to the Thoracic, Liver, and Operations and Safety Committees to consider during their fall meetings. These Committees were requested to provide feedback no later than October 31, 2014. The Committee will also work with the MPSC regarding any membership requirements related to domino donors.

The current plan is to distribute a policy proposal addressing domino donation during the January 2015 public comment cycle.

#### **5. Improve UNet<sup>sm</sup> Reporting of Aborted Procedures and Non Transplanted Organs**

Public Comment: *January 2015 (Estimated)*

Board Consideration: *November 2015 (Estimated)*

Under the current reporting system using the Living Donor Feedback form there is a potential for recovery hospitals to under report aborted living donor recovery procedures and living donors whose organs are not ultimately transplanted.

Current OPTN/UNOS policy requires living donor recovery programs to register a living donor using the Living Donor Feedback form prior to the donor organ recovery procedure. The LDF form requires the transplant program to enter a response to the question “Aborted procedure after donor received anesthesia?” before the form can be successfully submitted. Options for responding to this required question include “Yes,” “No” or “N/A.” A message on the form instructs the user to select “N/A” to complete the form prior to surgery and to modify the form to “Yes” or “No” after surgery. However, OPTN policy does not specifically require the transplant program to update the response post operatively.

Additionally, Policy 18.5.D (Reporting of Non-transplanted Living Donor Organs) requires members to report whenever a living donor organ is recovered but not transplanted through the Improving Patient Safety Portal. However, current OPTN/UNOS policy does not specifically require updating the Living Donor Feedback form if a living donor organ is recovered but not utilized. Consequently, if a living donor organ is recovered but not transplanted and the LDF form is not updated post operatively, the Living Donor Registration and Living Donor Follow-up forms would not generate and the living donor could be lost to follow-up.

#### **6. New Requirements for the Transport of Living Donor Organs**

Public Comment: *August 2015 (Estimated)*

Board Consideration: *June 2016 (Estimated)*

The Living Donor Committee first discussed this topic in May 2010 and determined that OPTN/UNOS policy had very specific requirements for organ packaging, but no specific requirements for how packaged organs must be transported if they are transported out of the donor recovery center.

During its April 2011 meeting, the Committee approved a set of [Recommendations to Reduce Transportation Delays or Failures for Living Donor Organs](#). The recommendations included requiring a courier to accompany any transported living donor organ and making

OPOs responsible for the packaging and transport of living donor organs. Additionally, in spring 2011, the Committee released a proposal for public comment titled [Proposal to Improve the Packaging, Labeling and Shipping of Living Donor Organs, Vessels, and Tissue Typing Material](#). Under the proposal, the packaging and shipping requirements for living donor organs were updated to mirror the packaging and shipping requirements for deceased donor organs. The Board approved the proposal in November 2011.

During its April 2012 meeting, the Committee discussed a new HRSA-sponsored project to investigate electronic tracking of donated organs. The Committee determined it should delay work on requirements for the transport of living donor organs until this project concluded to avoid any duplication of effort.

The Ad-Hoc Organ Tracking Committee reported its final recommendations to the Board in June 2013. A member of the Ad-Hoc Organ Tracking Committee provided an overview of the project to the Committee in June 2013 and verified that the current project would not include the packaging and transport of living donor organs.

In response, the Committee resumed work on this project during its fall 2013 meeting. Recently, the leadership of the Committee has discussed if this project might benefit from a Failure Mode Effects Analysis (FMEA). The Operations and Safety Committee (who is collaborating on this project) used an FMEA for its ABO Proposal, which was distributed for spring 2014 public comment, and an FMEA was performed in the HRSA-sponsored project to investigate electronic tracking of donated organs. The Committee anticipates that components of the FMEA for electronic tracking of donated organs could be utilized in the development of new requirements for the transport of living donor organs.

UNOS staff received FMEA training in late September 2014. The Committee is planning to apply an FMEA to this project and is planning to have a policy proposal prepared for fall 2015 public comment.

**7. Guidance Document Addressing Abnormal Lab Results During Living Donor Follow-up**

*Public Comment:* N/A

*Board Consideration:* N/A

After approval of this project, the Committee obtained new information regarding similar projects by other professional transplant organizations. To avoid redundancy of efforts the Committee leadership determined that the Committee's time could be better invested in other efforts.

**Committee Projects Pending Implementation**

**8. Modify the Patient Safety System for Living Donor Events**

*Public Comment:* March 5 – April 16, 2010

*Board Approval:* [November 2010](#)

*Implementation:* Spring 2015 (Estimated)

This project would update the Improving Patient Safety portal for better reporting of non-utilized and redirected living donor organs. Under this project, the portal would be modified to include specific fields for reporting non-utilized and redirected living donor organs. This project is scheduled for implementation in the first quarter of 2015.

## Implemented Committee Projects

### **9. Proposal to Establish Minimum Requirements for Living Kidney Donor Follow-up**

Public Comment: Fall 2011

Board Approval: [November, 2012](#)

Implementation: February 1, 2013

The proposal was intended to improve living kidney donor follow-up by establishing minimum threshold for collecting and reporting living kidney donor follow-up. Under Policy 18.5 (Reporting Requirements after Donation) living kidney donor recovery hospitals must report accurate, complete and timely donor status and clinical information for at least 60% of their living kidney donor who donated after policy implementation date. Living kidney donor recovery hospitals are also required to report laboratory data on at least 50% of their living kidney donors who donated after the policy implementation date. Under the policy, the required threshold donor status, clinical information, and laboratory data increase over time.

Preliminary 6-month follow-up results for living kidney donors who donated after February 1, 2013 reveal that 71.7% of recovery hospitals achieved the 60% clinical data threshold and 75.1% of recovery hospitals achieved the 50% lab data threshold.

### **10. Proposal to Establish Requirements for the Informed Consent of Living Kidney Donors**

Public Comment: Fall 2011

Board Approval: [November, 2012](#)

Implementation: February 1, 2013

The project was intended to improve and standardize the informed consent process for all living kidney donors. These new policy requirements were based on recommendations from a Joint Societies Work Group representing the AST, ASTS, and NATCO and fulfill a HRSA requirement to develop policies for living organ donors and living organ donor recipients. The Committee will use reports on the number of transplant centers found out of compliance during UNOS Living Donor Program Site Surveys to evaluate the proposal. UNOS's Department of Evaluation and Quality will report on the level of compliance at the Committee's spring 2015 meeting.

### **11. Proposal to Establish Requirements for the Medical Evaluation of Living Kidney Donors**

Public Comment: Fall 2011

Board Approval: [November, 2012](#)

Implementation: February 1, 2013

The project intended to improve and standardize the psychosocial and medical evaluations for all living kidney donors. These new policy requirements were based on recommendations from a Joint Societies Work Group representing the AST, ASTS and NATCO and fulfill a HRSA requirement to develop policies for living organ donors. The Committee will use reports on the number of transplant centers found out of compliance during UNOS Living Donor Program Site Surveys to evaluate the proposal. UNOS's Department of Evaluation and Quality will report on the level of compliance at the Committee's spring 2015 meeting.

## **12. Proposal to Establish Minimum Requirements for Living Liver Donor Follow-up**

Public Comment: Spring, 2012

Board Approval: [November, 2013](#)

Implementation: February 1, 2014

The proposal was intended to improve living liver donor follow-up by establishing minimum threshold for collecting and reporting living kidney donor follow-up. Under Policy 18.5 (Reporting Requirements after Donation) living liver donor recovery hospitals must report accurate, complete and timely donor status and clinical information for at least 80% of their living kidney donor who donated after policy implementation date.

Living liver donor recovery hospitals are also required to report laboratory data on at least 70% of their living liver donors who donated after the policy implementation date.

### **Review of Public Comment Proposals**

The Committee has reviewed 2 of the 18 proposals released for public comment from September – December, 2014.

## **13. Proposal to Address the Requirement Outlined in the HIV Organ Policy Equity Act (Organ Procurement Organization Committee)**

The Committee had a preliminary discussion regarding this proposal that was released for public comment in late September 2014. As confirmed with the OPO Committee, the current policy proposal is designed to permit to research involving HIV+ deceased donors. The Living Donor Committee will reconsider this issue if and when a future policy proposal addressing HIV+ living donors is submitted for public comment.

## **14. Implementation of the OPTN/s Oversight of Vascularized Composite Allografts (VCAs) (Vascularized Composite Allograft Committee)**

The Committee had a preliminary discussion regarding these policies that were approved by the Board in June 2014. Most Committee members were concerned that the Vascularized Composite Allograft (VCA) policies approved by the Board did not exclude potential living VCA donors. The Committee plans to submit a formal detailed response during the public comment period.

### **Other Committee Work**

None

### **Meeting Summaries**

The committee held meetings on the following dates:

- September 8, 2014

Meetings summaries for this Committee are available on the OPTN website at: <http://optn.transplant.hrsa.gov/converge/members/committeesDetail.asp?ID=59>.

**Proposal to Require the Reporting of Aborted Living Donor Recovery Procedures**

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**Proposal to Require the Reporting of Aborted Living Donor Recovery Procedures**

**Sponsoring Committee:** Living Donor

**Summary and Goals of the Proposal:**

Promoting patient safety is a critical component of the OPTN's mission. The OPTN seeks to protect the safety of transplant candidates, recipients, and living donors, but living donors are unique in that they put themselves at risk without any potential benefit to their own health. Due to a variety of reasons, including last minute recipient or donor health problems and unforeseen donor anatomy issues, living donor organ recovery procedures occasionally need to be aborted after anesthesia has been administered, but before the recovery of the organ. Monitoring the safety of these prospective donors is an important part of the OPTN's goal of promoting living donor safety.

The OPTN relies on the UNet<sup>SM</sup> Improving Patient Safety Portal for notification of patient safety concerns and living donor adverse events. Under this proposal, an aborted living donor organ recovery procedure would become a new category of living donor adverse event that recovery hospitals would need to report through the UNet<sup>SM</sup> Improving Patient Safety Portal. Additionally, the proposal would clarify current living donor adverse event reporting requirements by eliminating some redundant sections of policy.

**Background and Significance of the Proposal:**

Beginning in 2006, OPTN policy required members to report living donor adverse events for two years post-donation if one of the following events occurs:

- A living donor dies
- A living liver donor is registered on the liver waitlist
- A living kidney donor is listed on the kidney waitlist or begins dialysis

In 2010, the living donor adverse event reporting requirements were expanded to include the following events:

- A living donor organ is recovered, but not transplanted
- A living donor organ is recovered and transplanted into someone other than the intended recipient

These categories of living donor adverse events currently must be reported through the UNet<sup>SM</sup> Improving Patient Safety Portal.

In July 2013, the Living Donor Committee (the Committee) received a request to consider whether aborted living donor organ recovery procedures should be a new type of living donor adverse event and reported to the OPTN through the UNet<sup>SM</sup> Improving Patient Safety Portal. A potential living donor's medical evaluation and surgery to recover an organ expose that donor to risk. Living donors weigh the risk of donation against the benefit their intended recipient would receive from transplantation. In the unfortunate circumstance of an aborted living donor organ recovery procedure, the donor experiences risk, but their intended recipient receives no benefit from

transplantation. Collecting this safety information will help quantify the risk associated with living donation and provide information that potential living donors need as a component of the informed consent process. Although these prospective donors do not meet the OPTN's definition of living donor (i.e., A living individual from whom at least one organ is recovered for transplantation), they have put themselves at risk by receiving anesthesia for the purpose of donating an organ, and the Committee believes that the OPTN should monitor these events.

During this same time period, the Committee was aware of media reports on a series of aborted living donor organ recovery procedures at a member program occurring between 2008 through 2010. The aborted procedures were primarily related to intraoperative bleeding.

The Committee questioned if aborted living donor organ recovery procedures were reported to the OPTN, and if so, how the OPTN handles these events. The Committee was informed that the Living Donor Feedback form must be submitted to UNOS prior to any living donor organ recovery procedure, and that the form contains a question addressing if the recovery procedure was aborted after the donor received anesthesia. The Committee questioned if aborted living donor recovery procedures could be under-reported because reporting an aborted procedure requires revising the Living Donor Feedback form post operatively, which could fail to occur.

The Committee understands that there may be many mitigating circumstances that explain why an aborted living donor organ recovery procedure could occur, including unanticipated anatomy or health problems with the potential donor or intended organ recipient, which could create a need to discontinue the donation surgery. An aborted living donor organ recovery procedure does not necessarily reflect poorly on a recovery hospital. The Committee expects that aborted living donor organ recovery procedures will be rare events.

### ***Reporting Requirement***

After a thorough review of this issue, the Committee recommended that all aborted living donor organ recovery procedures should be reported via the UNet<sup>sm</sup> Improving Patient Safety Portal. Under the proposal, if a living donor organ recovery procedure is aborted, the member reporting the event will provide a written description of the event that will be reviewed upon receipt by UNOS staff and investigated as necessary. The events are reported to the Membership and Professional Standards Committee.

### ***Policy Clarification***

During review of the current categories of living donor adverse events that must be reported through the UNet<sup>sm</sup> Improving Patient Safety System, the Committee supported proposing to eliminating several sections of policy ((Policy 18.5.B (Submission of Living Donor Death and Organ Failure); Policy 18.5.C (Reporting of Non-transplanted Living Donor Organs); 18.5.D (Reporting of Living Donor Organs Not Transplanted in the Intended Recipient)) because these requirements are also included in Table 18.4 (Living Donor Adverse Event Reporting) and consequently were considered redundant. The new proposed reporting requirements under this proposal would be added to Table 18.4.

On December 12, 2013, the Committee met by web conference to review final draft policy language for this proposal and consider whether the proposal should be distributed for public comment. The Committee chair led a review of the proposed policy language, and the Committee voted to approve sending the proposal for public comment.

This policy proposal was sent for public comment between September XX and December XX, 2014. This proposal was included on the consent agenda for regional meetings occurring during this public comment period.

The Committee reviewed public comment responses on September 8, 2014. In response to public comment the Committee agreed that the phrase “receives anesthesia” in the original proposed policy language should be clarified to read “begun to receive general anesthesia.” There were no other changes to the proposed policy language and the Committee approved sending the proposal for Board consideration

### **Alternatives considered**

The Committee considered that an aborted living donor organ recovery procedure technically is not a living donor adverse event because a living donor organ was not recovered. However, because these prospective donors have put themselves at risk by receiving anesthesia for the purpose of donating an organ, the Committee unanimously agreed that an aborted living donor organ recovery procedure should be a reportable living donor adverse event.

The Committee and UNOS staff considered if the Living Donor Feedback form could be used to monitor aborted living donor recovery procedures. OPTN policy requires that the Living Donor Feedback form must be completed prior to the living donor recovery procedure. However, current policy does not specifically require updating the form to report if the procedure was aborted after the donor received anesthesia. Consequently, the Committee determined that this option would be problematic because aborted living donor recovery procedures could be under-reported if the Living Donor Feedback form is not revised post-operatively. The Committee will propose changes to the Living Donor Feedback form to help prevent under reporting of aborted living donor recovery procedures as a separate and future policy proposal.

### **Supporting Evidence and/or Modeling:**

Current policy does not specifically require reporting aborted living donor recovery procedures on the Living Donor Feedback form. Consequently, the OPTN may not have a complete count of aborted living donor organ recovery procedures. Since 2003, 12 cases have been reported where a donation surgery was aborted because of a threat to the donor’s health after anesthesia was administered.

### **Expected Impact on Living Donors or Living Donation**

Recovery hospital reporting of aborted living donor organ recovery procedures could help quantify the risks associated with living kidney donation.

### **Expected Impact on Specific Patient Populations**

There should be no negative impact for living organ donors or candidates for living donor transplant.

**Expected Impact on OPTN Key Goals:**

<i>HHS Program Goals</i>	<i>Strategic Plan Goals</i>
<b>Patient Safety</b>	Prompt reporting of aborted living donor organ recovery procedures through the Improving Patient Safety Portal could promote safe, high-quality care for transplant candidates, and living donors
<b>Best Use</b>	Prompt reporting of aborted living donor organ recovery procedures through the Improving Patient Safety Portal could lead to the refinement of policies by incorporating objective, measurable criteria related to concepts of donor risk/quality and recipient benefit
<b>Operational Effectiveness</b>	Prompt reporting of aborted living donor organ recovery procedures through the Improving Patient Safety Portal should help identify process and system improvements that best support critical network functions, and could be disseminated to all members who could benefit

**Plan for Evaluating the Proposal:**

One year after implementation of the policy, the Committee will request a report on the total number of aborted Living Donor recovery procedures reported in the UNet<sup>SM</sup> Improving Patient Safety Portal. The Committee will consider if policy modification or educational efforts are needed to assist members with policy compliance.

**Additional Data Collection:**

If this proposal is approved by the Board of Directors, the proposal will require adding a new option under “Living Donor Adverse Event” in the UNet<sup>SM</sup> Improving Patient Safety Portal, The new option would read “Recovery Procedure Aborted after Donor Received Anesthesia.” Until this new programming occurs, recovery centers would report aborted living donor procedures as an “other” event and provide a description in the free text field.

The proposal would require recovery hospitals to report aborted living donor recovery procedures via the UNet<sup>SM</sup> Improving Patient Safety Portal. This proposal would allow the OPTN to provide potential living donors with accurate information on the frequency of this type of event.

The Principles of Data Collection require institutional members to provide sufficient data to the OPTN to allow it to ensure patient safety when no alternative sources of data exist.

**Expected Implementation Plan:**

Based on favorable public comment, this proposal should be considered by the OPTN Board of Directors in November, 2014. If approved, this proposal will become effective on February 1, 2015.

Recovery hospitals will begin to report aborted living donor recovery procedures as Living Donor Adverse Events through the UNet<sup>SM</sup> Improving Patient Safety Portal.

**Communication and Education Plan:**

The proposal addresses new requirements and expectations for member reporting. Communication and education efforts will address awareness of the new requirements as well as processes needed to fulfill them.

Information about the new requirements would be included in an ongoing effort to provide educational webinars to members regarding patient and living donor safety, with particular emphasis on practices at living donor transplant programs. It also would be incorporated into the OPTN Evaluation Plan and addressed in the context of ongoing member notification as the plan is periodically updated.

In addition, notification of the amended policy requirements would be included in the following routine communication vehicles:

- Policy notice
- System notice
- UNOS Update article
- Member e-newsletter/blog article
- Notification to a list serve group for transplant administrators

**Compliance Monitoring:**

UNOS will investigate all reported instances of aborted living donor organ recoveries in order to verify that policy requirements were followed, including reporting through the UNet<sup>SM</sup> Improving Patient Safety Portal within 72 hours following the aborted procedure

**Policy or Bylaw Proposal:**

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

1  
 2 At a meeting of the OPTN/UNOS Board of Directors convened on November 12-13, 2014 in St.  
 3 Louis, MO, the following resolution is offered.  
 4  
 5 *A resolution to require reporting aborted living donor organ recovery procedures..*  
 6  
 7 Sponsoring Committee: Living Donor  
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 9 **RESOLVED, that new or modified Policies 18.5.C (Submission of Living Donor Death and**  
 10 **Organ Failure), 18.5.D (Reporting of Non-Transplanted Living Donor Organs), 18.5.E**  
 11 **(Reporting of Living Donor Organs Not Transplanted in the Intended Recipient), and 18.6**  
 12 **(Reporting of Living Donor Adverse Events) as set forth below, are hereby approved**  
 13 **effective February 1, 2015.**  
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**18.6 Reporting of Living Donor Adverse Events**

**18.6.A Reporting of Living Donor Adverse Events through the Improving Patient Safety Portal**

Recovery hospitals must report these living donor adverse or unanticipated events through the Improving Patient Safety Portal according to Table 18-4

**Table 18-4: Living Donor Adverse Event Reporting**

Recovery hospitals must report to the Patient Safety System when:	To the Improving Patient Safety Portal within 72 hours after:
<u>A living donor organ recovery procedure is aborted after the donor has begun to receive general anesthesia.</u>	The aborted organ recovery procedure
A living donor dies within 2 years after organ donation	The program becomes aware
A living liver donor is listed on the liver waitlist within 2 years after organ donation	The program becomes aware
A living kidney donor is listed on the kidney wait list or begins dialysis within 2 years after organ donation	The program becomes aware
A living donor organ is recovered but not transplanted	Organ recovery
A living donor organ is recovered and transplanted into someone other than the intended recipient	Organ recovery

The Membership and Professional Standards Committee will review all cases reported under Policy 18.5.B through 18.5.D according to Table 18-4 above and report to the OPTN Board of Directors.

**18.5.C Submission of Living Donor Death and Organ Failure**

Recovery hospitals must report all instances of a living donor's death or failure of the living donor's remaining organ function within 72 hours after the hospital becomes aware of the living donor death or failure of the living donor's remaining organ function. Living donors' remaining organ failure is defined as registering for liver transplant for liver donors, and as transplant, listing for transplant, or the need for dialysis for kidney donors. Recovery hospitals must report these incidents through the OPTN Contractor's Improving Patient Safety System for a period of two years from the date of the donation. The MPSC will review and report all adverse events to the OPTN Board of Directors.

**18.5.D Reporting of Non-transplanted Living Donor Organs**

The recovery hospital must report any time a living donor organ is recovered but not transplanted into any recipients. Recovery hospitals must report these incidents through the OPTN Patient Safety System within 72 hours of organ recovery. The MPSC will review and report all cases of non-transplanted living donor organs to the OPTN Board of Directors.

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**18.5.E Reporting of Living Donor Organs Not Transplanted in the Intended Recipient**

If a living donor organ is recovered for an intended recipient but ultimately redirected and transplanted to a different recipient, then all required donor and recipient information must still be reported to the OPTN Contractor.

Transplant hospitals must report these incidents through the OPTN Improving Patient Safety System within 72 hours of organ recovery. The Membership and Professional Standards Committee will review and report all cases of redirected living donor organs to the OPTN Board of Directors.

**Table 18-4: Living Donor Adverse Event Reporting**

<b>Recovery hospitals must report to the Patient Safety System when:</b>	<b>Within 72 hours after:</b>
A living donor dies within 2 years after organ donation	The _____ program becomes aware
A living liver donor is listed on the liver waitlist within 2 years after organ donation	The _____ program becomes aware
A living kidney donor is listed on the kidney wait list or begins dialysis within 2 years after organ donation	The _____ program becomes aware
A living donor organ is recovered but not transplanted	Organ recovery
A living donor organ is recovered and transplanted into someone other than the intended recipient	Organ recovery

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The Membership and Professional Standards Committee will review all cases reported under *Policy 18.5.B* through *18.5.D* and report to the OPTN Board of Directors.

#

**Public Comment Responses:**

**1. Public Comment Distribution**

Date of distribution: 3/14/2014

Public comment end date: 6/13/2014

Public Comment Response Tally					
Type of Response	Response Total	In Favor	In Favor as Amended	Opposed	No Vote/ No Comment/ Did Not Consider
Individual	21	17 (80.95%)	0	1 (4.7%)	3
Regional	11	11 (100 %)	0 (%)	0 (%)	0
Committee	3	3 (100%)	0 (%)	0 (%)	16

**2. Regional Public Comment Responses**

Region	Meeting Date	Motion to Approve as Written	Approved as Amended (see below)	Meeting Format
1	5/5/2014	13-0-0		In person
2	3/28/2014	27-0-0		In person
3	5/30/2014	16-0-1		In person
4	5/9/2014	25-0-0		In person
5	6/12/2014	14-0-4		In person
6	5/16/2014	50-0-0		In person
7	5/9/2014	18-0-0		In person
8	4/4/2014	15-0-0		In person
9	5/21/2014	15-0-0		In person
10	5/15/2014	18-0-0		In person
11	5/30/2014	24-0-0		In person

**3. Committee Public Comment Responses**

**Liver and Intestinal Organ Transplantation Committee:**

The Liver & Intestinal Committee did not consider this proposal.

**Membership and Professional Standards Committee:**

The Committee supported the proposal and offered the following suggestions:

- Clarify in Table 18-4 that “receives anesthesia” means induction of general anesthesia.
- Recommend reporting when the recipient surgery is aborted due to an adverse event and that in turn results in the donor surgery also being aborted.

**Sponsoring Committee Response:**

The Living Donor Committee appreciates this response and support for the proposal. The Committee has clarified the language in Table 18-4 to be more precise about the time frame by referring to when the donor has begun to receive general anesthesia. The wording was chosen to be consistent with the “plain language” mandate for policy.

**Pancreas Transplantation Committee:**

The Committee did not consider this proposal.

**Patient Affairs Committee:**

The Committee voted to unanimously support this proposal with minimal discussion (19 in favor, 0 against, 0 abstentions).

**Sponsoring Committee Response:**

The Living Donor Committee appreciates this response and the support for the proposal.

**Pediatric Transplantation Committee:**

The Pediatric Transplantation Committee did not consider this proposal.

**Transplant Coordinators Committee:**

(Support 10, Oppose 0, Abstain 3)) This proposal was presented to the Committee and after a brief discussion, they voted to support the proposal as written.

**Sponsoring Committee Response:**

The Living Donor Committee appreciates this response and the support for the proposal.

#### 4. Individual Public Comment Responses

##### Summary of Public Comments

#### 10. Living Donor Committee: Proposal to Require the Reporting of Aborted Living Donor Organ Recovery Procedures

As of 6/13/2014, 21 responses have been submitted to UNOS regarding this policy proposal. Of these, 17 (80.95%) supported the proposal, 1 (4.76%) opposed the proposal, and 3 (14.29%) had no opinion. Of the 18 who responded with an opinion, 17 (94.44%) supported the proposal and 1 (5.56%) opposed the proposal. Comments on the proposal received to date are as follows:

**Comment 1:**

*Vote: Support*

*Date Posted: 06/17/2014*

ASTS supports the intent of this policy to require reporting of aborted cases in an effort to monitor for activity that may indicate safety issues and to better quantify how often aborted cases occur. However, the current policy proposal uses the verbiage after donor has received anesthesia which we perceive as too vague. For example, if a donor has a vaso-vagal response in preop after receiving some sedation prior to entering the operating room and the case is canceled, would that need to be reported? ASTS would suggest a more definitive time point, i.e. after first skin incision is made as the point when the donation procedure actually begins. It is also unclear from the policy whether the mandatory follow-up monitoring of a living donor would apply to a donor where the case was aborted. This needs to be clarified. ASTS

suggests language such as If the organ that was planned for removal was surgically manipulated but not removed, mandatory follow-up should apply.

**Committee Response:**

The Living Donor Committee thanks the ASTS for its support of this proposal. The Committee has revised the policy language in Table 18.4 to be more precise regarding the time frame by referring specifically to when the donor has begun to receive general anesthesia.

This proposal is limited to reporting aborted procedure through the Improving Patient Safety Portal. The Committee is planning another policy proposal titled Improve UNet<sup>sm</sup> Reporting of Aborted Procedures and Non Transplanted Organs for spring 2015 public comment which will include clarification of follow-up reporting requirements for aborted procedures.

**Comment 2:**

*Vote: Support*

*Date Posted: 06/13/2014*

NATCO supports this proposal as written.

**Committee Response:**

The Living Donor Committee thanks NATCO for its support of this proposal.

**Comment 3:**

*Vote: Support*

*Date Posted: 06/16/2014*

The AST supports the proposal for mandatory reporting of aborted living donor organ recovery procedures post anesthesia administration to UNet through the Patient Safety Portal. The proposal should improve transparency and will not represent an added burden or a need for significant additional resources in transplant programs to maintain compliance. We also do not believe that gathering this information will negatively persuade living donors to move forward. On the contrary, it will provide a greater degree of transparency.

**Committee Response:**

The Living Donor Committee thanks the AST for its support of this proposal.

**Proposal to Modify or Establish New Requirements for the  
Informed Consent of Living Donors**

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**Proposal to Modify Existing or Establish New Requirements for the Informed Consent of Living Donors****Sponsoring Committee: Living Donor****Summary and Goals of the Proposal:**

This proposal would modify existing or establish new policy requirements for the informed consent of living donors. This proposal is in response to a directive from the Health Resources and Services Administration (HRSA) to develop such policy, and it is based on recommendations from a Joint Societies Steering Committee, composed of representatives of the American Society of Transplantation (AST), the American Society of Transplant Surgeons (ASTS), and the North American Transplant Coordinators Organization (NATCO), to the Living Donor Committee. Policy to standardize the informed consent of living kidney donors has already been established. This proposal would modify some elements of existing policy for the informed consent of living kidney donors and establish new requirements for living liver, lung, intestine, and pancreas organ donors.

**Background and Significance of the Proposal:**

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

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.

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

In 2010, a Joint Societies Policy Steering Committee (comprised of members from the AST, ASTS, NATCO, OPTN/UNOS, and HRSA) formed to make recommendations on any OPTN policy under development that has the potential to prescribe medical care. This Steering Committee preferred developing policy recommendations for living kidney and living liver donor informed consent as separate projects and favored addressing living kidney donor informed consent first and living liver donor informed consent as a future project.

The Living Donor Committee used these recommendations to help develop proposed new policy requirements for the consent of living kidney donors. The proposed consent requirements were distributed for public comment between September 16, 2011 and January 12, 2012, were approved by the OPTN/UNOS Board of Directors on November 12, 2012, and became effective on February 1, 2013.

Similarly, for this proposal a Joint Societies Policy Steering Committee (comprised of members from the AST, ASTS, NATCO, OPTN/UNOS, and HRSA) formed a JSWG to develop recommendations for the informed consent of living liver donors. This work group held its first meeting on August 7, 2012, and after several months of work, sent preliminary proposed policy recommendations to the leadership of the transplant professional societies on December 1, 2012, for an initial review.

After receiving feedback from the parent societies, the JSWG met to revise their initial proposed policy recommendations for the informed consent of living liver donors. The JSWG modified their policy recommendations and sent the revised recommendations back to the parent societies for approval on April 1, 2013.

On April 8, 2013, the Chairperson of the JSWG attended the Living Donor Committee meeting and gave a presentation on the work of the JSWG and its preliminary recommendations for living liver donor consent policy development.

After these preliminary recommendations were approved by each of the parent societies, the Committee considered the policy recommendations in the development of proposed policy requirements for the informed consent of living liver donors.

The Committee met by teleconference on June 10, 2013, to consider if a policy proposal for the informed consent of living liver donors should be distributed for public comment. The Committee determined that they needed additional time to review the final recommendations from the JSWG, and consequently the Committee agreed to delay the proposal until some future public comment cycle.

During subsequent review of the proposal, a subcommittee of the full Committee considered if common elements in existing policy for the informed consent of living kidney donor and proposed policy for the informed consent of living liver donors could be extended to apply to other types of living donors (ex. pancreas, intestine, and lung). The subcommittee determined 1) there should be minimum, common standards and protections for all living donors, 2) that as currently proposed, the informed consent of living pancreas, intestine, and lung donors would not be addressed in any policy, and 3) these likely would not be addressed in a separate policy development process because the volumes for these types of transplants are so small.

The subcommittee understood that proposed new general policies for the informed consent of other types of solid organ living donors was a new concept that had not been previously considered by a JSWG or any organ specific committee. In response, this committee sent letters to fourteen OPTN Committees asking those committees to comment or respond with concerns regarding the plan to modify or propose informed consent requirements for all types of living donors.

The full Committee met on September 16, 2013 and reviewed responses from five (Operations and Safety, Membership and Professional Standards, Pancreas, Ethics, and Disease Transmission Advisory Committee) committees that had responded before the deadline. Each of these committees supported the plan to propose informed consent requirements to include other types of living donors (ex. lung, intestine, and pancreas). Based on this feedback, the Committee agreed to prepare a policy proposal for public comment that would include informed consent requirements for all types of living donors (ex. kidney, liver, lung, intestine, and pancreas).

In November 2013, the OPTN/UNOS Board approved a “plain language” rewrite of OPTN policies. Under this project, the policy requirements for the informed consent of living kidney donors were rewritten into plain language (without changing the substance of the requirements) and moved from Policy 12 to Policy 14.

One of the new features of the revised policy is the increased use of tables to communicate policy requirements. Under this proposal, the existing policy requirements for living kidney donor informed consent and new proposed informed consent requirements for the other categories of living donors are integrated and presented in a table format. Under this integration, many existing policy requirements for the informed consent of living kidney donors are proposed as new policy requirements for the other categories of living donors. Some existing policy for the informed consent of living kidney donors is specific to kidney donation and cannot be extended to address other the categories of living donors. Consequently, the proposed policy contains informed consent requirements for the other categories of living donors, followed by existing requirements specific to living kidney donors and new proposed requirements specific to living liver donors.

On December 12, 2013, the Committee met by web conference to review final draft policy language for this proposal and to consider if the proposal should be distributed for public comment. The Committee chair lead a review of the proposed policy language, and the committee discussed and came to consensus on a few remaining issues with the proposed policy language. The Committee voted to approve sending the proposal for public comment.

This proposal was released for public comment between March 14 and June 13, 2014. During the public comment period a subcommittee of the Living Donor Committee monitored public comment and prepared responses to all comments for the full Committee to consider. During public comment, two Catholic organizations, the National Catholic Bioethics Center and the National Catholic Partnership on Disability, sent responses critical of the proposal. In response, the Committee sent a formal written response to each organization and invited the organizations to participate in a conference call to address any remaining questions. On August 18, 2014, the Committee leadership met with representatives of each organization to discuss their concerns and potential options to alleviate their concerns. The Chair of the Committee indicated she would send a follow-up message to representatives of the Catholic organizations after the Committee met in September.

The full Committee met on September 8, 2014 to review public comment and proposed responses regarding this proposal. Prior to this meeting, the Committee leadership came to understand that the vascularized composite allograft (VCA) policies approved by the Board in June did not exclude potential living VCA donation. The Chair of the Committee, also a member of the Board, contacted several other Board members and determined they also did not understand that the VCA policies did not exclude potential living VCA donation. The Committee leadership reported this concern to the leadership of the VCA Committee and UNOS staff.

The Committee leadership was asked to consider several options:

1. Limit the proposed policy to state it applies to only living kidney, liver, pancreas, intestine and lung donors, and not provide informed consent requirements for living VCA donors.
2. Continue to cover all living donors, including potential living VCA donors, as written in the public comment proposal
3. Selecting one of the above solutions and re-releasing the proposal for public comment. Arguably, either of the above options is a substantive change from the public comment proposal (either it covers a class of donors not previously considered or it is excluding a class or donors from a proposal meant to cover all living donors). Typically, committee do

not make large substantive changes after public comment. When they do, the proposals are typically re-released for public comment.

The Committee leadership did not support the second or third options but agreed to present them as options to be considered by the full Committee.

On September 8, 2014, the Chair and vice Chair of the VCA Committee joined the Living Donor Committee meeting by web conference to provide an overview of the VCA policies recently approved by the Board, and to respond to questions regarding potential living VCA donation. The Chair of the VCA Committee explained that the VCA policies had been developed and approved by the Board through an expedited process in order to have policies in place before changes to the Final Rule took effect on July 3, 2014. She further explained that the VCA policies have a sunset provision and will need to be reconsidered by the Board within one year. She confirmed that the current policy permitted approved programs to perform living VCA donation, but commented that the Board or Executive Committee of the Board would be asked to modify the VCA policies to limit programs to performing living VCA donation for which they were specifically approved. She reported that VCA approved programs have not performed living VCA donation to date. The vice Chair of the VCA committee reported that abdominal wall transplants have been performed in this country.

UNOS' Director of Policy was asked to explain if the Final Rule envisioned living VCA donation and to comment on the OPTN's authority under the Final Rule. He explained that based on consultation with UNOS's legal staff, the Final Rule is not specific to deceased donation. The OPTN does not have the authority to prohibit living VCA donation, but does have the authority to make membership requirements, performance standards, and patient safety requirements regarding living VCA donation.

The Chair of the VCA Committee concluded her comments by confirming that the VCA Committee is committed to protecting living donors. She voiced concern that if the informed consent and medical evaluation proposals are not modified to include living VCA donor it would lead to a unregulated vacuum and that extending the policies to include living VCA donation was needed to protect public safety and to preserve public trust. She commented that she had reviewed the proposed policy language and felt all of the proposed policy elements would be appropriate for potential living VCA donation. The Chair of the Living Donor Committee thanked the VCA Committee Chair for her comments, and explained that this proposal was based on recommendations from a Joint Societies Work Group that had not considered potential living VCA donors when they developed their policy recommendations. Additionally, inclusion of living VCA donors had not been considered during this Committee's development of the proposal so it was not explicitly addressed. Additionally, the Chair explained that she believes that there are elements of the proposed policy that would be inaccurate for living VCA donors.

The Chair presented three potential paths forward for the full Committee to consider:

1. Limit the proposed policy to state it applies to only living kidney, liver, pancreas, intestine and lung donors, and not provide informed consent requirements for living VCA donors.
2. Continue to cover all living donors, including potential living VCA donors, as written in the public comment proposal
3. Selecting one of the above solutions and re-releasing the proposal for public comment. Arguably, either of the above options is a substantive change from the public comment proposal (either it covers a class of donors not previously considered or it is excluding a class or donors from a proposal meant to cover all living donors). Typically, committee do

not make large substantive changes after public comment. When they do, the proposals are typically re-released for public comment.

The Chair explained that in her opinion option 2 should not be considered because potential VCA donation had not been considered by the Joint Societies Work Group (representatives from AST, ASTS, and NATO) when they provided recommendation for policy development to the Living Donor Committee. Additionally, inclusion of living VCA donors had not been explicitly presented to the other Committees or the regions during the public comment process.

Committee members offered a number of comments in opposition to extending this informed consent proposal to include potential living VCA donation including:

- VCA transplantation is a life enhancing procedure rather than a lifesaving procedure and that potential living donor VCA donation could create a permanent disability in the living donor. Consequently, the proposed policy would not be adequate to address the specific informed consent requirements for potential living VCA donors.
- Extending the proposal to include potential living VCA donors would be premature especially since living VCA donors were not included in the development of the proposed policy.
- “Haste makes bad policy.”
- Extending the proposed policy to include potential living VCA donors needs thoughtful consideration.
- If the proposed policy was extended to include potential living VCA donation, it could undermine public trust because that option had not been presented during the public comment process.
- Requirements for the informed consent or medical evaluation of potential living VCA donors should be sent for public comment before being added to proposed policy.
- While not including potential VCA donors in this proposed policy would create a unregulated vacuum, it has taken years to develop and approve policies for the informed consent of living kidney and liver donors; therefore, one could argue that there has been a unregulated vacuum for the categories of living donor for many years so why should the absence of potential living VCA donor policy be considered an emergent problem.

Most Committee members agreed that the proposed informed consent requirements in this proposal would not be adequate to address living VCA donors and that some requirements would be inaccurate for VCA donors. The Committee supported assisting with the development of specific informed consent requirements for living VCA donors if approved by the Board and as a separate future project.

After a lengthy discussion the Committee voted to exclude living VCA donors from this policy proposal (Vote: 15-Support, 2-Opposed, 0-Abstain). The Committee supported modifying the proposal to clarify it would only apply to living kidney, liver, pancreas, intestine or lung donors. The Committee supported making other small non substantive changes to this proposal based on public comment. The Committee approved sending this proposal for Board consideration (Vote: 17-Support, 0-Opposed, 0-Abstain).

### **Specific Feedback and Collaboration**

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

memorandum to fourteen other committees requesting feedback on the plan to propose extending informed consent requirements for other categories of living donors. The memorandum included information on what informed consent requirements would be proposed for all living donors and what informed consent requirements would be specific to living kidney and living liver donors. Seven committees (DTAC, Ops and Safety, Pancreas, Thoracic, MPSC, Pediatric, and Ethics) responded in support of extending informed consent requirements to all categories of living donors by the deadline identified in the memorandum. None of these Committees responded with specific concerns over any of the proposed requirements not being appropriate for a particular category of donor.

### ***Combined Consent Process and Existing Policy Clarifications***

Approved and implemented living kidney donor consent policy requires two separate consent processes: (1) a consent to be evaluated for living donation and (2) an informed consent for living donation. Based on feedback from the OPTN living donor program site surveyors, the Committee understood that the policy requirement for two separate consent processes created confusion for living donor programs. In response, the Committee favored combining all approved informed consent policy requirements into a single required consent process.

The Committee received several questions regarding the definition of the phrase “written assurance” in current living kidney donor policy. In response, the Committee is proposing to change policy to require the donor’s signature on a document that confirms that the donor is willing to donate, is free from coercion, and has been informed that they can decline to donate at any time.

The Committee received questions regarding the current requirement to disclose any infectious disease or malignancy pertinent to acute recipient care to the donor. The Committee understands that any medical condition identified in a donor would be disclosed to the donor as part of standard medical practice, and therefore supported removing this disclosure from the requirements to reduce confusion regarding this requirement.

The Committee considered requiring programs to disclose their living liver donor transplant volumes as a component of informed consent. Ultimately, the Committee did not support including this requirement because volume may not be a reliable indicator of program experience or expertise because a program’s volumes may vary with personnel changes. The Committee supported asking the transplant community for feedback regarding if living liver donor programs should be required to disclose their program volume to potential living liver donors.

### ***“Potential Living Donors” Terminology***

Under this proposal, all references to “potential living donors” would change to read “living donors” in current and future policy. The Committee is proposing this change because the term “potential living donor” is not defined in policy and programs define “potential living donors” differently. Committee members questioned which elements of current living donor informed consent and medical and psychosocial evaluation policy are required at various stages of the donor evaluation process. A Committee member questioned if a program could be cited for an incomplete informed consent or medical evaluation of a potential donor who discontinues the evaluation process prior to donation. The Committee understands that programs must fulfill all current policy requirements for informed consent only for actual living donors and consequently favors removing all references to potential donors.

Living donor program site surveyors were consulted and supported removing all references to potential living donors from policy. The site surveyors commented that they review the medical records of living donors, and would only review a potential donor medical record on rare occasions and for small volume programs with an insufficient number of actual living donor medical records available for review.

### ***Domino Donors***

The Committee considered but did not support requiring these proposed new informed consent requirements for domino liver donation. The Liver and Living Donor Committees may propose new policy requirements for domino liver donation as a separate and future project.

### ***Requirements for Living Donors***

At this time, living kidney donor recovery programs must follow OPTN policies for the informed consent of potential living kidney donors. However, under current policy, living liver donor recovery programs are required to develop and follow their own center-specific protocols for the informed consent of potential living liver donors. Programs that perform living lung, intestine, or pancreas donor recovery currently are not required to follow any OPTN policy or develop and follow their own center-specific protocols for the informed consent of potential living organ donors.

This proposal was originally intended to expand the same level of detail concerning the informed consent of living kidney donor to living liver donors. It is now expanded to include the other categories solid organ living donors (lung, intestine, and pancreas). The proposal would lead to the standardization of the informed consent process for the other categories of solid organ living donors. Under this proposal, all existing policy requirements for the informed consent of living kidney donors were compared to the (JSWG) recommended requirements for living liver donors. The common elements in existing living kidney donor policy and recommended requirements for living liver donors are proposed as new requirements for the other specified categories of living donors. The proposal would lead to standardization of the informed consent process for potential solid organ living donors.

The proposal contains additional elements as components of informed consent specific to living kidney and liver donors. In general, the additional elements address education about expected post-donation native organ function and potential medical and surgical risk associated with these specific types of living donation. The Committee considered, but did not propose, additional elements of informed consent specific to living lung, pancreas, or intestine donation because the volume of living lung, pancreas, and intestine donation is so low that that the risks associated with these surgeries may not be fully known. Given the low volumes, there are limited published data on complications or long term outcomes, and there is unlikely to be a consensus conference for the development of an expert opinion.

### **Supporting Evidence:**

These proposed policy requirements are based on recommendations from a Joint Society Work Group (JSWG) comprised of individuals appointed to represent the transplant professional societies including the American Society of Transplantation, the American Society of Transplant Surgeons, and the North American Transplant Coordinators Organization. The recommendations provided by this expert panel were based on an extensive literature review and approved by their parent organizations.

**Expected Impact on Living Donors or Living Donation:**

A standardized informed consent process should improve the transparency of the living donation process and could improve the confidence of living donors with regard to the safety of living donation. Over time, analysis of the living donor informed consent process could contribute to better outcomes.

**Expected Impact on Specific Patient Populations:**

There should be no impact on the candidate pool. However, the proposal has the potential to affect living kidney, liver, pancreas, intestine, and lung donors.

In 2013, there were 5989 living organ donors, including 5734 living kidney donors, 252 living liver donors, and two living lung donors.

Between 2007 and 2013, there were 13 living lung donors, six living intestinal donors, and two living pancreas donors.

**Expected Impact on OPTN Key Goals and Adherence to OPTN Final Rule:**

<i>HHS Program Goals</i>	<i>Strategic Plan Goals</i>
<b>Patient Safety</b>	New standardized informed consent requirement will promote safe, high-quality care for transplant candidates, transplant recipients, and living donors.
<b>Best Use</b>	New standardized informed consent requirements should lead to objective, and measurable criteria related to concepts of donor risk/quality and recipient benefit
<b>Operational Effectiveness</b>	New standardized informed consent requirements would lead to system improvements that best support critical network functions, and would be disseminated to all members who could benefit

**Plan for Evaluating the Proposal:**

The Committee will request biannual blinded reports on the number of centers found out of compliance during UNOS living donor program audits and will evaluate if the policy requirements for the informed consent of living donors need clarification or revision to aid centers with compliance.

**Additional Data Collection:**

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

**Expected Implementation Plan:**

If this policy proposal is approved by the Board of Directors, living donor recovery centers would be required to follow new policies for the informed consent of living donors. The UNOS Living

Donor Site Surveyors will evaluate center compliance. The proposal will not require programming in UNet<sup>SM</sup>.

### **Communication and Education Plan:**

The proposal addresses both modifications to existing policy and new requirements. Its applicability to all potential solid organ living donors (kidney, liver, pancreas, lung, intestine) requires an above-average effort to ensure that living donor transplant programs are aware of the requirements. Communication and education efforts will address the details of the new and revised requirements and support members who may need to revise their individual protocols.

Information about the new requirements would be included in an ongoing effort to provide instructional programs to members regarding patient and living donor safety, with particular emphasis on practices at living donor transplant programs. It also would be incorporated into the OPTN Evaluation Plan and addressed in the context of ongoing member notification as the plan is periodically updated.

In addition, notification of the amended policy requirements would be included in the following routine communication vehicles:

- Policy notice
- System notice
- Member e-newsletter/blog article
- Notification to appropriate list serve groups

### **Compliance Monitoring:**

**The following changes to existing routine monitoring of OPTN members will occur:**

*Policy 14.2.A ILDA Requirements for Living Donor Recovery Hospitals (previously titled ILDA Requirements for Kidney Recovery Hospitals)*

The specific requirements monitored by site surveyors are unchanged, but monitoring of members will be expanded to both living kidney donor and living liver donor recovery hospitals.

*Policy 14.2.B ILDA Protocols for Living Donor Recovery Hospitals (previously titled ILDA Protocols for Kidney Recovery Hospitals)*

The specific requirements monitored by site surveyors are unchanged, but monitoring of members will be expanded to both living kidney donor and living liver donor recovery hospitals.

*Policy 14.3 Informed Consent Requirements*

Requirements previously monitored by site surveyors under policy 14.3.A.i *Living Kidney Donor Informed Consent for Evaluation of Potential Living Donors* and policy 14.3.A.ii *Living Kidney Donor Informed Consent Requirements* will now be monitored under the new policy 14.3 *Informed Consent Requirements*. Monitoring of members will be expanded to both living kidney donor and living liver donor recovery hospitals.

At living kidney and liver donor recovery hospitals, site surveyors will:

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for a document signed by the living donor confirming that the donor:

- Is willing to donate

- Is free from inducement and coercion
- Has been informed that he/she may decline to donate at any time

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that:

- The donor was offered an opportunity to discontinue the donor consent or evaluation process in a way that is protected and confidential
- An ILDA was available to assist the donor during the consent process
- The recovery hospital provided the required information and disclosures to the living donor

Interview relevant staff and substantiate the information obtained in the interview through review of internal policies, procedures, and/or protocols; a sample of living donor medical records; or any material incorporated into the medical record by reference to obtain evidence that the hospital's standard practice is to provide information to donors in a language in which the donor is able to engage in a meaningful dialogue with the recovery hospital staff.

At living kidney donor recovery hospitals, site surveyors will review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that the recovery hospital provided the required kidney-specific information and disclosures to living kidney donors.

**The following new routine monitoring of OPTN members will occur:**

*Policy 14.3 Informed Consent Requirements*

At living liver donor recovery hospitals, site surveyors will review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that the recovery hospital provided the required liver-specific information and disclosures to living liver donors

**Policy or Bylaw Proposal:**

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

1 At a meeting of the OPTN/UNOS Board of Directors convened on November 12-13, 2014 in St.  
2 Louis, MO, the following resolution is offered.

3  
4 *A resolution to modify existing or establish new requirements for the informed consent of Living*  
5 *Donors.*

6  
7 Sponsoring Committee: Living Donor

8  
9 **RESOLVED, that the following new or modified Policies 14.2.A (ILDA Requirements for**  
10 **Kidney Recovery Hospitals), 14.2.B (Protocols for Kidney Recovery Hospitals), 14.3**  
11 **(Informed Consent Requirements), as set forth below are effective February 1, 2015.**

12  
13 #

14  
15 **14.2 Independent Living Donor Advocate (ILDA) Requirements**

16  
17 **14.2.A ILDA Requirements for Kidney Living Donor Recovery Hospitals**  
18

19 Living donor ILDA requirements do not apply to any individual who is undergoing transplant  
20 whose native organ is suitable for transplant to another transplant candidate.  
21

22 Living donor ILDA requirements apply to living kidney, liver, pancreas, intestine or lung donors.  
23

24 For any ~~potential~~ living kidney donor who is undergoing evaluation for donation, the living kidney  
25 donor recovery hospital must designate and provide each ~~potential~~ living donor with an ILDA who  
26 is not involved with the potential recipient evaluation and is independent of the decision to  
27 transplant the potential recipient. The ILDA may be one person or an independent living donor  
28 advocate team with multiple members. An ILDA team must designate one person from the team  
29 as the key contact for each ~~potential~~ living donor.  
30

31 The ILDA must:

- 32
- 33 1. Function independently from the transplant candidate's team.
  - 34
  - 35 2. Advocate for the ~~rights of the potential~~ living donor ~~and the living donor~~.
  - 36
  - 37 3. Fulfill the qualification and training requirements specified in the recovery hospital's  
38 protocols regarding knowledge of living organ donation, transplantation, medical ethics,  
39 informed consent, and the potential impact of family or other external pressure on the  
40 ~~potential~~ living donor's decision about whether to donate. Document that each requirement  
41 has been met.
  - 42
  - 43 4. Review whether the ~~potential~~ living donor has received information on each of the  
44 following areas and assist the ~~potential~~ donor in obtaining additional information from other  
45 professionals as needed about the:
    - 46
    - 47 • Informed—consent process as described in *Policy 14.3: Informed Consent*  
48 *Requirements* ~~and its subsections~~
    - 49
    - 50 • Evaluation process according to *Policies 14.3.A.ii, 14.51-A: Living Kidney Donor*  
51 *Psychosocial Evaluation Requirements* ~~and 14.4.B: Living Kidney Donor Medical~~  
52 *Evaluation Requirements* ~~and its subsections~~
    - 53
    - 54 • Surgical procedure
    - 55
    - 56 • Medical risks according to ~~*Policy 14.3.A.ii Tables 14-1 through 14-5*~~
    - 57
    - 58 • Psychosocial risks according to ~~*Policy 14.3.A.ii Tables 14-1 through 14-5*~~
    - 59
    - 60 • Follow-up requirements, and the benefit and need for participating in follow-up  
61 according to *Policies 18.1: Data Submission Requirements, 18.5.A: Reporting*  
62 *Requirements after Donation* and *18.5.B: Submission of Living Donor Death and*  
63 *Organ Failure*
    - 64
  - 65 5. Document that each topic was reviewed.

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#### **14.2.B ILDA Protocols for ~~Kidney~~ Living Donor Recovery Hospitals**

The living ~~kidney~~ donor recovery hospital must develop, and once developed must comply with written protocols for:

1. The composition of the ILDA team, if the hospital uses a team
2. The qualifications and training (both initial and ongoing) required for the ILDA. Minimum qualifications must include knowledge of living organ donation, transplantation, medical ethics, informed consent, and the potential impact of family or other external pressures on the ~~potential~~ living donor's donation decision.
3. The duties and responsibilities of the ILDA, which must include at least the functions and duties listed throughout *Policy 14.2.A: ILDA Requirements for ~~Kidney~~ Living Donor Recovery Hospitals*.
4. The process the living donor recovery hospital will provide for the ILDA to file a grievance when necessary to protect the rights or best interests of the living donor.
5. The process the living donor recovery hospital will use to address any grievance raised by the ILDA concerning the rights or best interests of the living donor.

#### **14.2.C ILDA Protocols for Liver Recovery Hospitals**

~~Liver recovery hospitals must develop and comply with written protocols for the duties and responsibilities of the ILDA that include, but are not limited to, all of the following elements:~~

- ~~1. Promoting the best interests of the potential living donor~~
- ~~2. Advocating for the rights of the living donor~~
- ~~3. Assisting the potential donor in obtaining and understanding information about the:
 
  - ~~a. Consent process~~
  - ~~b. Evaluation process~~
  - ~~c. Surgical procedure~~
  - ~~d. Benefit of follow up~~
  - ~~e. Need for follow up~~~~

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### **14.3 Informed Consent Requirements**

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~~Education is important so that the potential living donor understands all aspects of the donation process, especially the risks and benefits.~~

#### **14.3.A Informed Consent of Living Kidney Donors**

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~~Informed consent is required to ensure that a potential living donor understands:~~

- ~~1. That the living donor will undertake risk and will receive no medical benefit from donating a kidney.~~

117 2. ~~That there are both the general risks of the surgery as well as hospital specific~~  
 118 ~~risks.~~

119  
 120 **14.3. A.i Living Donor Informed Consent for Evaluation of Potential Living Donors**  
 121 The kidney recovery hospital must maintain documentation in the living donor's medical  
 122 record that the recovery hospital informed the potential living donor of *all* of the following:

123  
 124 **14.3.A.ii Living Donor Informed Consent Requirements**  
 125 The recovery hospital must obtain informed consent from any potential living kidney donor  
 126 that must include written assurance by the potential living donor of *all* of the following:

127  
 128 ~~The kidney recovery hospital must document in the potential donor's medical record that the~~  
 129 ~~hospital provided the potential donor with *all* of the following:~~

130  
 131 Living donor informed consent requirements do not apply to any individual who is undergoing  
 132 transplant whose native organ is suitable for transplant to another transplant candidate.

133  
 134 Living donor informed consent requirements apply to living kidney, liver, pancreas, and intestine  
 135 or lung donors.

136  
 137 The recovery hospital is responsible for informed consent which must include *all* of the  
 138 components in *Tables 14-1 – 14-5*.

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 140 Documentation of informed consent must be maintained in the donor medical record.

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**Table 14-1: Requirements for Living Donor Informed Consent**

The recovery hospital must:	These elements of informed consent
Obtain from all living donors	<p><del>Written assurance by the potential donor</del> <u>The donor's signature on a document that confirms that the donor:</u></p> <ul style="list-style-type: none"> <li><del>• That the potential donor is willing to donate</del></li> <li><del>• That the potential donor is free from inducement and coercion and</del></li> <li><del>• That the potential donor has been informed that he or she may decline to donate at any time.</del></li> </ul>

The recovery hospital must:	These elements of informed consent
<p><b>Provide to all living donors</b></p>	<p><del>The potential living donors must be offered a</del> An opportunity to discontinue the donor consent or evaluation process in a way that is protected and confidential.</p> <p>The ILDA must be available to assist the <del>potential</del> donor during <del>this</del> the <u>consent</u> process, according to <i>Policy 14.2: <u>Independent Living Donor Advocate (ILDA) Requirements.</u></i></p> <p>Instruction about all phases of the living donation process, which include:</p> <ul style="list-style-type: none"> <li>• <del>e</del>Consent</li> <li>• <del>m</del>Medical and psychosocial evaluations</li> <li>• <del>p</del>Pre and post operative care, and</li> <li>• <del>r</del>Required post-operative follow up according to <i>Policy 18.5: <u>Living Donor Data Submission Requirements.</u></i></li> </ul> <p>Teaching or instructional material can include any media, one-on-one or small group interaction.</p> <p>Teaching or instruction must be provided in a language in which the donor is able to engage in meaningful dialogue with <del>transplant program</del> recovery hospital's staff.</p>

The recovery hospital must:	These elements of informed consent
<p>Disclose to all living donors</p>	<p><del>The disclosure that t</del>The recovery hospital will take all reasonable precautions to provide confidentiality for the donor and recipient.</p> <p><del>The disclosure that i</del>It is a federal crime for any person to knowingly acquire, obtain or otherwise transfer any human organ for anything of value including, but not limited, to cash, property, and vacations.</p> <p><del>Disclosure t</del><u>That the</u> recovery hospital must provide an ILDA.</p> <p><del>The disclosure of a</del>Alternate procedures or courses of treatment for the recipient, including deceased donor transplantation, and that:</p> <ul style="list-style-type: none"> <li>a) A deceased donor <u>kidney organ</u> may become available for the <u>recipient candidate</u> before the recovery hospital completes the <u>potential</u> living donor’s evaluation or the living donor transplant occurs.</li> <li>b) Any transplant candidate may have risk factors for increased morbidity or mortality that are not disclosed to the <u>potential</u> donor.</li> </ul> <p><del>The disclosure that h</del>Health information obtained during the evaluation is subject to the same regulations as all <u>medical</u> records and could reveal conditions that must be reported to local, state, or federal public health authorities.</p> <p><del>The disclosure that t</del>The recovery hospital is required to:</p> <ul style="list-style-type: none"> <li>a) Report living donor follow up information, at the time intervals specified in <i>Policy 18.5: Living Donor</i>.</li> <li>b) Have the <u>potential</u> donor commit to post operative follow up testing coordinated by the recovery hospital.</li> </ul> <p><del>The disclosure that a</del>Any infectious disease or malignancy pertinent to acute recipient care discovered during the <u>potential</u> donor’s first two years of follow up care:</p> <p style="padding-left: 40px;"><del>Will be disclosed to the donor</del></p> <ul style="list-style-type: none"> <li>a) May need to be reported to local, state or federal public health authorities</li> <li>b) Will be disclosed to their recipient’s transplant center</li> <li>c) Will be reported through the OPTN Improving Patient Safety Portal.</li> </ul>

The recovery hospital must:	These elements of informed consent
<p><b>Disclose to all living donors</b></p>	<p><del>potential</del> A living donor must undergo a medical evaluation according to <i>Policy 14.4 ( Medical Evaluation Requirements for Living Donors)</i> and a psychosocial evaluation as required by <i>Policy 14.5.1 (Psychosocial Evaluation Requirements for Living Donors)</i></p> <p>The hospital may refuse the <del>potential</del> donor. In such cases, the recovery hospital must inform the <del>potential</del> donor that a different recovery hospital may evaluate the <del>potential</del> donor using different selection criteria.</p> <p>The following are inherent risks associated with evaluation for living donation:</p> <ul style="list-style-type: none"> <li>a) Allergic reactions to contrast</li> <li>b) Discovery of reportable infections</li> <li>c) Discovery of serious medical conditions</li> <li>d) Discovery of adverse genetic findings unknown to the donor</li> <li>e) 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</li> </ul> <p><del>That the following</del> There are surgical, medical, psychosocial, and financial risks <del>are</del> associated with living kidney donation. <del>This disclosure must state that these risks</del> <u>which</u> may be temporary or permanent and include, but are not limited to, <i>all</i> of the following:</p>

<p><b>Disclose to all living donors</b></p>	<ul style="list-style-type: none"> <li>a. Potential medical or surgical risks:           <ul style="list-style-type: none"> <li>i. Death</li> <li>ii. Scars, <u>hernia, wound infection, blood clots, pneumonia, nerve injury</u>, pain, fatigue, and other consequences typical of any surgical procedure</li> <li>iii. Abdominal symptoms such as bloating, nausea, and developing bowel obstruction</li> <li>iv. That the morbidity and mortality of the <del>potential</del> donor may be impacted by obesity, hypertension, or other donor-specific pre-existing conditions</li> <li><del>v. Decreased kidney function</del></li> <li><del>vi. Kidney failure and the need for dialysis or kidney transplant for the donor</del></li> </ul> </li> <li>b. Potential psychosocial risks:           <ul style="list-style-type: none"> <li>i. Problems with body image</li> <li>ii. Post-surgery depression or anxiety</li> <li>iii. Feelings of emotional distress or grief if the transplant recipient experiences any recurrent disease or if the transplant recipient dies</li> <li>iv. Changes to the donor's lifestyle from donation</li> </ul> </li> <li>c. Potential financial impacts:           <ul style="list-style-type: none"> <li>i. 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</li> <li>ii. Need for life-long follow up at the donor's expense</li> <li>iii. Loss of employment or income</li> <li>iv. Negative impact on the ability to obtain future employment</li> <li>v. Negative impact on the ability to obtain, maintain, or afford health insurance, disability insurance, and life insurance</li> <li>vi. Future health problems experienced by living donors following donation may not be covered by the recipient's insurance</li> </ul> </li> </ul>
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**Table 14-42: Required Recipient Outcome and Transplanted Kidney Organ Survival Data**

If the recovery hospital and the recipient hospital:	Then:	Including <i>all</i> the following information:
Are the same	The recovery hospital must provide the <del>potential</del> living donor with both national and that hospital's program-specific transplant recipient outcomes from the most recent Scientific Registry of Transplant Recipients (SRTR) hospital-specific reports.	<ul style="list-style-type: none"> <li>• National 1-year patient and transplanted <del>kidney organ</del> <u>organ</u> survival</li> <li>• The hospital's 1-year patient and transplanted <del>kidney organ</del> <u>organ</u> survival</li> <li>• Notification about all Centers for Medicare and Medicaid Services (CMS) outcome requirements not being met by the transplant hospital</li> </ul>
Will not be the same and the recipient hospital is known	The recovery hospital must provide the <del>potential</del> living donor with both national and the recipient hospital's program-specific transplant recipient outcomes from the most recent SRTR hospital-specific reports.	<ul style="list-style-type: none"> <li>• National 1-year patient and transplanted <del>kidney organ</del> <u>organ</u> survival</li> <li>• The recipient hospital's 1-year patient and transplanted <del>kidney organ</del> <u>organ</u> <u>survival</u></li> <li>• Notification about all CMS outcome requirements not being met by the recipient hospital</li> </ul>

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**Table 14-3: Additional Requirements for the Informed Consent of Living Kidney Donors**

The recovery program must	These additional elements as components of informed consent for living kidney donors
Provide to all living kidney donors	<p>Education about expected post-donation kidney function, and how chronic kidney disease (CKD) and end-stage renal disease (ESRD) might potentially impact the living donor in the future, to include:</p> <ol style="list-style-type: none"> <li>a. On average, living donors may have a 25-35% permanent loss of kidney function after donation.</li> <li>b. Baseline risk of ESRD for living kidney donors does not exceed that of the general population with the same demographic profile.</li> <li>c. Living donor risks must be interpreted in light of the known epidemiology of both CKD and ESRD. When CKD or ESRD occurs, CKD generally develops in mid-life (40-50 years old) and ESRD generally develops after age 60. The medical evaluation of a young <del>potential</del> living donor cannot predict lifetime risk of CKD or ESRD.</li> <li>d. Living 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 faster with only one kidney.</li> <li>e. Dialysis is required if the donor develops ESRD.</li> <li>f. Current practice is to prioritize prior living kidney donors who become kidney transplant candidates according to <i>Policy 8.3: Points</i></li> </ol>
Disclose to all living kidney donors	<p><del>Disclosure that these</del> <u>Surgical</u> risks may be transient or permanent and include but are not limited to:</p> <ul style="list-style-type: none"> <li>• Potential medical or surgical risks:               <ul style="list-style-type: none"> <li>○ Decreased kidney function</li> <li>○ Kidney failure and the need for dialysis or kidney transplant for the donor</li> </ul> </li> </ul>

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**Table 14-4: Additional Requirements for the Informed Consent of Living Liver Donors**

The recovery program must	These additional elements as components of informed consent for living liver donors
Disclose to all living liver donors	<p><u>Surgical risks may be transient or permanent and include but are not limited to:</u></p> <ul style="list-style-type: none"> <li>• <u>Acute liver failure with need for liver transplant.</u></li> <li>• <u>Transient liver dysfunction with recovery. The potential for transient liver dysfunction depends upon the amount of the total liver removed for donation.</u></li> <li>• <u>Risk of red cell transfusions or other blood products.</u></li> <li>• <u>Biliary complications, including leak or stricture that may require additional intervention.</u></li> <li>• <u>Hernia, wound infection, scars, blood clots, pneumonia, nerve injury, pain, fatigue, and other consequences typical of any surgical procedure.</u></li> <li>• <u>Post-donation laboratory tests may result in abnormal or false positive results that may trigger additional tests that have associated risks.</u></li> </ul>

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**Table 14-5: Additional Required Living Liver Donor Recipient Outcome and Transplanted Living Donor Liver Survival Data**

<u>If the recovery hospital and the recipient hospital:</u>	<u>Then:</u>	<u>Including all the following information:</u>
<u>Are the same</u>	<u>The recovery hospital must provide the living donor with the hospital's program-specific transplant recipient outcomes from the most recent Scientific Registry of Transplant Recipients (SRTR) hospital-specific reports.</u>	<ul style="list-style-type: none"> <li data-bbox="927 512 1346 638">• <u>The hospital's 1-year living donor recipient's survival and recipient's graft survival rates</u></li> </ul>
<u>Will not be the same and the recipient hospital is known</u>	<u>The recovery hospital must provide the living donor with the recipient hospital's program-specific transplant recipient outcomes from the most recent SRTR hospital-specific reports.</u>	<ul style="list-style-type: none"> <li data-bbox="927 814 1346 940">• <u>The recipient hospital's 1-year living donor recipient's survival and graft survival rates</u></li> </ul>

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**14.3.B Living Liver Donor Required Protocols for Informed Consent for Evaluation**

Liver recovery hospitals must develop and comply with written protocols for the informed consent process and for the living donor liver recovery that must include, but are not limited to, all 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. The assurance that all communication between the potential living donor and the transplant hospital will remain confidential.
3. A discussion of the potential living donor's right to opt out at any time during the donation process.
4. A discussion that the medical evaluation or donation may impact the potential donor's ability to obtain health, life, and disability insurance.
5. The disclosure by the liver 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.
6. A plan to collect the required follow up information about each donor.
7. Providing the toll free Patient Services Line that is available for living donors to report concerns or grievances to the OPTN.
8. The disclosure that it is a federal crime for any person to knowingly acquire, obtain, or otherwise transfer any human organ for anything of value, including, but not limited, to cash, property, and vacations. This documentation must be maintained in the potential donor's official medical record.

**#Public Comment Responses**

**1. Public Comment Distribution**

Date of distribution: March 14, 2013

Public comment end date: June 13, 2013

Public Comment Response Tally					
Type of Response	Response Total	In Favor	In Favor as Amended	Opposed	No Vote/ No Comment/ Did Not Consider
Individual	31	23 (74.19%)	0 (%)	2 (6.45%)	6 (19%)
Regional	11	9 (81.8 %)	2 (18.2 %)	0 (%)	0
Committee	7	7 (100 %)	0 (%)	0 (%)	12

**2. Primary Public Comment Concerns/Questions**

**3. Regional Public Comment Responses**

Region	Meeting Date	Motion to Approve as Written	Approved as Amended (see below)	Meeting Format
1	5/5/2014	Yes		In person
2	3/28/2014	Yes		In person
3	5/30/2014	No		In person
4	5/9/2014	Yes		In person
5	6/12/2014	Yes		In person
6	5/16/2014	Yes		In person
7	5/9/2014	Yes		In person
8	4/4/2014	Yes		In person
9	5/21/2014	Yes		In person
10	5/15/2014	Yes		In person
11	5/30/2014	No		In person

**Region 1:**

The region requested that a sample consent form and checklist be developed for members to review to ensure that their consent forms include all required elements.

**Committee Response:**

UNOS has prepared checklists to assist living kidney donor hospitals with developing their center-specific templates, tools and internal policies and procedures. These checklist are available on the OPTN web site at <http://optn.transplant.hrsa.gov/news/checklist-tools-can-help-with-new-optn-living-donor-policy-compliance/>.

UNOS' Department of Evaluation and Quality will prepare and post similar checklists to assist with living liver donor policy compliance.

**Region 3:**

The region did not support this proposal. There was a concern that the living donor program does not have to disclose the number of living donor deaths that occurred at their program. There was also a request that the committee consider developing a standardized consent form.

**Committee Response:**

Under the proposal, the recovery hospital must disclose to living donors that there are medical risks associated with living donation that include death. Living donor deaths are rare events. The recommendation of the Joint Societies Work Group, accepted by the Living Donor Committee, was that center-specific data about risks, including risk of death, should not be required within policy because individual center volume at most centers is too small to yield reliable estimates of risk of specific events (particularly if those events are rare) for any given center. In addition, the period of time that should be encompassed in the calculation of risk at any given center is unclear, especially since the composition of surgical teams may change over time. OPTN policy does not preclude individual centers from discussing recent donor deaths at their center (or any donor deaths in the history of their center) with donors.

The Living Donor Committee has previously discussed and does not support the development of standardized consent forms at this time for two reasons. First, consent requirements may continue to evolve in the future, creating a need to continuously update the standardized consent form. Second, UNOS has prepared checklists to assist living kidney donor hospitals with developing their center-specific templates (including consent form templates), tools, and internal policies and procedures. These checklist are available on the OPTN web site at <http://optn.transplant.hrsa.gov/news/checklist-tools-can-help-with-new-optn-living-donor-policy-compliance/>

UNOS' Department of Evaluation and Quality will prepare and post similar checklists to assist with living liver donor policy compliance.

**Region 10:**

The regional patient affairs committee representative requested that UNOS consider adding a member of the National Social Workers Society to the Joint Society Workgroup. In many institutions social workers who have the most contact with the living donors and they feel that their input into these proposal early would be of benefit.

**Committee Response:**

Social workers were represented on the Joint Society Work Groups, which provided past recommendations for living kidney and living liver donor informed consent, medical evaluation, and follow-up policies. The Living Donor Committee recognizes the important contributions of social workers in the evaluation and care of potential and actual living donors and supports continued representation by social workers.

**Region 11:**

See Region 3

**Committee Response:**

The policy proposal and its proposed disclosure requirements are based on recommendations from a Joint Societies Work Group comprised of representatives from the transplant professional societies.

Under the proposal, the recovery hospital must disclose to all living donors that there are medical risks associated with living donation that include death. Living donor deaths are rare events. The recommendation of the Joint Societies Work Group, accepted by the Living Donor Committee, was that center-specific data about risks, including risk of death, should not be required within policy because individual center volume at most centers is too small to yield reliable estimates of risk of specific events (particularly if those events are rare) for any given center. In addition, the period of time that should be encompassed in the calculation of risk at any given center is unclear, especially since the composition of surgical teams may change over time. OPTN policy does not preclude individual centers from discussing recent donor deaths at their center (or any donor deaths in the history of their center) with donors.

The Living Donor Committee has previously discussed and does not support the development of standardized consent forms at this time for two reasons. First, consent requirement may continue to evolve in the future, creating a need to continuously update the standardized consent form. Second, UNOS has prepared checklists to assist living kidney donor hospitals with developing their center-specific templates (including consent form templates), tools, and internal policies and procedures. These checklist are available on the OPTN web site at <http://optn.transplant.hrsa.gov/news/checklist-tools-can-help-with-new-optn-living-donor-policy-compliance/>

UNOS' Department of Evaluation and Quality will prepare and post similar checklists to assist with living liver donor policy compliance.

**4. Committee Public Comment Responses****Ad Hoc Disease Transmission Advisory Committee:**

The Committee considered this proposal after presentation by the Living Donor Committee Chair during its meeting. It was noted that this proposal extends the same informed consent requirements currently in place for living kidney donors to all living donor organ donors, with a few minor organ specific exceptions. A Committee member recognized that new literature regarding the function of the independent living donor advocate (ILDA) is not altogether favorable. There was concern regarding the current policy requirements related to the ILDA, and specifically, language that notes the ILDA as responsible for making sure that the psychosocial evaluation has taken place and that the donor understands the process. The question of informed consent is one to struggle with and must be structured on a case-by-case basis to some degree. A member suggested that expert advice can be offered, but one must have something specific to each organ to share (e.g. what is the consequence of losing a portion of your lung, your liver, and your islets?). This affects a very small number of living donors who are giving organs outside of kidney or liver, which is more common. The Chair noted that what was already common for liver and kidney was also applied for other organs. Items that were specific to liver or kidney were not included for other organs. There simply was not data to demonstrate how to approach this for these less frequently used living donor organs.

Another member noted that telling living donors that these other organs are rarely done is exactly the kind of information that needs to be shared with these potential living donors due to the rarity of these procedures and the additional risks related to it being a rare procedure. Three recent

large publications have come out regarding increased risk for living kidney donors. This information is currently being reviewed to determine if modifications to living kidney donor informed consent should be modified. A reminder was issued that policy mandates minimum requirements, not best practices.

After brief discussion, supported it as written (14 yes, 0 no, 1 abstained).

**Sponsoring Committee Response:**

The Living Donor Committee thanks DTAC for reviewing the proposal and providing feedback. This feedback will be provided for the full Committee to consider.

**Liver and Intestinal Organ Transplantation Committee:**

The Liver and Intestinal Committee considered this proposal in November 2013 prior to the formal release for public comment. While the number of living lung, pancreas and intestine donors is very low, these donors are not addressed under any existing OPTN policy or bylaws for living donor consent or medical evaluation. As currently proposed, the OPTN would have general consent and medical evaluation policies that would apply to all types of living donors, and other consent and medical evaluation policies that would be specific to living kidney and liver donors. The Committee felt that it makes sense to apply these protections to all types of living donors and therefore supports this proposal.

**Sponsoring Committee Response:**

The Living Donor Committee thanks the Liver Committee for its support of this proposal.

**Membership and Professional Standards Committee:**

The MPSC did not consider this proposal but had provided feedback during proposal development.

**Patient Affairs Committee:**

After a lengthy discussion, the Committee asked that the following points be considered with the proposal.

- 1) Transplant Programs should be encouraged to develop their own organ specific consents, which reflect risk of death and center-specific outcomes.
- 2) Informed consents should quantify the increased risk of death with both center specific and national statistics,
- 3) Informed consents should state the increased risk of living liver donation as compared to living kidney donation.

(Support – 16, Abstain – 0, Against – 0)

**Sponsoring Committee Response:**

The Living Donor Committee thanks the Patient Affairs Committee for its support of this proposal.

With regard to specific consent forms, UNOS has prepared checklists to assist living kidney donor hospitals with developing their center-specific templates (including consent form templates), tools and internal policies and procedures. These checklist are available on the OPTN web site at <http://optn.transplant.hrsa.gov/news/checklist-tools-can-help-with-new-optn-living-donor-policy-compliance/>. UNOS' Department of Evaluation and Quality will prepare and post similar checklists to assist with living liver donor policy compliance.

With regard to risk of death, under the proposal the recovery hospital must disclose to all living donors that there are medical risks associated with living donation that include death. This conforms to the recommendations of the Joint Societies Work Group. Living donor deaths are rare events, making it difficult to produce statistically reliable estimates of risk, even at a national level. At the level of the center, the Work Group recommended that center-specific data about risks, including risk of death, should not be required within policy because individual center volume at most centers is too small to yield reliable estimates of risk of specific events (particularly if those events are rare) for any given center. In addition, the period of time that should be encompassed in the calculation of risk at any given center is unclear, especially since the composition of surgical teams may change over time. OPTN policy does not preclude individual centers from discussing recent donor deaths nationally, or donor deaths at their center (or any donor deaths in the history of their center) with donors.

The Living Donor Committee does not support adding comparative information about risks associated with living liver vs. living kidney donation. Individuals considering living donation undergo evaluation for a single type of donation and thus information relative to a different type of donation is not relevant for them.

**Pediatric Transplantation Committee:**

The Committee considered this proposal during its June 4 meeting after a presentation by Lee Bolton, Living Donor Transplantation Committee Liaison.

Two Committee members had feedback regarding the requirement to inform the living donor of “abnormal post-donation lab results which could lead to additional testing with associated risks”. One member felt the requirement was too sweeping. Policy should specify the information that needs to be shared and give guidance on educating the donor about the appropriate level of risk associated with testing. He felt that otherwise, when implemented, this requirement would show up as a “blanket, general statement” given to living donors that would either not be meaningful or needlessly discourage them. Another Committee member suggested that this requirement also specify when and why the post-donation tests would be performed.

Another Committee member asked how much discretion a program would have in how to present this information to a living donor based on the level of potential risk, specifically citing the requirement to disclose a risk of acute liver failure to living liver donors. Similar to the concerns raised regarding risks associated with post-donation testing, this Committee member wanted to ensure that these disclosures intimated an appropriate level of risk.

Finally, one Committee member was concerned that this policy does not include special disclosures for living lung, pancreas, or intestine donors. Mr. Bolton explained that the Living Donor Transplantation Committee did not find evidence in the literature supporting special disclosures, and she agreed that evidence is lacking because of how uncommon these procedures are.

The Committee voted to support this proposal (11 yes, 0 no, 0 abstentions).

**Sponsoring Committee Response:**

The Living Donor Committee thanks the Pediatric Committee for these comments and its support for the proposal.

The Committee agrees that policy must be specific regarding the information that must be provided to donors. Policy requirements must be measurable in order to evaluate compliance.

Existing policy (18.5 Reporting Requirements after Living Liver Donation) addresses required testing and the timeline for testing. The proposed policy refers to abnormal results obtained specifically from the required tests. Each living donor recovery program may provide information on level of risk associated with additional testing. Regarding the presentation of information on all areas of risk, including risk of acute liver failure to living liver donors, policy does not specify and thus centers would have discretion in the presentation of this information. UNOS has prepared checklists to assist living kidney donor hospitals with developing their center-specific templates (including consent form templates), tools, and internal policies and procedures. These checklist are available on the OPTN web site at <http://optn.transplant.hrsa.gov/news/checklist-tools-can-help-with-new-optn-living-donor-policy-compliance/>. UNOS' Department of Evaluation and Quality will prepare and post similar checklists to assist with living liver donor policy compliance.

**Transplant Administrators Committee:**

The Committee received a presentation on the proposal and supports it as written.

Committee Vote: 12 in favor, 0 oppose, 0 abstentions

**Sponsoring Committee Response:**

The Living Donor Committee thanks the Transplant Administrators Committee for its support of the proposal.

**Transplant Coordinators Committee:**

(Support 12, Oppose 0, Abstain 1) This proposal was presented to the Committee and after a brief discussion, they voted to support the proposal as written.

**Sponsoring Committee Response:**

The Living Donor Committee thanks the Transplant Coordinators Committee for its support of the proposal.

**5. Individual Public Comment Responses**

**Comment 1:**

Vote: Oppose

Date Posted: 03/15/2014

People who have not yet donated and who are under eval to donate should be called Living Donor Candidates NOT Living Donors. Using the later term creates lots of confusion. I see this ALL THIS TIME when I peer review journal manuscripts. We all need to speak one, clear common language.

**Committee Response:**

In OPTN/UNOS policy the word "candidate" is defined as a person registered on the organ transplant waiting list. When a candidate appears on the match run, the candidate is then referred to as a potential transplant recipient. Consequently, the Committee opines that it would be problematic to use the word "candidate" for living donors.

**Comment 2:**

Vote: Support

Date Posted: 06/17/2014

ASTS supports this proposal as written and based on recommendations from the Joint Society Workgroups.

**Committee Response:**

The Living Donor Committee thanks ASTS for reviewing and responding in support of the proposal.

**Comment 3:**

Vote: Support

Date Posted: 06/13/2014

NATCO supports this proposal as written.

**Committee Response:**

The Living Donor Committee thanks NATCO for reviewing and responding in support of the proposal.

**Comment 4:**

Vote: Support

Date Posted: 05/16/2014

OPTN/UNOS should provide a sample consent that has all the REQUIRED ELEMENTS to be in compliance. Centers could modify the consent as to their individual needs (or not, if they so choose). The OPTN consent would serve as a guideline rather than being prescriptive. ASTS leadership in the past and a large majority at our recent Region 1 meeting favored this approach. OPTN and CMS have used the excuse that they do not want to dictate the consent - that's simply unhelpful. Without a template centers are vulnerable to being "out of compliance" despite their best efforts.

**Committee Response:**

The Living Donor Committee thanks this respondent for their support of the proposal.

UNOS prepared checklist to assist living kidney donor hospitals with developing their center specific templates, tools, and internal policies and procedures. These checklist are available on the OPTN web site at <http://optn.transplant.hrsa.gov/news/checklist-tools-can-help-with-new-optn-living-donor-policy-compliance/>

UNOS' Department of Evaluation and Quality will prepare and post similar checklists to assist with living liver donor policy compliance.

**Comment 5:**

Vote: Support

Date Posted: 03/21/2014

Single consent much less likely to be lost or forgotten.

**Committee Response:**

The Living Donor Committee thanks this respondent for their support of the proposal.

**Comment 6:**

Vote: Support

Date Posted: 06/16/2014

The AST supports this proposal and wants to thank all who contributed to its development. We do offer the following comments:

Regarding Table 14-3: Additional Requirements for the Informed Consent of Living Kidney Donors. The surgical risks specific to kidney donation are vague in comparison to the liver donation specific risks. We would like to see the same language used in both cases. Specifically, the bullet under liver donation specific risks that reads: hernia, wound infection, scars, blood clots, pneumonia, nerve injury, pain, fatigue, and other consequences typical of any surgical procedure should be included in the kidney donation specific risks as well.

There was significant discussion regarding Table 14-3, point B, which contains the following language: Baseline risk of ESRD for living kidney donors does not exceed that of the general population with the same demographic profile. Some proposed that the language should be updated based on more recent publications that suggest the risk of ESRD in living kidney donors may be increased somewhat compared to the general population (i.e., JAMA.2014; 311:579-586), however others felt that this data was still controversial and not supported by other studies and that policy, which does not change rapidly, should likely not specify the specifics of the risk. In the final analysis, it is recommended that since the risk of ESRD in the living donor is continuously being reassessed as new data are defined, each living donor program should be required to include specific information concerning the risk of ESRD in the living donor in the consent process with citation of the source of the information they provide.

Tables 14-2 and 14-5 state that the recovery hospital is required to provide the living donor with both national and the recipient hospitals program-specific transplant recipient outcomes from the most recent SRTR hospital-specific reports. In doing this, care must be taken not to inform the donor about where the kidney will be transplanted, to protect the identity of both non-directed donors and recipients.

#### **Committee Response:**

The Living Donor Committee thanks the AST for its review and support of the proposal.

The full Committee will consider modifying the surgical risk disclosures for living kidney donors as recommended by AST.

The Living Donor Committee considered modifying living kidney donor consent policy to reflect recent studies indicating an increased risk of ESRD for living kidney donors compared with selected “healthy” non-donors. At that time, the Committee opined that, given the ongoing debate and controversy regarding the methodological details used to generate “healthy non-donor” comparisons, it would be premature to modify consent policy requirements. The Committee will continue to reassess as the transplant community continues to vet the new studies in public discussions, and as new data emerge. The current policy does not preclude centers from incorporating emerging data with citation in their educational and/or informed consent practices.

Under this proposal, the recovery hospital is required to disclose that it will take all reasonable precautions to provide confidentiality for the donor and the recipient, which should include using caution when providing SRTR hospital-specific reports.

A Joint Society Work Group addressing KPD consent requirements will propose revisions to this table during the fall 2014 public comment period.

**Comment 7:**

Vote: Support

Date Posted: 03/15/2014

This policy desperately needs revising. As the domonio [sic] for 8 people to receive a kidney at Northwestern in Chicago, I have no mentored over 33 people on living donorship and consistently keeping any medical advice in discussions but encourage them to be extremely pro active in not hesitating to contact their transplant coordinator with ANY issues or concerns. The exit process after donating a kidney is so minimal that it's truly a disgrace for living donors. It's basically here, go home with pain meds and a stool softener (which over 80% of the people I mentored had no idea that it could take up to five days to finally have a bowel movement. It does not give any kind of plan such as your are going to "feel" extremely full, so you may want to eat several times a day but small quantities. The more you are able to walk and expel the gas the better. Make plans if you pets or children so that that will not injur you in jumping. If you are no married with no one had home, thinkg about having someone stay with you for at least the first night. DO NOT vaccum. Just because you start feeling better don't get cocky and re-arrange furniture or go back to lifing for more than five pounds. In form them in they have titanium staples..so that they understand they are safe for an MRI in the future should they need one. Be realistic about going back to work in two weeks. Out of 33 I only know 2 who could do it. Same with driving. Everyone handles these things differently but there was no way I could drive it was without a doubt the most excruiating task for me and I learned it the hard way trying to drive on the highway. Just because the superficial scars of healed, you still have internal healing for a much longer period of time.

**Committee Response:**

The Living Donor Committee thanks this respondent for their support of the proposal.

Related new national policy requirements for the informed consent, psychosocial and medical evaluations, and follow-up of living kidney donor took effect on February 1, 2013. These new policy requirements standardized and should improve the care of living kidney donors. The Living Donor Committee will continue to be responsive to evolving or new problems in the care of future living organ donors.

**Comment 8:**

Vote: No Opinion

Date Posted: 06/16/2014

The National Catholic Bioethics Center (NCBC) wishes to respond to the call for comment concerning the Proposal to Modify Existing or Establish New Requirements for the Informed Consent of all Living Donors (Requirements). This proposal would modify some elements of existing policy for the informed consent of living kidney donors and establish new requirements for the informed consent of all living donors.

As you know, the NCBC is a non-profit research and educational institute committed to applying the moral teachings of the Catholic Church to ethical issues arising in health care and the life sciences, including biomedical research. The NCBC serves numerous health care agencies in their development and analysis of policies and protocols, including protocols for DCD. The Center has 2500 members throughout the United States, and provides consultations to hundreds of institutions and individuals seeking its opinion on this and other matters as they pertain to the appropriate application of Catholic moral teaching.

As we have shared with you in the past, the Catholic Church encourages organ donation as providing a gift of life to those in need. In terms of living donors, the same generosity of donors is recognized, as long as there is respect for true informed consent (as well as the protection of the bodily integrity of the donor to be addressed in our response to the Proposal to Modify Existing or Established New Requirements for the Psychosocial and Medical Evaluation of all Living Donors). That is why rigorous standards for informed consent must be in place and regularly monitored for compliance by OPTN.

The proposed Requirements have standardized the information to be provided in achieving informed consent for all living donors, and expand the population of living donors for whom such criteria for achieving informed consent are required.

While citing the need for achieving true informed consent for all living donors, organ specific information is only identified for those who are living donors of kidneys and livers. Other tissues that are cited as being available from living donors include lung, pancreas and intestinal tissue. Since these are documented sources of donation, regardless of how infrequent, these donors deserve the same protections, or perhaps even more, due to the potential risks that kidney and liver donors are provided. This also is true for “Domino Donors” (liver), for whom no criteria have been developed, and for whom donors may let emotions drive their consent, as they anticipate a domino-like effect as their donations trigger other donations. Furthermore, by intent, these Requirements open the door to the donation of all tissues from living patients, not just those listed, above. This is a very dangerous regulatory omission since it allows the unregulated donation of any tissue, regardless of how mutilating such a donation may be to the donor, both physically and psychologically. As microscopic surgery advances, a parent of a child, for whom it has been established after an accident that both hands cannot be salvaged, could decide to donate one hand to a child. Reproductive organs could be donated for an adult sibling unable to have children, and later the donor could decide that losing childbearing potential was a great mistake. The examples of potential harm can be expanded.

In terms of the Monitoring and Evaluation criteria for living donor recovery hospitals, the very fact that surveyors “may” and not “shall” evaluate for the specific indices presents a regulatory vacuum, in terms of what must be assessed to demonstrate compliance with the Requirements. Mandatory timeframes for reporting and surveying by/of living donor recovery hospitals need to be specified.

Of significant concern is the lack of identified exclusion criteria, which should trigger an automatic denial of living organ donor status. Despite the informed consent indices for living donors, few identified indices will lead to a denial of the donation. The dangers to the donor are enhanced when this omission is coupled with the fact that much of the donor protection requirements will be left up to the living donor recovery hospitals, and that for all living donor denials only “high suspicion of donor coercion” will trigger a denial. Any evidence of coercion requires a thorough investigation, and confirmation of its presence or lack thereof, and then a denial if there is evidence of coercion. Furthermore only an “uncontrolled” diagnosable psychiatric condition or suicidal ideation triggers a denial. Psychiatric conditions can be labile, and a decision of someone controlled today by medication, may not represent the psychiatric status of the person in the future, when they are suffering from the loss of an organ. [See NCBC testimony Re: Proposal to Modify Existing or Establish New Requirements for the Psychosocial and Medical Evaluation of all Living Donors.]

We ask that these Requirements be amended to enhance requirements for achieving full informed consent for all organs/tissues available for donation from living donors. Of great importance is the

need to limit, at least at this time, living donations to kidneys and tissue from the liver, the pancreas, lung and intestines. Furthermore, specific indices for these latter three tissue donations, including “Domino “Donation” need to be developed. Lastly, and most importantly, exclusion criteria touching on inadequate informed consent for all living donor donations need to be identified, as well as psychological conditions requiring exclusion such as psychiatric disorders that fall in the diagnostic categories beyond adjustment disorders and psychosis, as well as exclusion for any evidence of coercion.

We thank you for the opportunity to review this proposal, and we look forward to our ongoing collaboration with you to enhance not only donor safety, but also a culture in which donors and their families are confident that such policies are protective of their good will and generosity.

**Committee Response:**

The Living Donor Committee notes that some remarks from the National Catholic Bioethics Center intertwine concerns regarding the informed consent proposal and the psychosocial and medical evaluation proposal. Please review the Committee’s point-by-point response for both proposals.

1. The Living Donor Committee thanks the National Catholic Bioethics Center for its recognition that the existing policy and current proposal standardizes the information to be provided during the living donor informed consent process.

The Committee also thanks the Center for recognizing that it is important that living donor informed consent policy address not only liver and kidney donors, but donors of other organs (ex. lung, pancreas, intestines). The OPTN recently implemented a standardized informed consent process, as described in Policy 14, for living kidney donors. However, under current policy, living liver donor recovery programs must develop and follow center-specific protocols for the informed consent of living liver donors. Furthermore, living lung, intestine, or pancreas donor programs are not required to develop or follow a center-specific protocol and are not subject to any OPTN requirement for the informed consent of living donors. Therefore, if the current proposal is not approved, living liver donor programs will continue to follow non-standardized requirements for living liver donors and programs that perform living lung, pancreas, and intestinal donation will not be required to follow any informed consent process for these categories of living donors.

2. A domino donor is an individual who donates an organ that is removed as a treatment for a medical condition and who subsequently receives a replacement organ from another donor (living or deceased). Domino donors are rare; domino donation only occurs an average of twelve times per year. Based on the Center’s response (e.g., that domino donors trigger other donations), the Center may be confusing domino donors with living kidney donors who participate in donor chains within a kidney paired donation exchange. Kidney paired donation (KPD) is addressed in a separate section of policy (Policy 13), while the current policy proposal refers to Policy 14. Kidney donors participating in KPD are already subject to the consent requirements in Policy 14. Paired liver exchanges have not occurred in this country. As an informational item, the Living Donor Committee is planning to distribute new proposed policy requirements for domino liver donation for public comment in spring 2015.

3. The Center voiced a concern that the current policy about informed consent would “open the door” to allow unregulated donation of any tissue, such as vascularized composite allografts (VCAs). The Committee notes that the policy has been now been revised to pertain specifically to the types of solid organ living donors that were considered by the Committee when it drafted the proposal and and its background materials and were included in the materials sent out for public comment, i.e., kidney, liver, pancreas, lung, intestine donors. The policy therefore does not

pertain to any other types of donation. This modification to the proposal does not prohibit the donation of VCAs from living donors. It does, however, mean that living VCA donors will not have the same protections and oversight as other living donors.

4. The Center was concerned with requirements for surveyor monitoring of living donor recovery hospitals. The evaluation plan for this proposal is consistent with OPTN standards for site surveys and monitoring plans. The compliance monitoring plan described in the public comment document represents the best estimation of how a proposed policy could be monitored at the time that the policy language is developed for public comment. Words such as “may”, “shall” or “will” should not be construed as indicating the level of commitment to monitoring the proposed policy. Once final policy language is approved by the OPTN Board of Directors, the monitoring plan is revised as necessary to reflect the approved policy language. The final monitoring plan is published in the OPTN Evaluation Plan prior to implementation of the policy.

It is expected that the final monitoring criteria for this proposal would be incorporated into the existing routine site survey process. However, OPTN members must comply with all OPTN obligations regardless of whether the particular obligation is routinely reviewed. To that end, UNOS has processes in place to investigate potential noncompliance with OPTN obligations reported or discovered through avenues other than the routine site survey process.

5. Regarding exclusion criteria for potential living donors, this is not part of the current policy proposal on informed consent.

As the Committee describes in response to public comment on the policy proposal on the medical and psychosocial evaluation, high suspicion of coercion would be an automatic rule-out but this does not preclude transplant programs from further investigation should they suspect any degree of coercion. In addition, this proposed policy notes that there must be a full assessment of whether the donor’s decision to donate is free of inducement, coercion, and other undue pressure, in order to determine whether an individual is suitable for proceeding with living donation. Within the current proposal regarding informed consent, the living donor is required to sign a statement indicating that they are free from inducement or coercion.

There is no evidence that individuals with controlled psychiatric conditions are unable to give informed consent to undergo medical procedures. As the Committee describes in response to public comment on the policy proposal on the medical and psychosocial evaluation, the policy proposal’s list of exclusion criteria for donation are based on recommendations from a Joint Societies Work Group comprised of representatives from the American Society of Transplant Surgeons, the American Society of Transplantation, and the North American Transplant Coordinators Organization. Based on these experts’ experience and on evidence in the literature, there is no rationale for excluding individuals who have prior psychiatric illness or psychiatric illness controlled with treatment from serving as living donors.

Finally, it should be noted that existing and proposed policy address absolute contraindications to living donation. Living donor recovery hospitals may apply their own relative contraindications to approve or exclude potential living donors who, by virtue of mental health history or any other characteristic, are judged to be at too great a risk to reasonably be approved for donor surgery. These case-by-case decisions, made at most centers by multidisciplinary teams including mental health specialists, cannot be precisely prescribed by any given national policy. Moreover, OPTN policy cannot and does not address every issue of donor selection that clinical experts in transplant programs would understand, by virtue of their training and experience, are exclusions for donation. For example, it is not necessary for policy to state that chronic kidney disease in a

potential donor is a contraindication to kidney donation. The Living Donor Committee does not therefore accept the view that if a factor or condition is not explicitly excluded by policy then that factor or condition must be allowed under policy.

**Comment 9:**

National Catholic Partnership on Disability (NCPD) was established over thirty years ago to implement the U.S. Catholic bishops' Pastoral Statement on People with Disability. On behalf of NCPD, I offer the following comments:

The Living Donor Committee has solicited public comment on two proposals: The first modifies or establishes requirements for the informed consent of all living donors; the second does the same for their psychosocial and medical evaluation. Taken together, the proposals permit recovery hospitals to accept organ donations where an adult living donor is incompetent, or there is some reason to suspect coercion, or the donation would compromise the donor's bodily integrity. This is clearly unacceptable.

As their titles indicate, both proposals apply to "all living donors." The background of the second proposal demonstrates that this was a deliberate choice. Its stated goal was to "establish new policy requirements for the psychosocial and medical evaluation of all types of living donors." According to its preamble, "[t]his proposal was originally intended to expand the same level of detail concerning ... [such] evaluation of living kidney donors to living liver donors." As the proposal developed, it was suggested that the elements common to living kidney and liver donors might also "be extended to apply to other types (pancreas, intestine, and lung) of living organ donors." In its final form, however, the proposal was "expanded to include all living donors [,]" without exception.

Undoubtedly, medical science will soon have the ability to transplant organs that will necessarily result in compromising a living donor's bodily integrity. Such techniques are morally illicit since they would constitute mutilation. Yet, they are implicitly condoned by the two proposals' extension to "all living donors."

(Though the second proposal requires additional medical evaluations and exclusion criteria for living kidney and liver donors, see § 14.4.C-E; tb.14-7, 8, & 9, it makes no corresponding provision for the other types of donations it expressly references. Likewise, the first proposal requires recovery hospitals to disclose risks specific to kidney and liver donation, see § 14.3 & 4, but not for the other types of referenced donations.)

The second proposal compounds the problem by permitting recovery hospitals to accept mentally incompetent adults as living organ donors. Not surprisingly, such hospitals are required to assess "the living donor's ability to make an informed decision [,]" § 14.1.A (7), and to determine whether such donor "understands the short and long- term medical and psychosocial risks [associated with the donation.]" § 14.1.A (5). In addition, the first proposal imposes detailed responsibilities on such hospitals to facilitate donors' informed consent. See § 14.3. Despite these requirements, only donors "mentally incapable of making an informed decision" who are "less than 18 years old" are categorically excluded by the second proposal, § 14.4.E; tb. 14-9, leaving the suitability of such adult donors to "the hospital's medical judgment [,]" § 14.4.E. It is shocking to think a recovery hospital could accept as a living donor any person, regardless of age, whose mental capacity to provide informed consent is in question.

Likewise, though the hospital must assess “whether the decision to donate is free of inducement, coercion, and other undue pressure [,]” § 14.1.A (6), it is only required by the second proposal to exclude donors when the suspicion of coercion (but not inducement or other forms of undue pressure) is “high.” § 14.4.E; tb. 14-9. It is hard to understand why the first proposal would require such hospitals to obtain signed confirmation that the donor is “free from inducement and coercion [,]” § 14.3; tb. 14-1, provide the donor with an advocate knowledgeable about “the potential impact of family or other external pressure on the living [donor,]” § 14.2.A (3), and authorize such advocate to “protect the rights or best interests of the living donor [,]” 14.2.B (4), while only a “high suspicion of coercion” will trigger exclusion. (Additionally, though the hospital must exclude donors with “Uncontrolled diagnosable psychiatric conditions requiring treatment before donation, § 14.4.E; tb. 14-9 (emphasis added), it can nonetheless accept donors whose mental health issues “could complicate... [their] recovery and could be identified as risks for poor psychosocial outcome.” § 14.1.A(1). In any event, it is simply outrageous to think hospitals could accept organ donations when there is a reasonable suspicion that the donor is not acting voluntarily.

Adoption of the following modifications to § 14.4.E should go far to resolve these issues:

“Living donor recovery hospitals must exclude all donors who meet any of the following exclusion criteria:

- Offering to donate an organ that would compromise the living donor’s functional integrity;
- A donor (regardless of age) who is mentally incapable of providing informed consent;
- A reasonable suspicion that the decision to donate is not free of inducement, coercion, or other undue pressure;
- The presence of mental health issues that might complicate the donor’s recovery and could be identified as risks for poor psychosocial outcome.”

The proposals should further require disclosure of and evaluation for any known risks associated with pancreas, intestine, and lung donations.

These problems were likely the product of inattention to the inconsistencies within and between the two proposals. Otherwise, they would surely raise a chilling specter, imperiling the lives and bodily integrity of those persistently comatose, brain injured, and those with other severe cognitive or volitional impairments.

#### **Committee Response:**

The Living Donor Committee notes that many remarks from the representative of the National Catholic Partnership on Disability (NCPD) intertwine concerns about the informed consent proposal and the psychosocial and medical evaluation proposal.

The NCPD representative viewed the proposals as condoning future ability by medical science to engage in transplantation of organs that compromises donors’ bodily integrity and are morally illicit. The Committee notes that the informed consent proposal (as well as the psychosocial and medical evaluation proposal) pertain to specific activities concerning living donors. The Committee notes that the policy has been now been revised to pertain specifically to solid organ living donors (i.e., kidney, liver, pancreas, lung, intestine donors). The policy therefore does not pertain to any other types of donation, such as vascularized composite allografts (VCAs). This modification to the proposal does not prohibit the donation of VCAs from living donors. It does,

however, mean that living VCA donors will not have the same protections and oversight as other living donors.

The NCPD representative expressed concerns that the informed consent proposal and the psychosocial and medical evaluation proposal do not address specific issues in either the consent or evaluation process for donors providing tissue other than kidney or liver. The Committee considered but did not propose any additional requirements for the informed consent or evaluation of living lung, pancreas, or intestine donors (e.g., the disclosure of any known risks associated with these types of donation) because the volume of these types of donation is so low that it is not possible to specify any additional elements of informed consent and it is not possible to determine the value of any additional medical testing for such individuals. Given the low volumes, there are limited published data on these issues in such donors and there is unlikely to be a consensus conference for the development of expert opinion on best practices.

The NCPD representative also expressed concerns about the exclusion criteria for living donors included in the psychosocial and medical policy proposal. With regard to kidney donors, it is important to note that these criteria are already included in current policy. They derive from the recommendations of a Joint Societies Work Group composed of the transplant professional societies (American Society of Transplantation; American Society of Transplant Surgeons; North American Transplant Coordinators Organization) to the Living Donor Committee. However, under current policy, living liver donor recovery programs must develop and follow center-specific protocols for the evaluation of living liver donors. Furthermore, living lung, intestine, or pancreas donor programs are not required to develop or follow a center-specific protocol and are not subject to any OPTN requirement for the evaluation of living donors. Therefore, if the current proposal is not approved, living liver donor programs will continue to follow non-standardized requirements for living liver donors and programs that perform living lung, pancreas, and intestinal donation will not be required to follow any evaluation process for these categories of living donors.

As the Committee describes in response to public comment on the policy proposal on the medical and psychosocial evaluation, the policy proposal's list of exclusion criteria for donation are based on recommendations from a Joint Societies Work Group comprised of representatives from the transplant professional societies. It should be noted that existing and proposed policy address absolute contraindications to living donation. Living donor recovery hospitals may apply their own relative contraindications to approve or exclude potential living donors who are judged by the recovery hospital to be at too great a risk to reasonably be approved for donor surgery. These case-by-case decisions, made at most centers by multidisciplinary teams, cannot be precisely prescribed by any given national policy.

Moreover, OPTN policy cannot and does not address every issue of donor selection that clinical experts in transplant programs would understand, by virtue of their training and experience, are exclusions for donation. For example, it is not necessary for policy to state that chronic kidney disease in a potential donor is a contraindication to kidney donation. The Living Donor Committee does not therefore accept the view that if a factor or condition is not explicitly excluded by policy then that factor or condition must be allowed under policy.

The NCPD representative emphasized a concern over the issue of a potential donor's mental capacity and why it would ever be permissible to allow an individual who is mentally incapable of providing informed consent to donate. The Joint Societies Work Group and the Committee recognized that, if one uses the yardstick of the best interests of the individual (in this case, the prospective donor), there have been situations where it has been judged with the courts or social services systems, as well as by the mental health and psychosocial experts on transplant teams,

to be in the donor's best interest to allow that person to serve as a living donor. These cases have most often involved an adult child (the prospective donor) who relied on a parent for care, and the parent needed a transplant in order to continue to reasonably provide such care. These situations are extremely rare but, in the view of the Joint Societies Work Group and the Living Donor Committee, should not be ruled out automatically on the basis of OPTN policy. Rather, each center should be able to review all evidence in such circumstances.

Regarding the concern about coercion, as the Committee describes in response to public comment on the policy proposal on the medical and psychosocial evaluation, high suspicion of coercion would be an automatic rule-out but this does not preclude transplant programs from further investigation should they suspect any degree of coercion. In addition, this proposed policy notes that there must be a full assessment of whether the donor's decision to donate is free of inducement, coercion, and other undue pressure, in order to determine whether an individual is suitable for proceeding with living donation. Within the current proposal regarding informed consent, the living donor is required to sign a statement indicating that they are free from inducement or coercion.

**Post Public Comment Consideration:**

The Committee was asked to consider if the risk of surgical complications or death associated with living liver donation should be quantified in the proposal. Existing policy lists death as a potential medical or surgical risk. Some respondents opined that stating there is a risk of death is not sufficient for living liver donation. The Committee considered this option but ultimately did not support adding organ specific risk of complications or death to the proposal.

The proposal was modified to clarify it does not apply to domino liver donors. Policy requirements for domino donors will be proposed in a separate future policy proposal.



University of Pittsburgh  
*School of Medicine and Medical Center*

**Clinical Epidemiology  
 Program**

3811 O'Hara Street  
 Pittsburgh, PA 15213-2593  
 412-624-3373  
 Fax: 412-383-4846

October 16, 2014

Stephen L. Mikochik, Professor Emeritus  
 Temple University School of Law  
 Chair Emeritus, National Catholic Partnership on Disability  
 The McCormick Pavilion  
 415 Michigan Avenue, N.E., Suite 95  
 Washington, D.C. 20017-4501

Dear Professor Mikochik:

Thank you for talking with me, other members of the OPTN/UNOS Living Donor Committee, and UNOS staff on August 18 regarding the comments you submitted in two letters on behalf of the National Catholic Bioethics Center (NCBC) concerning OPTN/UNOS policy proposals regarding informed consent of living organ donors and the psychosocial and medical evaluation of living organ donors. As Chair of the OPTN/UNOS Living Donor Committee, which is sponsoring the two proposals, I had promised to write to you and to Dr. Hilliard after the Committee's deliberations and vote on September 8 on the final versions of the proposals. The Committee reviewed and carefully considered all of the comments received from other OPTN/UNOS committees, OPTN regions, and the general public.

Therefore, on the following pages, I have tried to provide an update regarding the key issues that were left unresolved after our August 18 phone call with you. Some of the content below is also included in my letter to Dr. Hilliard—I apologize for the overlap but I wanted to make sure that both of your organizations had complete information regarding Committee deliberations on your concerns.

First, a very central issue in your original letter and on our phone call concerned your view that the proposals condoned future ability by medical science to engage in transplantation of organs that compromises donors' bodily integrity and is morally illicit. Further, as you noted in a follow-up letter to me dated September 3, 2014, "the only body parts the proposals reference are kidney, liver, lung, intestine, and pancreas. If the Committee wish to include VCAs [vascularized composite allografts], it should have done so expressly. Moreover, to include them now would compromise the fairness of the comment process since the public might well have demanded more safeguards if it were known that VCAs were included."

On September 8, the Committee extensively discussed and then voted to revise the wording of both the proposed policy on informed consent and the proposed policy on the psychosocial and medical evaluation of living donors so that both policies would pertain specifically to the types of living donors that were considered by the Committee when it drafted the proposal and its Background materials, and when the materials were sent out for public comment, i.e., kidney, liver, pancreas, lung, and intestine donors. The revised policy proposals therefore do not pertain to any other types of donation. These revised policy proposals will be considered by the OPTN/UNOS Board of Directors. We believe that our revision fully addresses your concern.

Another major point of discussion on our August 18 call concerned specific exclusion criteria for living donors included in the psychosocial and medical policy proposal. As a general framework, I emphasize that the psychosocial and medical evaluation policy proposal's list of exclusion criteria for donation are based on recommendations from a Joint Societies Work Group composed of the transplant professional societies (American Society of Transplantation; American Society of Transplant Surgeons; North American Transplant Coordinators Organization) to our Committee. It should also be noted that existing and proposed policy address absolute contraindications to living donation. Living donor recovery hospitals may apply their own relative contraindications to approve or exclude potential living donors who are judged by the recovery hospital to be at too great a risk to reasonably be approved for donor surgery. These case-by-case decisions, made at most centers by multidisciplinary teams, cannot be precisely prescribed by any given national policy.

Your letters of June 12 and September 3, and your comments during our call, emphasized a concern over the issue of a potential donor's mental capacity and why it would ever be permissible to allow an individual who is mentally incapable of providing informed consent to donate. As we discussed during our call, the Joint Societies Work Group and the Committee recognized that, if one uses the yardstick of the best interests of the individual (in this case, the prospective donor), there have been situations where it has been judged within the courts or social services systems, as well as by the mental health and psychosocial experts on transplant teams, to be in the donor's best interest to allow that person to serve as a living donor. These cases have most often involved an adult child (the prospective donor) who relied on a parent for care, and the parent needed a transplant in order to continue to reasonably provide such care. These situations are extremely rare but, in the view of the Joint Societies Work Group and the Living Donor Committee, should not be ruled out automatically on the basis of OPTN policy. In fact, existing OPTN policy already allows for these rare circumstances because that policy only excludes donors who are under age 18 and mentally incapable of giving informed consent. Thus the current proposal does not state this exclusion for the first time; it only extends it beyond kidney donors to other solid organ donors. Based on what is in existing policy, and based on the combined experience and expertise of the Work Group and the Committee, it was felt that each center should be able to review all evidence in such circumstances that would exist should an adult come forward who is mentally incapable of providing informed consent to donate.

In addition, as I noted in my earlier letter, the Living Donor Committee does not accept a view that if a factor or condition is not explicitly excluded by OPTN policy then that factor or condition must be allowed under policy. OPTN policy cannot and does not address every issue of donor selection that clinical experts in transplant programs would understand, by virtue of their training and experience, are exclusions for donation. For example, it is not necessary for policy to state that chronic kidney disease in a potential donor is a contraindication to kidney donation.

On our call on August 18, you suggested that we consider wording that referred to excluding mentally incompetent adults as donors unless it could be demonstrated that it was in the adult's best interest to donate. We cannot include such a criterion because OPTN policy can only state absolute exclusions, not relative contraindications to donation. If the proposed policy had been modified, for example, to state that an exclusion was "mentally incompetent donors unless it could be demonstrated that it was in the donor's best interest," that is tantamount to a relative contraindication, because relative contraindications refer to factors that may or may not be exclusions depending on unspecified and potentially unmonitorable circumstances. Moreover, stating an absolute exclusion of mentally incompetent adults would be denying the right of these individuals to come forward as potential donors, which has been upheld in the court and social services systems.

However, neither existing nor proposed policy should be construed as indicating a choice to ignore donors' best interests. Indeed, that is an important rationale for the policy, and it is explicitly addressed.

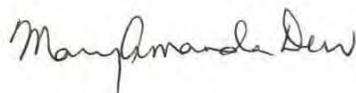
Thus, for example, the existing policy for kidney donors and the proposed policy also require that all donors have an independent living donor advocate (ILDA) to provide further safeguards for donors. This

individual's responsibility, as stated in policy, is to "advocate for the rights" of the donor, and "promote the best interests" of the donor. This includes having the ability to file a grievance when necessary to "protect the rights or best interests of the donor." These policy requirements obviously become particularly critical should a mentally incompetent adult ever be considered as a potential living donor. Overall, then, the Living Donor Committee did not judge that there was sufficient rationale at this time to modify the proposed policy exclusion criterion. Thus, the Committee agreed that individuals both less than 18 years old and mentally incapable of making an informed decision should be excluded from donation, but did not judge that additional exclusions should be specified.

Regarding the concern about coercion, the Committee also supported retaining the language regarding exclusion due to coercion. First, it is noteworthy that this language already exists in policy covering living kidney donors. The proposed policy now seeks to include other solid organ donors. Second, as we noted in our earlier letter to you, high suspicion of coercion would be an automatic rule-out but this does not preclude transplant programs from further investigation should they suspect any degree of coercion. In addition, the informed consent proposed policy notes that there must be a full assessment of whether the donor's decision to donate is free of inducement, coercion, and other undue pressure, in order to determine whether an individual is suitable for proceeding with living donation. Within the proposal regarding informed consent, the living donor is required to sign a statement indicating that they are free from inducement or coercion. Therefore, the existing wording in policy is judged to be sufficient regarding the goal of ascertaining that individuals are making the decision to donation in a manner that is free from coercion or undue pressure.

I am also sending you a copy of the letter that I have sent to Dr. Hilliard, because we discussed several additional issues that were originally raised by the National Catholic Bioethics Center in Dr. Hilliard's letter of June 4 to the OPTN. I know from your comments during our call that you were concerned about those issues as well. I hope that the explanations I have provided regarding changes that we did and did not make to the proposed policies will be helpful. The Committee must balance the concerns of a number of different constituencies, and it deliberated carefully in attempting to address all of the issues raised during the public comment period. Please do not hesitate to get in touch with me should you wish to discuss any of the points in this letter further.

Sincerely,



Mary Amanda Dew, Ph.D.  
Professor of Psychiatry, Psychology, Epidemiology, Biostatistics,  
and Clinical and Translational Science

Director, Clinical Epidemiology Program  
Western Psychiatric Institute and Clinic

Co-Director  
Advanced Center for Interventions and  
Services Research in Late Life Depression Prevention

Director, Quality of Life Research, Artificial Heart Program  
Adult Cardiothoracic Transplantation

Cc: Marie T. Hilliard, JCL, PhD, RN



University of Pittsburgh  
*School of Medicine and Medical Center*

**Clinical Epidemiology  
 Program**

3811 O'Hara Street  
 Pittsburgh, PA 15213-2593  
 412-624-3373  
 Fax: 412-383-4846

October 16, 2014

Marie T. Hilliard, JCL, PhD, RN  
 Director of Bioethics and Public Policy  
 National Catholic Bioethics Center  
 6399 Drexel Road  
 Philadelphia, PA 19151

Dear Dr. Hilliard,

Thank you for talking with me, other members of the OPTN/UNOS Living Donor Committee, and UNOS staff on August 18 regarding the comments you submitted in two letters on behalf of the National Catholic Bioethics Center (NCBC) concerning OPTN/UNOS policy proposals regarding informed consent of living organ donors and the psychosocial and medical evaluation of living organ donors. As Chair of the OPTN/UNOS Living Donor Committee, which is sponsoring the two proposals, I had promised to write to you after the Committee's deliberations and vote on September 8 on the final versions of the proposals. The Committee reviewed and carefully considered all of the comments received from other OPTN/UNOS committees, OPTN regions, and the general public. I wanted to give you an update on issues that were left unresolved after our August 18 phone call with you.

First, perhaps the key issue raised by the NCBC was the concern that our proposed policy about informed consent would "open the door" to allow unregulated donation of any tissue. Further, as Dr. Mikochik noted in a follow-up letter dated September 3, 2014, "the only body parts the proposals reference are kidney, liver, lung, intestine, and pancreas. If the Committee wish to include VCAs [vascularized component allografts], it should have done so expressly. Moreover, to include them now would compromise the fairness of the comment process since the public might well have demanded more safeguards if it were known that VCAs were included."

On September 8, the Committee extensively discussed and then voted to revise the wording of both the proposed policy on informed consent and the proposed policy on the psychosocial and medical evaluation of living donors so that both policies would pertain specifically to the types of living donors that were considered by the Committee when it drafted the proposal and its Background materials, and when the materials were sent out for public comment, i.e., kidney, liver, pancreas, lung, and intestine donors. The revised policy proposals therefore do not pertain to any other types of donation. These revised policy proposals will be considered by the OPTN/UNOS Board of Directors. We believe that our revision fully addresses your concern.

Another point of discussion on our August 18 call concerned the proposed policy on the psychosocial and medical evaluation, and the exclusion criteria that were listed for potential living donors. In particular, we discussed the exclusion criterion regarding "uncontrolled psychiatric conditions requiring treatment." As I stated in my earlier letter to you, there is no evidence that individuals with controlled psychiatric conditions are unable to give informed consent to undergo medical procedures. The

proposed policy on the psychosocial and medical evaluation and its list of exclusion criteria for donation are based on recommendations from a Joint Societies Work Group comprised of representatives from the transplant professional societies (the American Society of Transplant Surgeons, the American Society of Transplantation, and the North American Transplant Coordinators Organization). Based on these experts' experience and on evidence in the literature, there is no rationale for excluding individuals who have prior psychiatric illness or psychiatric illness controlled with treatment from serving as living donors. We also noted that existing and proposed policy address absolute contraindications to living donation. Living donor recovery hospitals may apply their own relative contraindications to approve or exclude potential living donors who, by virtue of mental health history or any other characteristic, are judged to be at too great a risk to reasonably be approved for donor surgery. These case-by-case decisions, made at most centers by multidisciplinary teams including mental health specialists, cannot be precisely prescribed by any given national policy.

Professor Mikochik observed on our call that the word, "uncontrolled" had been added to the criterion in question in our psychosocial and medical evaluation policy proposal (which is designed to expand beyond kidney donor policy—already in place—to include liver, pancreas, intestine, and lung donors). He noted that the word is not included in current (already approved) policy regarding kidney donors, which states the criterion as "psychiatric conditions requiring treatment." He is correct: the word was added based on feedback from transplant programs that the current policy wording was ambiguous—it could imply, for example, that individuals with a psychiatric condition that was well-controlled and kept in full remission with medication might need to be excluded as donors, which would not be in keeping with (a) expert experience and evidence in the literature, and (b) the intent of the Joint Societies Work Group and the Living Donor Committee when the policy for kidney donors was originally written and approved. (As noted above, there is no evidence that individuals with controlled psychiatric disorders—e.g., those in remission because they are controlled with treatment—should be unable to serve as donors.) Therefore, as part of the "plain language rewrite" of OPTN policy, which UNOS has been undertaking simultaneously with the development and revisions of policy, the word, "uncontrolled" was added to clarify the specific nature of the exclusion criterion. The clarification is consistent with the goals of the JSWG when they formulated their recommendations for living donor policy in this area. It is not uncommon for transplant programs to alert UNOS when wording that—despite the best intention of the writers and reviewers of the policy—turns out to be ambiguous in practice. Every attempt is then made to remove the ambiguities. This was not viewed by UNOS or by the Living Donor Committee to be a major substantive change; it was a clarification to reflect true intent.

In sum, for the reasons described, the Committee did not feel that further amendments were needed to this exclusion criterion at this time. The Committee also supported retaining the language regarding exclusion due to coercion. As we noted in our earlier letter to you, high suspicion of coercion would be an automatic rule-out but this does not preclude transplant programs from further investigation should they suspect any degree of coercion. In addition, the informed consent proposed policy notes that there must be a full assessment of whether the donor's decision to donate is free of inducement, coercion, and other undue pressure, in order to determine whether an individual is suitable for proceeding with living donation. Within the proposal regarding informed consent, the living donor is required to sign a statement indicating that they are free from inducement or coercion. Therefore, the existing wording in policy is judged to be sufficient regarding the goal of ascertaining that individuals are making the decision to donation in a manner that is free from coercion or undue pressure.

Regarding your concern about the lack of qualifications criteria for physicians performing the medical evaluation, the Committee felt that the position that we had described to you in our earlier letter was most appropriate at this time. Namely, the existing medical evaluation requirements in policy for living kidney donors do not require the evaluation be performed by a "physician who is board certified in the area of organ functioning of the [organ or] tissue to be donated." Requiring the medical evaluation of potential living liver donors to be performed by a board certified hepatologist would create different standards for living kidney donor and living liver donor medical evaluations. There is no rationale for different standards for physicians conducting kidney vs. liver donors' medical evaluations. In addition,

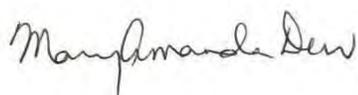
requiring that only board certified hepatologists could perform living liver donor medical evaluations would require a bylaw change which is outside the scope of this proposal. Thus the proposed policy cannot specify a requirement for board certified hepatologists at this time. Please see our earlier letter for other information regarding this issue because our proposed policy cannot create a situation that is inconsistent with bylaws. In addition, our proposed policy is consistent with the Joint Society Work Groups' recommendations for required elements.

Finally, on our call on August 18, we briefly discussed your concerns with requirements for surveyor monitoring of living donor recovery hospitals. As I had written to you earlier, the compliance monitoring plan described in the public comment document represents the best estimation of how a proposed policy could be monitored at the time that the policy language is developed for public comment. Words such as "may", "shall" or "will" should not be construed as indicating the level of commitment to monitoring the proposed policy. Once final policy language is approved by the OPTN Board of Directors, the monitoring plan will be revised as necessary to reflect the approved policy language. The final monitoring plan is published in the OPTN Evaluation Plan prior to implementation of the policy. The Living Donor Committee does not write the monitoring plan, and that plan is not subject to a vote by the Board of directors when they vote on our Committee's proposed policies in November. Therefore, I believe that your concerns about the monitoring plan will need to be pursued through contacts with UNOS beyond our specific Committee.

It is expected that the final monitoring criteria for this proposal would be incorporated into the existing routine site survey process. However, OPTN members must comply with all OPTN obligations regardless of whether the particular obligation is routinely reviewed. To that end, UNOS has processes in place to investigate potential noncompliance with OPTN obligations reported or discovered through avenues other than the routine site survey process.

I hope that these explanations regarding changes that we did and did not make to the proposed policies will be helpful. The Committee must balance the concerns of a number of different constituencies, and it deliberated carefully in attempting to address all of the issues raised during the public comment period. Please do not hesitate to get in touch with me should you wish to discuss any of the points in this letter further.

Sincerely,



Mary Amanda Dew, Ph.D.  
Professor of Psychiatry, Psychology, Epidemiology, Biostatistics,  
and Clinical and Translational Science

Director, Clinical Epidemiology Program  
Western Psychiatric Institute and Clinic

Co-Director  
NIMH Advanced Center for Interventions and  
Services Research in Late Life Depression Prevention

Director, Quality of Life Research, Artificial Heart Program  
Adult Cardiothoracic Transplantation

Cc: Stephen L. Mikochik, Professor Emeritus

**Proposal to Modify Existing or Establish New Requirements for the Psychosocial and Medical Evaluation for Living Donor**

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**Title: Proposal to Modify Existing or Establish New Requirements for the Psychosocial and Medical Evaluation for Living Donors****Sponsoring Committee: Living Donor Committee****Summary and Goals of the Proposal:**

This proposal would modify existing policy and establish new policy requirements for the psychosocial and medical evaluation of living donors. This proposal is in response to a directive from the Health Resources and Services Administration (HRSA) to develop such policy, and is based on recommendations from a Joint Societies Steering Committee composed of representatives of the American Society of Transplantation (AST), the American Society of Transplant Surgeons (ASTS), and the North American Transplant Coordinators Organization (NATCO) to the Living Donor Committee. Policy to standardize the medical evaluation of living kidney donors has already been established. This proposal would modify some elements of existing policy for the psychosocial and medical evaluation of living kidney donors and establish new requirements for the psychosocial and medical evaluation for living organ donors.

**Background and Significance of the Proposal:**

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

In July 2009, the Committee released Guidelines for the Medical Evaluation of Living Liver Donors for public comment. Overall public comment supported the resource. Most comments in opposition to the resource questioned if UNOS should be involved in developing this type of resource rather than specific criticism of the content of the resource. The ASTS provided a statement opposing the resource stating it was “beyond the scope of the OPTN/UNOS mission”. The committee revised the proposal and approved sending the guidelines to the Board for consideration. The Board approved the resource during its November 16, 2009 meeting. Since Board approval, the resource has been available on the [OPTN website](#).

In December 2009, HRSA informed the OPTN that although helpful, the voluntary guidelines for the medical evaluation of living donors developed to date were not sufficient, and policies were still required. In 2010, a Joint Society Policy Steering Committee (comprised of members from the AST, ASTS, NATCO, OPTN/UNOS, and HRSA) formed to make recommendations on any OPTN policy under development that has the potential to prescribe medical care, and it would make its first recommendations on OPTN policies in development for the medical evaluation of living kidney donors. This Steering Committee preferred developing policy recommendations for living kidney and living liver donor psychosocial and medical evaluation as separate projects and favored addressing living kidney donor psychosocial and medical evaluation first and living liver donor psychosocial and medical evaluation as a future project.

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 Committee used the JSWG's position paper to create proposed new policy requirements for the medical evaluation of living kidney donors. The proposed medical evaluation requirements were distributed for public comment between September 16, 2011 and January 12, 2012, approved by the OPTN/UNOS Board of Directors on November 12, 2012, and became effective on February 1, 2013.

Similarly, for this proposal a Joint Societies Policy Steering Committee (comprised of members from the AST, ASTS, NATCO, OPTN/UNOS, and HRSA) formed a JSWG to develop recommendations for the medical evaluation of living liver donors. This work group held its first meeting on August 7, 2012 and after several months of work sent preliminary proposed policy recommendations to the leadership of the transplant professional societies on December 1, 2012 for an initial review.

After receiving feedback from the parent societies, the JSWG met to revise their initial policy recommendations for psychosocial and medical evaluation of living liver donors. The JSWG modified their policy recommendations and sent the revised recommendations back to the parent societies for approval on April 1, 2013.

On April 8, 2013, the Chairperson of the JSWG attended the Committee meeting and gave a presentation on the work of the JSWG and its preliminary recommendations for living liver donor consent policy development.

After these preliminary recommendations were approved by each of the parent societies, the Committee considered the policy recommendations in the development of these proposed policy requirements for the medical evaluation of living liver donors.

The Committee met by teleconference on June 10, 2013 to consider if a policy proposal for the psychosocial and medical evaluation of living liver donors should be distributed for public comment. The Committee determined that they wanted additional time to review the final recommendations from the JSWG, and consequently the Committee agreed to delay the proposal until some future public comment cycle.

During subsequent review of the proposal, a subcommittee of the full Committee considered if common elements in existing policy for the psychosocial and medical evaluation of living kidney donors and proposed policy for the psychosocial and medical evaluation of living liver donors could be extended to apply to other types of living donors (ex. pancreas, intestine, and lung). The subcommittee determined that 1) there should be minimum, common standards and protections for all living donors, 2) as currently proposed the medical evaluation of living pancreas, intestine, and lung donors would not be addressed in any policy, and 3) these likely would not be addressed in a separate policy development process because the low volume of these types of transplants.

The subcommittee understood that proposed new general policies for the medical evaluation of other types of living donors were a new concept that had not been previously considered by either JSWG or any organ specific committee. In response, this committee sent letters to fourteen OPTN Committees, asking those committees to comment or identify concerns regarding the plan to modify or propose psychosocial and medical evaluation requirements for all types of living donors.

The full Committee met on September 16, 2013 and reviewed responses from five (Operations and Safety, Membership and Professional Standards, Pancreas, Ethics, and Disease Transmission Advisory Committee) committees that had responded before the deadline. Each of these committees supported the plan to propose psychosocial and medical evaluation requirements to include all types of living donors (ex. pancreas, intestine, lung). Based on this feedback, the Committee agreed to prepare a policy proposal for public comment that would include psychosocial and medical evaluation requirements for all types of living donors (ex. kidney, liver, pancreas, intestine, lung).

In November 2013, the OPTN/UNOS Board approved a “plain language” rewrite of OPTN policies. Under this project, the policy requirements for the psychosocial and medical evaluation of living kidney donors were rewritten into plain language (without changing the substance of the requirements) and moved from Policy 12 to Policy 14.

One of the new features of the revised policy is the increased use of tables to communicate policy requirements. Under this proposal, the existing policy requirements for living kidney donor psychosocial and medical evaluation and new proposed psychosocial and medical evaluation requirements for the other categories of living donors are integrated and presented in a table format. Under this integration, many existing policy requirements for the psychosocial and medical evaluation of living kidney donors are proposed as new policy requirements for the other categories of living donors. Some existing policy for the medical evaluation of living kidney donors is specific to kidney donation and cannot be extended to address other the categories of living donors. Consequently, the proposed policy contains evaluation requirements for the other categories of living donors, followed by existing requirements specific to living kidney donors and new proposed requirements specific to living liver donors.

On December 12, 2013, the Committee met by web conference review final draft policy language for this proposal and to consider if the proposal should be distributed for public comment. The Committee chair lead a review of the proposed policy language, and the committee discussed and came to consensus on a few remaining issues with the proposed policy language. The Committee voted to approve sending the proposal for public comment.

This proposal was released for public comment between March 14 and June 13, 2014. During the public comment period a subcommittee of the Living Donor Committee monitored public comment and prepared responses to all comments for the full Committee to consider. During public comment, two Catholic organizations. The National Catholic Bioethics Center and the National Catholic Partnership on Disability sent responses critical of the proposal. In response, the Committee sent a formal written response to each organization and invited the organizations to participate in a conference call to address any remaining questions. On August 18, 2014, the Committee leadership met with representatives of each organization to discuss their concerns and potential options to alleviate their concerns. The Chair indicated she would send a follow-up response to the Catholic organization after the Committee met in September.

The full Committee met on September 8, 2014 to review public comment and proposed responses regarding this proposal. Prior to this meeting, the Committee leadership came to understand that the vascularized composite allograft (VCA) policies approved by the Board in June did not exclude potential living VCA donation. The Chair of the Committee, also a member of the Board, contacted several other Board members and determined they also did not understand that the VCA policies did not exclude potential living VCA donation. The Committee leadership reported this concern to the leadership of the VCA Committee and UNOS staff.

The Committee leadership was asked to consider several options:

1. Limit the proposed policy to state it applies to only living kidney, liver, pancreas, intestine and lung donors, and not provide informed consent requirements for living VCA donors.
2. Continue to cover all living donors, including potential living VCA donors, as written in the public comment proposal
3. Selecting one of the above solutions and re-releasing the proposal for public comment. Arguably, either of the above options is a substantive change from the public comment proposal (either it covers a class of donors not previously considered or it is excluding a class or donors from a proposal meant to cover all living donors). Typically, committee do not make large substantive changes after public comment. When they do, the proposals are typically re-released for public comment.

The Committee leadership did not support the second or third options but agreed to present them as options to be considered by the full Committee.

On September 8, 2014, the Chair and vice Chair of the VCA Committee joined the Living Donor Committee meeting by web conference to provide an overview of the VCA policies recently approved by the Board, and to respond to questions regarding potential living VCA donation. The Chair of the VCA Committee explained that the VCA policies had been developed and approved by the Board through an expedited process in order to have policies in place before changes to the Final Rule took effect on July 3, 2014. She further explained that the VCA policies have a sunset provision and will need to be reconsidered by the Board within one year. She confirmed that the current policy permitted approved programs to perform living VCA donation, but commented that the Board or Executive Committee of the Board would be asked to modify the VCA policies to limit programs to performing living VCA donation for which they were specifically approved. She reported that VCA approved programs have not performed living VCA donation to date. The vice Chair of the VCA committee reported that abdominal wall transplants have been performed in this country.

UNOS' Director of Policy was asked to explain if the Final Rule envisioned living VCA donation and to comment on the OPTN's authority under the Final Rule. He explained that based on consultation with UNOS's legal staff, the Final Rule is not specific to deceased donation. The OPTN does not have the authority to prohibit living VCA donation, but does have the authority to make membership requirements, performance standards, and patient safety requirements regarding living VCA donation.

The Chair of the VCA Committee concluded her comments by confirming that the VCA Committee is committed to protecting living donors. She voiced concern that if the informed consent and medical evaluation proposals are not modified to include living VCA donor it would lead to a unregulated vacuum and that extending the policies to include living VCA donation was needed to protect public safety and to preserve public trust. She commented that she had reviewed the proposed policy language and felt all of the proposed policy elements would be appropriate for potential living VCA donation. The Chair of the Living Donor Committee thanked the VCA Committee Chair for her comments, and explained that this proposal was based on recommendations from a Joint Societies Work Group that had not considered potential living VCA donors when they developed their policy recommendations. Additionally, inclusion of living VCA donors had not been considered during this Committee's development of the proposal so it was not explicitly addressed. Additionally, the Chair explained that she believes that there are elements of the proposed policy that would be inaccurate for living VCA donors.

The Chair presented three potential paths forward for the full Committee to consider:

1. Limit the proposed policy to state it applies to only living kidney, liver, pancreas, intestine and lung donors, and not provide informed consent requirements for living VCA donors.
2. Continue to cover all living donors, including potential living VCA donors, as written in the public comment proposal
3. Selecting one of the above solutions and re-releasing the proposal for public comment. Arguably, either of the above options is a substantive change from the public comment proposal (either it covers a class of donors not previously considered or it is excluding a class or donors from a proposal meant to cover all living donors). Typically, committee do not make large substantive changes after public comment. When they do, the proposals are typically re-released for public comment.

The Chair explained that in her opinion option 2 should not be considered because potential VCA donation had not been considered by the Joint Societies Work Group (representatives from AST, ASTS, and NATO) when they provided recommendation for policy development to the Living Donor Committee. Additionally, inclusion of living VCA donors had not been explicitly presented to the other Committees or the regions during the public comment process.

Committee members offered a number of comments in opposition to extending this informed consent proposal to include potential living VCA donation including:

- VCA transplantation is a life enhancing procedure rather than a lifesaving procedure and that potential living donor VCA donation could create a permanent disability in the living donor. Consequently, the proposed policy would not be adequate to address the specific informed consent requirements for potential living VCA donors.
- Extending the proposal to include potential living VCA donors would be premature especially since living VCA donors were not included in the development of the proposed policy.
- “Haste makes bad policy.”
- Extending the proposed policy to include potential living VCA donors needs thoughtful consideration.
- If the proposed policy was extended to include potential living VCA donation, it could undermine public trust because that option had not been presented during the public comment process.
- Requirements for the informed consent or medical evaluation of potential living VCA donors should be sent for public comment before being added to proposed policy.
- While not including potential VCA donors in this proposed policy would create a unregulated vacuum, it has taken years to develop and approve policies for the informed consent of living kidney and liver donors; therefore, one could argue that there has been a unregulated vacuum for the categories of living donor for many years so why should the absence of potential living VCA donor policy be considered an emergent problem.

Most Committee members agreed that the proposed informed consent requirements in this proposal would not be adequate to address living VCA donors and that some requirements would be inaccurate for VCA donors. The Committee supported assisting with the development of specific informed consent requirements for living VCA donors if approved by the Board and as a separate future project.

After a lengthy discussion the Committee voted to exclude living VCA donors from this policy proposal (Vote: 15-Support, 2-Opposed, 0-Abstain). The Committee supported modifying the proposal to clarify it would only apply to living kidney, liver, pancreas, intestine or lung donors.

The Committee supported making other small non substantive changes to this proposal based on public comment. The Committee approved sending this proposal for Board consideration (Vote: 17-Support, 0-Opposed, 0-Abstain).

### ***Specific Feedback and Collaboration***

The proposal is based on recommendations from a Joint Societies Work Group composed of representatives of the AST, ASTS, and NATCO. The recommendations from the workgroup were approved by the leadership of the parent organizations. Living Donor Committee representatives participated in this process. The Committee sent a memorandum to fourteen other committees requesting feedback on the plan to propose medical and psychosocial evaluation requirements for all categories of living donors. The memorandum included information on what medical and psychosocial evaluation requirements would be proposed for all living donors and what medical and psychosocial evaluation requirements would be specific to living kidney and living liver donors. Seven committees responded to the memorandum by the requested deadline, and each of the responses supported the plan to propose medical and psychosocial evaluation requirements for all categories of living donors. None of these Committees responded with specific concerns over any of the proposed requirements not being appropriate for a particular category of donor.

### ***Disease Testing***

In August 2013, the Ad Hoc Disease Transmission Advisory Committee (DTAC) provided recommended changes to the current requirements for infectious disease testing in potential living kidney donors. The DTAC recommendations specified that the proposed changes to infectious disease testing would be appropriate for all types of living organ donors. The DTAC recommendations included:

- An addition that testing be completed by a CLIA-certified laboratory or in a laboratory meeting equivalent requirements as determined by Centers for Medicare and Medicaid Services (CMS) using a FDA-licensed, approved, or cleared test. This will allow requirements for deceased and potential living donors to be more closely aligned and enhance patient safety by preventing the use of test kits not recognized by the FDA. Please note, this language would allow the use of screening or diagnostic tests.
- Removal of requirement for Hepatitis B surface antibody testing. This test is not related to potential for donor-derived transmission, but rather for healthcare of a living donor. While it indicates whether a donor has been immunized for Hepatitis B, it is of no value for donor selection, and is not required for deceased donor testing.
- Removal of specific rapid plasma regain (RPR) testing requirement for syphilis. In its place, any FDA-licensed, approved or cleared syphilis test may be used. This same change has been recommended for deceased donors and will be going out for public comment this fall. The DTAC agreed that either test type would be appropriate because both all treponemal and non-treponemal test types approved by the FDA provide accurate results. The RPR requirement is somewhat outdated based upon advances in the testing industry.
- Requirement for living donor hospitals to develop a written protocol for identifying and testing potential donors at risk for transmissible seasonal or geographically defined endemic disease as part of their medical evaluation process. While the DTAC is supportive of removing the

specific requirements for Chagas, West Nile Virus, and Strongyloides that appear in current living donor kidney policy, it recognizes that these and other diseases must be considered as a potential risk factor in some living donors. Developing internal policy on how to address these concerns will give living donor centers more flexibility in how they want to incorporate this important process into evaluation and make compliance monitoring more straightforward for OPTN staff.

### ***Clinical Social Workers Qualifications and Existing Policy Clarifications***

The existing policy requirements for the psychosocial evaluation of living kidney donors require that the evaluation be conducted by a psychiatrist, psychologist, or clinical social worker. Since enactment of the policy, the committee has received questions regarding the definition of “clinical” social worker. To clarify existing and future policy requirements, the Committee has proposed clarifying the requirement to be a master’s prepared social worker or a licensed clinical social worker, which is consistent with CMS requirements.

The current policy for the medical evaluation of living kidney donors includes a goal statement. The Committee understands that policy must be monitorable and measureable, and because goal statements are neither, the goal statement is proposed for elimination.

### ***“Potential Living Donors” Terminology***

Under this proposal, all references to “potential living donors” would change to read “living donors” in current and future policy. The Committee is proposing this change because the term “potential living donor” is not defined in policy, and programs define “potential living donors” differently. Committee members questioned which elements of current living donor informed consent and medical and psychosocial evaluation policy are required at various stages of the donor evaluation process. Committee member questioned if a program could be cited for an incomplete informed consent or medical evaluation of a potential donor who discontinues the evaluation process prior to donation. The Committee understands that programs must fulfill all current and approved future policy requirement for the medical and psychosocial evaluation only for actual living donors and consequently favors removing all references to potential donors.

Living donor program site surveyors were consulted and supported removing all references to potential living donors from policy. The site surveyors commented that they review the medical records of living donors, and they would only review a potential donor medical record on rare occasions and for small volume programs with an insufficient number of actual living donor medical records available for review.

### ***Domino Donors***

The Committee considered, but did not support, requiring these proposed new psychosocial and medical evaluation requirements for domino liver donation. The Liver and Living Donor Committees may propose new policy requirements for domino liver donation as a separate and future project.

### ***Requirements for Living Donors***

At this time, living kidney donor recovery programs must follow OPTN policies for the psychosocial and medical evaluation of potential living kidney donors. However, under current policy, living liver donor recovery programs are required to develop and follow their own center-specific protocols

for the psychosocial and medical evaluation of potential living liver donors. Programs that perform living lung, intestine, or pancreas donor recovery are not required to follow any OPTN policy or develop and follow their own center-specific protocols for the psychosocial and medical evaluation of potential living organ donors.

This proposal was originally intended to expand the same level of detail concerning the psychosocial and medical evaluation of living kidney donors to living liver donors. It is now expanded to include the other categories living donors (ex. lung, intestine, pancreas). Under this proposal, all existing policy requirements for the psychosocial and medical evaluations of living kidney donors were compared to the JSWG recommended requirements for living liver donors. The common elements in existing living kidney donor policy and recommended requirements for living liver donors are proposed as new requirements for the other specified categories of living donors. The proposal would lead to some standardization of the psychosocial and medical evaluation process for all potential living donors.

The proposal contains additional elements as components of the medical evaluation specific to living kidney and liver donors. In general, the additional elements address specific testing required for the psychosocial and medical evaluation of living kidney and liver donors. The Committee considered, but did not propose, additional requirements for the psychosocial and medical evaluation of living lung, pancreas, or intestine donation because the volume of living lung, pancreas, and intestine donation is so low that the value of additional testing may not be substantiated. Given the low volumes, there are limited published data on required testing, and there is unlikely to be a consensus conference for the development of an expert opinion.

#### **Supporting Evidence:**

These proposed policy requirements are based on recommendations from a Joint Society Work Group (JSWG) comprised of individuals appointed to represent the transplant professional societies including the American Society of Transplantation, the American Society of Transplant Surgeons, and the North American Transplant Coordinators Organization. The recommendations provided by this expert panel were based on an extensive literature review and approved by their parent organizations.

#### **Expected Impact on Living Donors or Living Donation:**

A standardized medical evaluation process should improve the transparency of the living donation process and could improve the confidence of living donors with regard to the safety of living donation. Over time, analysis of the living donor psychosocial and medical evaluation process could contribute to improved donor evaluation process and improved donor care and outcomes.

#### **Expected Impact on Specific Patient Populations:**

There should be no impact on the candidate pool. However, the proposal has the potential to affect all living liver donors.

In 2013, there were 5989 living organ donors, including 5734 living kidney donors, 252 living liver donors, and two living lung donors.

Between 2007 and 2013, there were 13 living lung donors, six living intestinal donors, and two living pancreas donors.

The proposed policy would affect all potential living donors, living donors, and their recipients.

**Expected Impact on OPTN Key Goals and Adherence to OPTN Final Rule:**

<i>HHS Program Goals</i>	<i>Strategic Plan Goals</i>
<b>Patient Safety</b>	New standardized psychosocial and medical evaluation requirements will promote safe, high-quality care for transplant candidates, transplant recipients, and living donors
<b>Best Use</b>	New standardized psychosocial and medical evaluation requirements should lead to objective and , measurable criteria related to concepts of donor risk/quality and recipient benefit
<b>Operational Effectiveness</b>	New standardized psychosocial and medical evaluation requirements would lead to system improvements that best support critical network functions, and would be disseminates to all members who could benefit

**Plan for Evaluating the Proposal:**

The Committee will request annual blinded reports on the number of centers found out of compliance during UNOS living donor program audits and will evaluate if the policy requirements for the medical and psychosocial evaluation of living donors need clarification on revision to aid centers with compliance.

**Additional Data Collection:**

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

**Expected Implementation Plan:**

If this policy proposal is ultimately approved by the Board of Directors, living donor recovery centers would be required to follow new policies for the medical evaluation of living kidney donors. UNOS Living Donor Programs Auditors will evaluate center compliance. The proposal will not require programming in UNet<sup>SM</sup>.

**Communication and Education Plan:**

The proposal addresses both modifications to existing policy and new requirements. Its applicability to all potential living donors requires an above-average effort to ensure that living donor transplant programs are aware of the requirements. Communication and education efforts will address the details of the new and revised requirements and support members who may need to revise their individual protocols.

Information about the new requirements would be included in an ongoing effort to provide instructional programs to members regarding patient and living donor safety, with particular emphasis on practices at living donor transplant programs. It also would be incorporated into the

OPTN Evaluation Plan and addressed in the context of ongoing member notification as the plan is periodically updated.

In addition, notification of the amended policy requirements would be included in the following routine communication vehicles:

- Policy notice
- System notice
- Member e-newsletter/blog article
- Notification to appropriate list serve groups

### **Compliance Monitoring:**

**The following changes to existing routine monitoring of OPTN members will occur:**

*Policy 14.1.A Living Donor Psychosocial Evaluation Requirements (previously 14.5.A Living Kidney Donor Psychosocial Evaluation Requirements)*

At living kidney and liver donor recovery hospitals, site surveyors will interview relevant staff and substantiate the information obtained in the interview through review of internal policies, procedures, and/or protocols; a sample of living donor medical records; or any material incorporated into the medical record by reference, to obtain evidence that the hospital's standard practice is:

- That those performing psychosocial evaluations of living donors are psychiatrists, psychologists, masters-prepared social workers, or licensed clinical social workers.

*Policy 14.4.B Living Donor Medical Evaluation Requirements (previously 14.4.B Living Kidney Donor Medical Evaluation Requirements)*

At living kidney and liver donor recovery hospitals, site surveyors will:  
Interview relevant staff and substantiate the information obtained in the interview through review of internal policies, procedures, and/or protocols; a sample of living donor medical records; or any material incorporated into the medical record by reference, to obtain evidence that the hospital's standard practice is that those performing the medical evaluations are physicians or surgeons.

Review the living donor recovery hospital's internal policies, procedures and/or protocols to verify that the hospital has developed and implemented written protocols that address:

- Cancer screening for
  - Cervical cancer
  - Breast cancer
  - Prostate cancer
  - Colon cancer
  - Lung cancer
- A process for determining if a donor is at increased risk for tuberculosis (TB)
- Identifying and testing donors at risk for transmissible seasonal or geographically defined endemic disease

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that:

- The living donor’s medical evaluation was completed
- There are results for required tests
- Evaluation of the living donor included required assessments

Policy 14.4.C *Additional Requirements for the Medical Evaluation of Living Kidney Donors*  
Requirements specific to the medical evaluation of living kidney donors that have been routinely monitored under old policy 14.4.B *Living Kidney Donor Medical Evaluation Requirements* will now be monitored under new policy 14.4.C.

**The following new routine monitoring of OPTN members will occur:**

Policy 14.4.D *Additional Requirements for the Medical Evaluation of Living Liver Donors*

At living liver donor recovery hospitals, site surveyors will:

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that:

- There are results for required tests
- Evaluation of the living liver donor included required assessments

Review the living donor recovery hospital’s internal policies, procedures and/or protocols to verify that the hospital has developed and implemented written protocols that address:

- Hypercoagulable state evaluation
- Testing for genetic diseases
- Screening for autoimmune disease
- Pre-donation liver biopsy

**Policy or Bylaw Proposal:**

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

1 At a meeting of the OPTN/UNOS Board of Directors convened on November 12-13, 2014 in St.  
2 Louis, MO, the following resolution is offered.

3  
4 *A resolution to modify existing or establish new requirements for the psychosocial and medical*  
5 *evaluation of Living Donors:*

6  
7 Sponsoring Committee: Living Donor

8  
9 **RESOLVED, that the following new or modified Policies 14.1 (Required Protocols for**  
10 **Recovery Hospitals), 14.5 (Psychosocial Evaluations Requirements for Living Donors),**  
11 **14.4 (Medical Evaluation Requirements for Living Donors), 14.6 (Registration and Blood**  
12 **Type Verification of Living Donors Before Donation), 14.7.A (Prospective Crossmatching**  
13 **Prior to Kidney Placement, 14.7.B (Placement of Non-directed Living Donor Kidneys,**  
14 **14.7.C (Transplant Hospital Acceptance or Living Donor Organs), 14.8 (Packaging,**  
15 **Labeling, and Transporting of Living Donor Organs, Vessels, and Tissue Typing**  
16 **Materials as set forth below are effective February 1, 2015**

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18 **14.1 Required Protocols for Recovery Hospitals**

19  
20 **14.1.A Required Protocols for Kidney Recovery Hospitals**

21  
22 ~~Kidney recovery hospitals must develop and comply with written protocols to address all~~  
23 ~~phases of the living donation process.~~

24  
25 **14.1.B Required Protocols for Liver Recovery Hospitals**

26  
27 ~~Liver recovery hospitals must develop and comply with written protocols to address all~~  
28 ~~phases of the living donation process. Specific protocols must include the evaluation,~~  
29 ~~pre-operative, operative, and post-operative care, and submission of required follow up~~  
30 ~~forms at 6 months, one year, and two years post donation.~~

31  
32 ~~Liver recovery hospitals must document that all phases of the living donation process~~  
33 ~~were performed in adherence to the hospital's protocols. This documentation must be~~  
34 ~~maintained by the recovery hospital.~~

35  
36 **14.51 Psychosocial Evaluation Requirements for Living Donors**

37  
38 **14.5.1.A Living Kidney Donor Psychosocial Evaluation Requirements**

39  
40 Living donor psychosocial evaluation requirements do not apply to any individual who is  
41 undergoing transplant whose native organ is suitable for transplant to another transplant  
42 candidate.

43  
44 Living donor psychosocial evaluation requirements apply to living kidney, liver, pancreas, lung  
45 or intestine donors.

46  
47  
48 ~~This living kidney donor psychosocial evaluation must be performed by a psychiatrist,~~  
49 ~~psychologist, or clinical social worker masters prepared social worker, or licensed clinical social~~  
50 ~~worker. Documentation of the psychosocial evaluation must be maintained in the living donor~~  
51 ~~record and include *all* of the following components:~~

- 52  
53 1. An evaluation for any psychosocial issues, including mental health issues, that might  
54 complicate the living donor's recovery and could be identified as ~~potential~~ risks for  
55 poor psychosocial outcome  
56 2. An evaluation for the presence of behaviors that may increase risk for disease  
57 transmission as defined by the U.S. *Public Health Service (PHS) Guideline (Policy*  
58 *3.1.1.4)*  
59 3. A review of the living donor's history of smoking, alcohol, and drug use, abuse, and  
60 dependency  
61 4. The identification of factors that warrant educational or therapeutic intervention prior  
62 to the final donation decision  
63 5. The determination that the ~~potential~~ living donor understands the short and long-term  
64 medical and psychosocial risks for both the living donor and recipient associated with  
65 living donation  
66 6. An assessment of whether the decision to donate is free of inducement, coercion,  
67 and other undue pressure by exploring the reasons for donating and the nature of  
68 the relationship, if any, to the transplant candidate

- 69 7. An assessment of the ~~potential~~ living donor's ability to make an informed decision  
 70 and the ability to cope with the major surgery and related stress. This includes  
 71 evaluating whether the ~~potential~~ donor has a realistic plan for donation and recovery,  
 72 with social, emotional and financial support available as recommended  
 73 8. A review of the ~~potential~~ living donor's occupation, employment status, health  
 74 insurance status, living arrangements, and social support  
 75 9. The determination that the ~~potential~~ living donor understands the potential financial  
 76 implications of living donation  
 77

78 • **14.4 Medical Evaluation Requirements for Living Donors**

79  
 80 **14.4.B Living Kidney Donor Medical Evaluation Requirements**

81  
 82 Living donor medical evaluation requirements do not apply to any individual who is undergoing  
 83 transplant whose native organ is suitable for transplant to another transplant candidate.

84  
 85 Living donor medical evaluation requirements only apply to living kidney, liver, pancreas, lung or  
 86 intestine donors.

87  
 88 A medical evaluation of the ~~potential~~ living kidney donor must be performed by the recovery  
 89 hospital and by a physician or surgeon experienced in living donation. ~~The goals of the medical~~  
 90 ~~evaluation are all of the following:~~

- 91  
 92 ~~1. To assess the immunologic compatibility of the living donor to the recipient~~  
 93 ~~2. To assess the general health and surgical risk of donation to the living donor~~  
 94 ~~including screening for conditions that may predict future complications from having~~  
 95 ~~only one kidney.~~  
 96 ~~3. To determine if there are diseases present that may be transmitted from the living~~  
 97 ~~donor to the recipient~~  
 98 ~~4. To assess the anatomy and function of the living donor's kidneys~~  
 99

100 Documentation of the medical evaluation must be maintained in the donor medical record.

101  
 102 The medical evaluation must include *all* of the components in Tables 14-26 through 14-9 below.  
 103  
 104

**Table 14-26: Requirements for Living Kidney Donor Medical Evaluations**

This evaluation must be completed:	Including evaluation for and assessment of this information:
<b>A General living donor history</b>	<ol style="list-style-type: none"> <li>1. A personal history of significant medical conditions which include but are not limited to:               <ol style="list-style-type: none"> <li>a. Hypertension</li> <li>b. Diabetes</li> <li>c. Lung disease</li> <li>d. Heart disease</li> <li>e. Gastrointestinal disease</li> <li>f. Autoimmune disease</li> <li>g. Neurologic disease</li> <li>h. Genitourinary disease</li> <li>i. Hematologic disorders</li> <li>j. Bleeding or clotting disorders</li> <li>k. History of cancer <u>including melanoma</u></li> </ol> </li> <li>2. History of infections  <del>A kidney-specific personal history including:</del> <ol style="list-style-type: none"> <li><del>a. Genetic renal diseases</del></li> <li><del>b. Kidney disease, proteinuria, hematuria</del></li> <li><del>c. Kidney injury</del></li> <li><del>d. Diabetes including gestational diabetes</del></li> <li><del>e. Nephrolithiasis</del></li> <li><del>f. Recurrent urinary tract infections</del></li> </ol> </li> <li>3. Active and past medications with special consideration for known nephrotoxic <u>and hepatotoxic</u> medications <u>or chronic use of pain medication</u></li> <li>4. Allergies</li> <li>5. An evaluation for coronary artery disease</li> </ol>
<b>General family history</b>	<p><del>The living donor's family history of coronary heart disease and cancer</del></p> <ul style="list-style-type: none"> <li>• <u>Coronary artery disease</u></li> <li>• <u>Cancer</u></li> </ul>
<b>Kidney-specific family history</b>	<p><del>The living donor's family history of:</del></p> <ul style="list-style-type: none"> <li>• <del>Kidney disease</del></li> <li>• <del>Diabetes</del></li> <li>• <del>Hypertension</del></li> <li>• <del>Kidney Cancer</del></li> </ul>

This evaluation must be completed:	Including evaluation for and assessment of this information:
<b>Social history</b>	<p>The living donor's history of:</p> <ul style="list-style-type: none"> <li>• Occupation,</li> <li>• Employment status,</li> <li>• Health insurance status,</li> <li>• Living arrangements, and</li> <li>• Social support</li> <li>• Smoking, alcohol and drug use and abuse</li> <li>• Psychiatric illness, depression, suicide attempts</li> <li>• <u>Criteria to assess increased risk for disease transmission behavior as defined by the PHS Guideline <i>Policy 1.2 (Definitions)</i></u></li> </ul>
<b>Physical Exam</b>	<p>A physical exam of the living donor including:</p> <ul style="list-style-type: none"> <li>• Height</li> <li>• Weight</li> <li>• BMI</li> <li>• <u>Vital signs</u></li> <li>• Examination of all major organ systems</li> <li>• <del>Blood pressure taken on at least two different occasions or 24-hour or overnight blood pressure monitoring</del></li> </ul>
<b>General laboratory and imaging tests</b>	<ul style="list-style-type: none"> <li>• Complete blood count (CBC) with platelet count</li> <li>• Blood type and <u>subtype as specified in <i>Policy 14.4.A (Living Donor Blood Type Determination)</i> and its subsections</u> <del>screen</del></li> <li>• Prothrombin Time (PT) or International Normalized Ratio (INR)</li> <li>• Partial Thromboplastin Time (PTT)</li> <li>• Metabolic testing (to include electrolytes, BUN, creatinine, albumin, calcium, phosphorus)</li> <li>• HCG quantitative pregnancy test for premenopausal women without surgical sterilization</li> <li>• Chest X-Ray</li> <li>• Electrocardiogram (ECG)</li> </ul>
<b>Other metabolic testing</b>	<ul style="list-style-type: none"> <li>• <del>Fasting blood glucose</del></li> <li>• <del>Fasting lipid profile (cholesterol, triglycerides, HDL cholesterol, and LDL cholesterol)</del></li> <li>• <del>Glucose tolerance test or glycosylated hemoglobin in first degree relatives of diabetics and in high risk individuals</del></li> </ul>

This evaluation must be completed:	Including evaluation for and assessment of this information:
<b>Kidney-specific tests</b>	<ul style="list-style-type: none"> <li>• Urinalysis or urine microscopy</li> <li>• Urine culture if clinically indicated</li> <li>• Measurement of urinary protein and albumin excretion</li> <li>• Measurement of glomerular filtration rate by isotopic methods or a creatinine clearance calculated from a 24-hour urine collection</li> <li>• Hospitals must develop and comply with a protocol for polycystic kidney disease or other inherited renal disease as indicated by family history</li> <li>• Patients with a history of nephrolithiasis or nephrolithiasis (&gt;3mm) identified on radiographic imaging must have a 24-hour urine stone panel measuring:               <ul style="list-style-type: none"> <li>○ Calcium</li> <li>○ Oxalate</li> <li>○ Uric acid</li> <li>○ Citric acid</li> <li>○ Creatinine</li> <li>○ Sodium</li> </ul> </li> </ul>
<b>Anatomic assessment</b>	<p>An assessment to determine:</p> <ul style="list-style-type: none"> <li>• Whether the kidneys are of equal size</li> <li>• If the kidneys have masses, cysts, or stones</li> <li>• If the kidneys have other anatomical defects</li> <li>• Which kidney is more anatomically suited for transplant.</li> </ul> <p>The choice of test for radiologic imaging may be determined based on the local radiological expertise and surgical preference, and may include CT angiogram or MR angiogram.</p>

This evaluation must be completed:	Including evaluation for and assessment of this information:
<b>Transmissible disease screening</b>	<p>Infectious disease testing must <u>be performed in a CLIA-certified laboratory or in a laboratory meeting equivalent requirements as determined by Centers for Medicare and Medicaid Services (CMS) using a FDA-licensed, approved, or cleared test.</u> Testing must include <i>all</i> the following:</p> <ol style="list-style-type: none"> <li>1. CMV (Cytomegalovirus) antibody</li> <li>2. EBV (Epstein Barr Virus) antibody</li> <li>3. HIV 1, 2 (Human Immunodeficiency Virus) antibody testing</li> <li>4. HepBsAg (Hepatitis B surface antigen)</li> <li>5. HepBcAB (Hepatitis B core antibody)</li> <li>6. HCV (Hepatitis C Virus) antibody testing</li> <li>7. HepBsAB (Hepatitis B surface antibody)</li> <li>8. <del>RPR (Rapid Plasma Reagin test for syphilis)</del> <u>Syphilis testing</u></li> </ol> <p>For tuberculosis (TB), <del>living donor recovery hospitals must determine if the potential donor is at increased risk for tuberculosis (TB) this infection, and if TB risk is suspected, so testing must include screening for latent infection using either:</del></p> <ul style="list-style-type: none"> <li>• <del>Screening for latent TB using either intradermal PPD</del></li> <li>• <del>Interferon Gamma Release Assay (IGRA)</del></li> </ul>
<b>Endemic transmissible diseases</b>	<p><u>Each living donor hospital must develop and follow a written protocol for identifying and testing donors at risk for transmissible seasonal or geographically defined endemic disease as part of its medical evaluation.</u></p> <p><del>For the following infectious diseases, recovery hospitals must determine if the potential donor is from an endemic area, and if so must test for:</del></p> <ul style="list-style-type: none"> <li>• <del>Strongyloides</del></li> <li>• <del>Trypanosoma cruzi</del></li> <li>• <del>West Nile</del></li> </ul>
<b>Cancer screening</b>	<p>Recovery hospitals must develop and comply with protocols consistent with the American Cancer Society (ACS) <u>or the U.S. Preventative Services Task Force</u> to screen for:</p> <ul style="list-style-type: none"> <li>• Cervical cancer</li> <li>• Breast cancer</li> <li>• Prostate cancer</li> <li>• Colon cancer</li> <li>• <del>Skin cancer</del></li> <li>• Lung cancer</li> </ul>

This evaluation must be completed:	Including evaluation for and assessment of this information:
<b>Exclusion criteria</b>	<p><del>Kidney recovery hospitals may exclude a donor with any condition that, in the hospital's medical judgment, causes the donor to be unsuitable for organ donation.</del></p> <p><del>Kidney recovery hospitals must exclude all donors who meet any of the following exclusion criteria:</del></p> <ul style="list-style-type: none"> <li><del>• Is both less than 18 years old and mentally incapable of making an informed decision</del></li> <li><del>• HIV</del></li> <li><del>• Diabetes</del></li> <li><del>• Uncontrollable hypertension or history of hypertension with evidence of end stage organ damage</del></li> <li><del>• Active malignancy, or incompletely treated malignancy</del></li> <li><del>• High suspicion of donor coercion</del></li> <li><del>• High suspicion of illegal financial exchange between donor and recipient</del></li> <li><del>• Evidence of acute symptomatic infection (until resolved)</del></li> <li><del>• Diagnosable psychiatric conditions requiring treatment before donation, including any evidence of suicidality</del></li> </ul>

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**14.4.C Required Medical Evaluation Protocols for Liver Recovery Hospitals Additional Requirements for the Medical Evaluation of Living Kidney Donors**

~~Liver recovery hospitals must develop and comply with written protocols for the medical evaluation of potential living donors that must include, but are not limited to, all the following elements:~~

- ~~1. A thorough medical evaluation by a physician or surgeon experienced in living donation to assess and minimize risks to the potential donor post-donation, which must include a screen for any evidence of occult liver disease.~~
- ~~2. A psychosocial evaluation of the potential living donor by a psychiatrist, psychologist or social worker with experience in transplantation must be provided to assess decision making capacity, screen for any pre-existing psychiatric illness, and evaluate the potential living donor for signs of potential coercion to donate.~~
- ~~3. Screening for evidence of transmissible diseases such as cancers and infections.~~
- ~~4. A radiographic assessment to ensure adequate anatomy and volume of the donor and the remaining liver segment.~~

**Table 14-7: Additional Requirements for the Medical Evaluation of Living Kidney Donors**

<u>This evaluation must be completed:</u>	<u>Including evaluation for and assessment of this information:</u>
<u>Kidney - specific donor history</u>	<p><u>A personal history of significant medical conditions which include, but are not limited to:</u>  <u>A kidney-specific personal history including:</u></p> <ol style="list-style-type: none"> <li>a. <u>Genetic renal diseases</u></li> <li>b. <u>Kidney disease, proteinuria, hematuria</u></li> <li>c. <u>Kidney injury</u></li> <li>d. <u>Diabetes including gestational diabetes</u></li> <li>e. <u>Nephrolithiasis</u></li> <li>f. <u>Recurrent urinary tract infections</u></li> </ol>
<u>Kidney-specific family history</u>	<ul style="list-style-type: none"> <li>• <u>Kidney disease</u></li> <li>• <u>Diabetes</u></li> <li>• <u>Hypertension</u></li> <li>• <u>Kidney Cancer</u></li> </ul>
<u>Physical Exam</u>	<ul style="list-style-type: none"> <li>• <u>Blood pressure taken on at least two different occasions or 24-hour or overnight blood pressure monitoring</u></li> </ul>
<u>Other metabolic testing</u>	<ul style="list-style-type: none"> <li>• <u>Fasting blood glucose</u></li> <li>• <u>Fasting lipid profile (cholesterol, triglycerides, HDL cholesterol, and LDL cholesterol)</u></li> <li>• <u>Glucose tolerance test or glycosylated hemoglobin in first degree relatives of diabetics and in high risk individuals</u></li> </ul>
<u>Kidney-specific tests</u>	<ul style="list-style-type: none"> <li>• <u>Urinalysis or urine microscopy</u></li> <li>• <u>Urine culture if clinically indicated</u></li> <li>• <u>Measurement of urinary protein and albumin excretion</u></li> <li>• <u>Measurement of glomerular filtration rate by isotopic methods or a creatinine clearance calculated from a 24-hour urine collection</u></li> <li>• <u>Hospitals must develop and comply with a written protocol for polycystic kidney disease or other inherited renal disease as indicated by family history</u></li> <li>• <u>Patients with a history of nephrolithiasis or nephrolithiasis (&gt;3 mm) identified on radiographic imaging must have a 24-hour urine stone panel measuring:</u> <ul style="list-style-type: none"> <li>○ <u>Calcium</u></li> <li>○ <u>Oxalate</u></li> <li>○ <u>Uric acid</u></li> <li>○ <u>Citric acid</u></li> <li>○ <u>Creatinine</u></li> <li>○ <u>Sodium</u></li> </ul> </li> </ul>

<u>This evaluation must be completed:</u>	<u>Including evaluation for and assessment of this information:</u>
<u>Anatomic assessment</u>	<p><u>Determine:</u></p> <ul style="list-style-type: none"> <li>• <u>Whether the kidneys are of equal size</u></li> <li>• <u>If the kidneys have masses, cysts, or stones</u></li> <li>• <u>If the kidneys have other anatomical defects</u></li> <li>• <u>Which kidney is more anatomically suited for transplant.</u></li> </ul>

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**14.4.D Additional Requirements for the Medical Evaluation of Living Liver Donors**

**Table 14-8: Additional Requirements for the Medical Evaluation of Living Liver Donors**

<u>This evaluation must be completed:</u>	<u>Including evaluation for and assessment of this information:</u>
<u>Liver specific family history</u>	<ul style="list-style-type: none"> <li>• <u>Liver diseases</u></li> <li>• <u>Bleeding or clotting disorders</u></li> </ul>
<u>General laboratory and imaging tests</u>	<ul style="list-style-type: none"> <li>• <u>Hospitals must develop and follow a written protocol for hypercoagulable state evaluation</u></li> </ul>
<u>Liver-specific tests</u>	<ul style="list-style-type: none"> <li>• <u>Hepatic function panel</u></li> <li>• <u>Ceruloplasmin in a donor with a family history of Wilson’s Disease</u></li> <li>• <u>Iron, iron binding capacity, ferritin</u></li> <li>• <u>Alpha-1-antitrypsin level: those with a low alpha-1-antitrypsin levels should have a phenotype</u></li> <li>• <u>must develop and follow a written protocol for testing for genetic diseases</u></li> <li>• <u>Hospitals must develop and follow a written protocol for screening for autoimmune disease</u></li> <li>• <u>Hospitals must develop and follow a written protocol for pre-donation liver biopsy</u></li> </ul>

<p><u>This evaluation must be completed:</u></p>	<p><u>Including evaluation for and assessment of this information:</u></p>
<p><u>Anatomic assessment</u></p>	<p><u>A radiological assessment must be performed to determine if the liver is anatomically suitable for transplantation, and to assess safety of resection for the donor.</u></p> <p><u>The evaluation must include at least all of the following:</u></p> <ul style="list-style-type: none"> <li>• <u>Assessment of projected graft volume</u></li> <li>• <u>Donor's remnant volume,</u></li> <li>• <u>Vascular anatomy</u></li> <li>• <u>Presence of steatosis</u></li> </ul>

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**14.4 E Living Donor Exclusion Criteria**

**Table 14-9: Living Donor Exclusion Criteria**

<p><u>Exclusion criteria for all Living Donors</u></p>	<p><u>Living donor recovery hospitals may exclude a donor with any condition that, in the hospital's medical judgment, causes the donor to be unsuitable for organ donation.</u></p> <p><u>Living donor recovery hospitals must exclude all donors who meet any of the following exclusion criteria:</u></p> <ul style="list-style-type: none"> <li>• <u>Is both less than 18 years old and mentally incapable of making an informed decision</u></li> <li>• <u>HIV</u></li> <li>• <u>Active malignancy, or incompletely treated malignancy</u></li> <li>• <u>High suspicion of donor coercion</u></li> <li>• <u>High suspicion of illegal financial exchange between donor and recipient</u></li> <li>• <u>Evidence of acute symptomatic infection (until resolved)</u></li> <li>• <u>Uncontrolled diagnosable psychiatric conditions requiring treatment before donation, including any evidence of suicidality</u></li> </ul>
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<u>Additional Exclusion Criteria for Living Kidney Donor</u>	<p><u>Kidney recovery hospitals must exclude all donors who meet any of the following additional exclusion criteria:</u></p> <ul style="list-style-type: none"> <li>• <u>Uncontrollable hypertension or history of hypertension with evidence of end stage organ damage</u></li> <li>• <u>Diabetes</u></li> </ul>
<u>Additional Exclusion Criteria for Living Liver Donors</u>	<p><u>Liver recovery hospitals must exclude all donors who meet any of the following additional exclusion criteria:</u></p> <ul style="list-style-type: none"> <li>• <u>HCV RNA positive</u></li> <li>• <u>HBsAg positive</u></li> <li>• <u>Donors with ZZ, Z-null, null-null and S-null alpha-1-antitrypsinphenotypes and untype-able phenotypes</u></li> <li>• <u>Expected donor remnant volume less than 30% of native liver volume</u></li> <li>• <u>Prior living liver donor</u></li> </ul>

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• **14.65 Registration and Blood Type Verification of Living Donors before Donation**

Recovery hospitals must use source documents from both an initial and second determination blood typings and subtypings (when used to determine transplant compatibility), to enter the living donor’s blood type data on the Living Donor Feedback Form. Additionally, each living donor program must develop and comply with a protocol to verify that the living donor’s blood type and type was correctly entered on the Living Donor Feedback Form with both the initial and second determination blood typing and subtyping source documents by an individual other than the person initially entering the donor’s blood type data.

Recovery hospitals must document that each blood typing and subtyping entry was performed according to the program’s protocol and must maintain this documentation.

**14.76 Placement of Living Donor Organs**

**14.76.A Prospective Crossmatching prior to Kidney Placement**

A prospective crossmatch is mandatory for all potential kidney living donor recipients. Guidelines for policy development, including assigning risk and timing of crossmatch testing, are outlined in Policy 4: Histocompatibility.

**14.76.B Placement of Non-directed Living Donor Kidneys**

163 Prior to determining the placement of a non-directed living donor kidney, the recovery hospital  
164 must obtain the match run of its waiting list candidates from its local OPO or the Organ Center.  
165 When a non-directed living donor kidney is allocated, the recovery hospital must document how  
166 the organ is allocated and the rationale for allocation.

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168 This requirement does not apply to non-directed living kidney donors who consent to participate  
169 in a Kidney Paired Donation (KPD) arrangement.

#### 171 **14.76.C Transplant Hospital Acceptance of Living Donor Organs**

172  
173 Transplant hospitals that perform living donor transplants must only accept and transplant living  
174 donor organs recovered at OPTN member recovery hospitals that are approved to perform  
175 living donor recovery for that organ type. If the OPTN does not have approval criteria for a living  
176 donor recovery hospital for a particular organ type, then transplant hospitals that perform living  
177 donor transplants must only accept and transplant living donor organs recovered at OPTN  
178 member transplant hospitals with current transplant program approval for that organ type.

#### 180 **14.87 Packaging, Labeling, and Transporting of Living Donor Organs, Vessels, and 181 Tissue Typing Materials**

182  
183 Recovery hospitals are responsible for packaging and labeling any living donor organs, tissue  
184 typing specimens, or vessels that are recovered from living donors according to Policy 16:  
185 Organ and Vessel Packaging, Labeling, Shipping, and Storage when either of the following  
186 occurs:

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- 188 • Living donor organs, tissue typing specimens, or vessels are recovered and must be
- 189 transported outside the recovery hospital
- 190 • A living donor organ requires repackaging by a transplant hospital for transport
- 191 outside the transplant hospital

#### 193 **14.87.A Living Donor Vessel Recovery and Transplant**

194  
195 A recovery hospital may only recover extra vessels for transplant if the living donor consents  
196 to the removal of extra vessels for transplant. The vessels from a living donor can only be used  
197 for the implantation or modification of a solid organ transplant for the original intended recipient.

#### 199 **14.87.B Living Donors Vessel Storage**

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201 Any vessels recovered from living donors must be stored according to Policy 16.7: Vessel  
202 Recovery, Transplant, and Storage.

#### 204 **14.98 Reporting Requirements**

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206 Members are responsible for submitting living donor forms according to Policy 18.5: Living  
207 Donor.

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## Public Comment Responses

### 1. Public Comment Distribution

Date of distribution: March 14, 2014

Public comment end date: June 13, 2014

Public Comment Response Tally					
Type of Response	Response Total	In Favor	In Favor as Amended	Opposed	No Vote/ No Comment/ Did Not Consider
Individual	27	20 (74.1 %)	0 (%)	2 (7.4 %)	5 (18.5%)
Regional	11	11 (100 %)	0 (%)	0 (%)	0 (0%)
Committee	19	5 (26.3%)	0 (%)	0 (%)	14 (73.9%)

### 2. Regional Public Comment Responses

Region	Meeting Date	Motion to Approve as Written	Approved as Amended (see below)	Meeting Format
1	5/5/2014	Yes		In person
2	3/28/2014	Yes		In person
3	5/30/2014	Yes		In person
4	5/9/2014	Yes		In person
5	6/12/2014	Yes		In person
6	5/16/2014	Yes		In person
7	5/9/2014	Yes		In person
8	4/4/2014	Yes		In person
9	5/21/2014	Yes		In person
10	5/15/2014	Yes		In person
11	5/30/2014	Yes		In person

#### Region 2:

There was some concern about UNOS policy dictating medical decision making and a suggestion that these requirements should be guidelines and not policies.

#### Committee Response:

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.

**Region 4:**

Policy 14.4 E, table 14-9: Additional Exclusion Criteria for Living Liver Donors

The region commented that the “expected donor remnant volume less than 30% of native liver volume” should be stricken and replaced with “ratio between expected donor remnant volume and weight of the donor”.

**Committee Response:**

The Committee appreciates this response. The current proposed policy language regarding donor remnant volume was recommended by a Joint Societies Work Group. The Committee consider this recommendation but did not support modifying this exclusion criteria regarding donor remnant volume.

**Region 5:**

- Regional members were concerned that this policy continues making policies that dictate medical practice. This type of line may have already been crossed with the development and implementation of the living donor kidney policies, but this is continuing down this same path which is of concern to some members.
- There was concern around the exclusion criteria concerning the volume of liver remaining. Regional members strongly felt that this was an individual practitioners decision and should not have a hard percentage put into policy. This should certainly be something that the attending surgeon reviews and is aware of, but there should not be an absolute restriction due to remaining size.
- Several regional members are concerned that the practice of living donation is continuously evolving. As UNOS puts more clinical guidance and restrictions in policy it becomes harder for centers to incorporate new clinical practice since changing a policy is an arduous process. UNOS needs to strongly consider ways to assist practitioners in ensuring level care is provided to all living donors but done in a way that is easily adaptable should a practice need to be changed or improved.

**Committee Response:**

The Committee appreciates this response.

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.

The current proposed policy language regarding donor remnant volume was recommended by a Joint Societies Work Group. The Committee will considered but did not support modifying the exclusion criteria regarding donor remnant volume.

Both the Committee and the Joint Societies Work Group are comprised of a group of diverse experts in the practice of living donor transplantation. Both groups agree that the practice of living donation is continuously evolving, and the goal of the current proposal was to fulfill HRSA directives (noted above) and to standardize the evaluation of living donors. The proposed policy does not preclude centers from additional consideration of medical or psychosocial characteristics of living donors based on evolving clinical knowledge and practice.

#### **Region 6:**

There was some discussion about the need for HepBsAg testing for liver donors since this is really not a problem for the recipient. However this was not added as an amendment or comment. The member who opposed did not participate in the discussion?

#### **Committee Response:**

The Committee appreciates this response. All testing or screening requirements in the proposal are based on recommendations from a Joint Societies Work Group and the Disease Transmission and Advisory Committee.

#### **Region 10:**

The committee should be aware that there is a specific certification for social workers who work with living donors. It may be beneficial to include this in the policy language.

#### **Committee Response:**

This proposal was based on recommendation from a Joint Societies Work Group comprised of representatives from the AST, ASTS, and NATCO. Social work was represented on the Joint Societies Work Group. Neither the Committee nor the Joint Societies Work recommended that specific certification for social workers should be required as part of policy at this time.

### **3. Committee Public Comment Responses**

#### **Ad Hoc Disease Transmission Advisory Committee:**

After receiving a presentation from the Chair of the Living Donor Committee, members discussed this proposal. A member asked if psychosocial evaluation was included in this proposal. It was noted that the evaluation for livers is identical to that of kidneys. A member recognized that new literature regarding the function of the independent living donor advocate (ILDA) raised some concerns. There was concern regarding the current policy requirements related to the ILDA, and specifically, language that the notes the ILDA as responsible for making sure that the psychosocial evaluation has taken place and that the donor understands the process. The Living Donor Committee Chair noted that much of the IDA language falls within the next proposal, on informed consent.

After this brief discussion, the Committee supported it as written (13 yes, 0 no, 2 abstained).

#### **Sponsoring Committee Response:**

The Living Donor Committee appreciates this response and will consider these comments.

#### **Liver and Intestinal Organ Transplantation Committee:**

The Liver & Intestinal Committee did not consider this proposal.

**Membership and Professional Standards Committee:**

The MPSC did not consider this proposal but had provided feedback during proposal development.

**Pancreas Transplantation Committee:**

The Committee did not consider this proposal.

**Patient Affairs Committee:**

After some discussion the Committee concluded that the proposal is a positive move for the transplant community. The Committee supported establishing overall changes to the requirements for psychosocial and medical evaluation for living donors. The Committee discussion focused more the substitution of the term living donor for the previous language 'potential living donor'.

The Committee recognized the potential for transplant programs to be cited during survey for failure to complete an entire evaluation on a living donor candidate who ruled out early in the evaluation process, while operating under the potential living donor policy language. The language change is not particularly significant to persons who hope to be living donors. The Committee felt continuation of the word 'potential' and any resulting citations during survey could create an administrative hardship for transplant programs, thereby discouraging some programs for doing living donor transplant. Any decrease in living donor programs creates a hardship for patients.

The Committee was also concerned that Living Donor Social Workers were not included in the Joint Societies Workgroup. This was felt to be an issue since social workers are key members of the living donor team, and often serve as the Living Donor Advocates at their programs. The Committee voted unanimously to support this proposal (19 in favor, 0 against, 0 abstentions)

**Sponsoring Committee Response:**

The Living Donor Committee appreciates this response and support for the proposal.

Social workers were represented on the Joint Societies Work Groups which provided past recommendations for living kidney and living liver donor medical and psychosocial evaluation. The Living Donor Committee recognizes the important contributions of social workers in the evaluation and care of potential and actual living donors and supports continued representation by social workers.

**Pediatric Transplantation Committee:**

The Committee considered this proposal during its June 4 meeting after a presentation by Lee Bolton, Living Donor Transplantation Committee Liaison.

One Committee member questioned the necessity of specific requirements for low volume programs, such as living lung, pancreas, or intestine programs.

Another Committee member questioned whether donors with alpha-1-antitrypsinphenotypes should be excluded if they have a normal liver histology. Mr. Bolton explained that this exclusion criterion was recommended by the Joint Societies Workgroup and suggested that the member submit a comment suggesting a post-Public Comment modification.

The Committee voted to support this proposal (11 yes, 0 no, 0 abstentions).

**Sponsoring Committee Response:**

The Committee appreciates this response and support of the proposal.

**Transplant Administrators Committee:**

The Committee received a presentation on the proposal and supports it as written.

Committee Vote: 12 in favor, 0 oppose, 0 abstentions

**Sponsoring Committee Response:**

The Living Donor Committee appreciates this support for the proposal.

**Transplant Coordinators Committee:**

(Support 13, Oppose 0, Abstain 0) This proposal was presented to the Committee and voted to unanimously support the proposal as written.

**Sponsoring Committee Response:**

The Living Donor Committee appreciates this support for the proposal.

**4. Individual Public Comment Responses**

**Comment 1:**

*Vote: Oppose*

*Date Posted: 03/15/2014*

1. It adds confusion to term people who have not yet donated an organ as a living donor. These people should be termed "living donor candidates". Calling everyone a living donor can create problems, especially if you are using this term to refer to someone who has been a donor once before and is donating again (and is in the testing process) vs someone who has never donated before.

2. The exclusion criteria for all 'living donors', "Is both less than 18 years old and mentally incapable of making an informed decision" is ethically and legally problematic because we know there are court cases where judges have allowed mentally incompetent youth to be living donors because it actually had some benefit to them-- it saved their sibling who they were very attached to.

**Committee Response:**

Existing Policy 1.2 (*Definitions*) defines candidate as a person registered on the organ transplant waiting list. When a candidate appears on the match run, the candidate is then referred to as a potential transplant recipient. Consequently, the Committee determined that the phrase "living donor candidate" would not conform with existing policy and could be potentially confusing.

The proposed exclusion criteria for a donor who is both less than 18 years old and mentally incapable of making an informed decision would only apply to future potential donors. The proposed exclusion is already included in current policy for living kidney donors. The proposed exclusion was based on recommendation from a Joint Societies Work Group comprised of representatives from the AST, ASTS, and NATCO.

**Comment 2:***Vote: Oppose**Date Posted: 03/21/2014*

Portions of the policy are acceptable, but I don't agree with medical management being dictated in so much detailed so by policy.

**Committee Response:**

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.

**Comment 3:***Vote: Support**Date Posted: 06/17/2014*

ASTS supports this proposal as written. ASTS notes that the newly designated 14.6.C addresses the allocation of non-directed kidney donors but fails to address the allocation of non-directed liver donors.

**Committee Response:**

The Committee appreciates the ASTS' review and support of the Proposal.

Under this proposal, Policy 14.6 (*Transplant Hospital Acceptance of Living Donor Organs*) would apply to living liver donation. The Committee is preparing a proposal to address domino liver donation for spring 2014 public comment which will clarify the requirements for placement of non-directed living liver donation that arises from domino donor hepatectomy. The Committee did not feel that there was a need to have a policy for non-directed living liver donors outside of the domino liver situation.

**Comment 4:***Vote: Support**Date Posted: 06/13/2014*

NATCO supports this proposal as written.

**Committee Response:**

The Living Donor Committee thanks NATCO for their support of the proposal.

**Comment 5:***Vote: Support**Date Posted: 06/16/2014*

The AST supports this proposal. We believe it offers consistency for work-up of all living organs donors and clarifies guidelines for the evaluation of living kidney and living liver donors. We do offer two minor comments:

1. Table 14-6, Requirement for Living Donor Medical Evaluations, Endemic transmissible diseases. Each living donor hospital must develop and follow a written protocol for identifying and testing donors at risk for transmissible seasonal or geographically defined endemic disease as part of its medical evaluation. a. We recommend provision be made for sharing center-specific protocols in addition to testing results in the context of paired exchange, in which the receiving center may lack expertise in endemic disease risk at the donor testing/recovery center.
2. 14.4 E, Table 14-9 Exclusion criteria for all living donors, Active malignancy, or incompletely treated malignancy. a. We believe added clarification would be helpful. Not all tumors are considered to have the same risk of transmission or recurrence; in addition, patients who have finished their treatment may still have higher risk of recurrence or cancer transmission. We recommend that the policy reference as well written piece such as recommendations from the Consensus Statement of the Amsterdam Forum, or better encompass these considerations in the state exclusion criteria. For example, it could state: active malignancy or incompletely treated malignancy with risk of transmission or recurrence, or treated malignancy considered at higher risk of recurrence or cancer transmission.

**Committee Response:**

The Committee thanks the AST for its support of this proposal.

Historically, the Committee has relied on the Disease Transmission Advisory Committee to provide expert opinion on infectious disease testing and related resources. The Committee will consider this recommendation and provide the recommendation to the DTAC for consideration.

In response to the comment on Table 14-9, the Committee considered but did not support revising the current requirement regarding malignancies.

**Comment 6:***Vote: No Opinion**Date Posted: 06/16/2014*

The National Catholic Bioethics Center (NCBC) wishes to respond to the call for comment concerning the Proposal to Modify Existing or Establish New Requirements for the Psychosocial and Medical Evaluation of all Living Donors (Requirements). This proposal would modify some elements of existing policy for the psychosocial and medical evaluation of living kidney donors and establish new requirements for the psychosocial and medical evaluation of all living donors.

As you know, the NCBC is a non-profit research and educational institute committed to applying the moral teachings of the Catholic Church to ethical issues arising in health care and the life sciences, including biomedical research. The NCBC serves numerous health care agencies in

their development and analysis of policies and protocols, including protocols for DCD. The Center has 2500 members throughout the United States, and provides consultations to hundreds of institutions and individuals seeking its opinion on this and other matters as they pertain to the appropriate application of Catholic moral teaching.

As we have shared with you in the past, the Catholic Church encourages organ donation as providing a gift of life to those in need. In terms of living donors, the same generosity of donors is recognized, as long as there is respect for true informed consent (to be addressed in the Proposal to Modify Existing or Established New Requirements for the Informed Consent of all Living Donors), as well as the protection of the bodily integrity of the donor. That is why rigorous standards for psychosocial and medical evaluation must be in place and regularly monitored for compliance by OPTN.

The proposed Requirements have standardized the qualifications of persons completing the psychosocial evaluations for all living donors, and expand the population of living donors for whom such evaluations are required. However, a glaring omission is the specific criteria for physicians who are performing the medical evaluation for such donors (“physician or surgeon experienced in living donation”). What is needed is a physician who is board certified in the area of organ functioning of the tissue to be donated.

While psychosocial and medical evaluation for all donors is needed, there are cited omissions in specific medical evaluation criteria for donors providing tissue other than a kidney or liver. Since these are documented sources of donation, regardless of how infrequent, these donors deserve the same protections, or perhaps even more due to the potential risks, that kidney or liver donors are provided. Furthermore, by intent, these Requirements open the door to the donation of all tissues from living patients, not just pancreas, intestines, and lungs. This is a very dangerous regulatory omission since it allows the unregulated donation of any tissue, regardless of how mutilating such a donation may be to the donor, both physically and psychologically. As microscopic surgery advances, a parent of a child, for whom it has been established after an accident that both hands cannot be salvaged, could decide to donate one hand to a child. Reproductive organs could be donated for an adult sibling unable to have children, and later the donor could decide that losing childbearing potential was a great mistake. The examples of potential physical and psychological harm can be expanded.

In terms of the Monitoring and Evaluation criteria for living donor recovery hospitals, the very fact that surveyors “may” and not “shall” evaluate for the specific indices presents a regulatory vacuum, in terms of what must be assessed to demonstrate compliance with the Requirements. Mandatory timeframes for reporting and surveying by/of living donor recovery hospitals need to be specified.

Of significant concern is the paucity of “Living Donor Exclusion Criteria.” Despite the evaluation indices for living donors, few identified indices will lead to a denial of the donation. Much of the donor protection requirements will be left up to the living donor recovery hospitals. Of specific concern is that for all living donor denials only “high suspicion of donor coercion” will trigger a denial. Any evidence of coercion requires a thorough investigation, and confirmation of its presence or lack thereof, and then a denial if there is evidence of coercion. Furthermore only an “uncontrolled” diagnosable psychiatric condition or suicidal ideation triggers a denial. Psychiatric conditions can be labile, and a decision of someone controlled today by medication, may not represent the psychiatric status of the person in the future, when they are suffering from the loss of an organ or tissue.

We ask that these Requirements be amended to enhance credentialing criteria for the medically evaluating physician and to require specific timeframes for living recovery donor program surveillance. Of great importance is the need to limit, at least at this time, living donations to kidneys and tissue from the liver, pancreas, lung and intestines. Furthermore, specific indices for these latter three tissue donations need to be developed. Lastly, and most importantly, exclusion criteria for all living donor donations need to be expanded for medical exclusions, as well as for exclusion for psychiatric disorders that fall in the diagnostic categories beyond adjustment disorders, such as psychosis (regardless of whether they are “controlled”), as well as exclusion for any evidence of coercion.

We thank you for the opportunity to review this proposal, and we look forward to our ongoing collaboration with you to enhance not only donor safety, but also a culture in which donors and their families are confident that such policies are protective of their good will and generosity.

### **Committee Response:**

The Living Donor Committee notes that some remarks from the National Catholic Bioethics Center intertwine concerns regarding the informed consent proposal and the psychosocial and medical evaluation proposal. Please review the Committee’s point-by-point response for both proposals.

1. The Living Donor Committee thanks the National Catholic Bioethics Center for its recognition that the existing policy and current proposal standardizes the information to be provided during the living donor informed consent process.

The Committee also thanks the Center for recognizing that it is important that living donor informed consent policy address not only liver and kidney donors, but donors of other organs (lung, pancreas, intestines). The OPTN recently implemented a standardized informed consent process, as described in Policy 14, for living kidney donors. However, under current policy, living liver donor recovery programs must develop and follow center-specific protocols for the informed consent of living liver donors. Furthermore, living lung, intestine, or pancreas donor programs are not required to develop or follow a center-specific protocol and are not subject to any OPTN requirement for the informed consent of living donors. Therefore, if the current proposal is not approved, living liver donor programs will continue to follow non-standardized requirements for living liver donors and programs that perform living lung, pancreas, and intestinal donation will not be required to follow any informed consent process for these categories of living donors.

2. A domino donor is an individual who donates an organ that is removed as a treatment for a medical condition and who subsequently receives a replacement organ from another donor (living or deceased). Domino donors are rare; domino donation only occurs an average of twelve times per year. Based on the Center’s response (e.g., that domino donors trigger other donations), the Center may be confusing domino donors with living kidney donors who participate in donor chains within a kidney paired donation exchange. Kidney paired donation (KPD) is addressed in a separate section of policy (Policy 13), while the current policy proposal refers to Policy 14. Kidney donors participating in KPD are already subject to the consent requirements in Policy 14. Paired liver exchanges have not occurred in this country. As an informational item, the Living Donor Committee is planning to distribute new proposed policy requirements for domino liver donation for public comment in spring 2015.

3. The Center voiced a concern that the current policy about informed consent would “open the door” to allow unregulated donation of any tissue, such as vascularized composite allografts. The Committee notes that the policy has been now been revised to pertain specifically to specific types of solid organ living donors, i.e., kidney, liver, pancreas, lung, intestine donors. The policy therefore does not pertain to any other types of donation. This modification to the proposal does not prohibit the donation of VCAs from living donors. It does, however, mean that living VCA donors will not have the same protections and oversight as other living donors.

4. The Center was concerned with requirements for surveyor monitoring of living donor recovery hospitals. The evaluation plan for this proposal is consistent with OPTN standards for site surveys and monitoring plans. The compliance monitoring plan described in the public comment document represents the best estimation of how a proposed policy could be monitored at the time that the policy language is developed for public comment. Words such as “may”, “shall” or “will” should not be construed as indicating the level of commitment to monitoring the proposed policy. Once final policy language is approved by the OPTN Board of Directors, the monitoring plan is revised as necessary to reflect the approved policy language. The final monitoring plan is published in the OPTN Evaluation Plan prior to implementation of the policy.

It is expected that the final monitoring criteria for this proposal would be incorporated into the existing routine site survey process. However, OPTN members must comply with all OPTN obligations regardless of whether the particular obligation is routinely reviewed. To that end, UNOS has processes in place to investigate potential noncompliance with OPTN obligations reported or discovered through avenues other than the routine site survey process.

5. Regarding exclusion criteria for potential living donors, this is not part of the current policy proposal on informed consent.

As the Committee describes in response to public comment on the policy proposal on the medical and psychosocial evaluation, high suspicion of coercion would be an automatic rule-out but this does not preclude transplant programs from further investigation should they suspect any degree of coercion. In addition, this proposed policy notes that there must be a full assessment of whether the donor’s decision to donate is free of inducement, coercion, and other undue pressure, in order to determine whether an individual is suitable for proceeding with living donation. Within the current proposal regarding informed consent, the living donor is required to sign a statement indicating that they are free from inducement or coercion.

There is no evidence that individuals with controlled psychiatric conditions are unable to give informed consent to undergo medical procedures. As the Committee describes in response to public comment on the policy proposal on the medical and psychosocial evaluation, the policy proposal’s list of exclusion criteria for donation are based on recommendations from a Joint Societies Work Group comprised of representatives from the American Society of Transplant Surgeons, the American Society of Transplantation, and the North American Transplant Coordinators Organization. Based on these experts’ experience and on evidence in the literature, there is no rationale for excluding individuals who have prior psychiatric illness or psychiatric illness controlled with treatment from serving as living donors.

Finally, it should be noted that existing and proposed policy address absolute contraindications to living donation. Living donor recovery hospitals may apply their own relative contraindications to approve or exclude potential living donors who, by virtue of mental health history or any other characteristic, are judged to be at too great a risk to reasonably be approved for donor surgery.

These case-by-case decisions, made at most centers by multidisciplinary teams including mental health specialists, cannot be precisely prescribed by any given national policy. Moreover, OPTN policy cannot and does not address every issue of donor selection that clinical experts in transplant programs would understand, by virtue of their training and experience, are exclusions for donation. For example, it is not necessary for policy to state that chronic kidney disease in a potential donor is a contraindication to kidney donation. The Living Donor Committee does not therefore accept the view that if a factor or condition is not explicitly excluded by policy then that factor or condition must be allowed under policy.

#### **Comment 7:**

National Catholic Partnership on Disability (NCPD) was established over thirty years ago to implement the U.S. Catholic bishops' Pastoral Statement on People with Disability. On behalf of NCPD, I offer the following comments:

The Living Donor Committee has solicited public comment on two proposals: The first modifies or establishes requirements for the informed consent of all living donors; the second does the same for their psychosocial and medical evaluation. Taken together, the proposals permit recovery hospitals to accept organ donations where an adult living donor is incompetent, or there is some reason to suspect coercion, or the donation would compromise the donor's bodily integrity. This is clearly unacceptable.

As their titles indicate, both proposals apply to "all living donors." The background of the second proposal demonstrates that this was a deliberate choice. Its stated goal was to "establish new policy requirements for the psychosocial and medical evaluation of all types of living donors." According to its preamble, "[t]his proposal was originally intended to expand the same level of detail concerning ... [such] evaluation of living kidney donors to living liver donors." As the proposal developed, it was suggested that the elements common to living kidney and liver donors might also "be extended to apply to other types (pancreas, intestine, and lung) of living organ donors." In its final form, however, the proposal was "expanded to include all living donors [,]" without exception.

Undoubtedly, medical science will soon have the ability to transplant organs that will necessarily result in compromising a living donor's bodily integrity. Such techniques are morally illicit since they would constitute mutilation. Yet, they are implicitly condoned by the two proposals' extension to "all living donors."

(Though the second proposal requires additional medical evaluations and exclusion criteria for living kidney and liver donors, see § 14.4.C-E; tb.14-7, 8, & 9, it makes no corresponding provision for the other types of donations it expressly references. Likewise, the first proposal requires recovery hospitals to disclose risks specific to kidney and liver donation, see § 14.3 & 4, but not for the other types of referenced donations.)

The second proposal compounds the problem by permitting recovery hospitals to accept mentally incompetent adults as living organ donors. Not surprisingly, such hospitals are required to assess "the living donor's ability to make an informed decision [,]" § 14.1.A (7), and to determine whether such donor "understands the short and long- term medical and psychosocial risks [associated with the donation.]" § 14.1.A (5). In addition, the first proposal imposes detailed responsibilities on such hospitals to facilitate donors' informed consent. See § 14.3. Despite these requirements, only donors "mentally incapable of making an informed

decision” who are “less than 18 years old” are categorically excluded by the second proposal, § 14.4.E; tb. 14-9, leaving the suitability of such adult donors to “the hospital’s medical judgment [.]” § 14.4.E. It is shocking to think a recovery hospital could accept as a living donor any person, regardless of age, whose mental capacity to provide informed consent is in question.

Likewise, though the hospital must assess “whether the decision to donate is free of inducement, coercion, and other undue pressure [.]” § 14.1.A (6), it is only required by the second proposal to exclude donors when the suspicion of coercion (but not inducement or other forms of undue pressure) is “high.” § 14.4.E; tb. 14-9. It is hard to understand why the first proposal would require such hospitals to obtain signed confirmation that the donor is “free from inducement and coercion [.]” § 14.3; tb. 14-1, provide the donor with an advocate knowledgeable about “the potential impact of family or other external pressure on the living [donor,]” § 14.2.A (3), and authorize such advocate to “protect the rights or best interests of the living donor [.]” 14.2.B (4), while only a “high suspicion of coercion” will trigger exclusion. (Additionally, though the hospital must exclude donors with “Uncontrolled diagnosable psychiatric conditions requiring treatment before donation, § 14.4.E; tb. 14-9 (emphasis added), it can nonetheless accept donors whose mental health issues “could complicate... [their] recovery and could be identified as risks for poor psychosocial outcome.” § 14.1.A(1). In any event, it is simply outrageous to think hospitals could accept organ donations when there is a reasonable suspicion that the donor is not acting voluntarily.

Adoption of the following modifications to § 14.4.E should go far to resolve these issues:

“Living donor recovery hospitals must exclude all donors who meet *any* of the following exclusion criteria:

- Offering to donate an organ that would compromise the living donor’s functional integrity;
- A donor (regardless of age) who is mentally incapable of providing informed consent;
- A reasonable suspicion that the decision to donate is not free of inducement, coercion, or other undue pressure;
- The presence of mental health issues that might complicate the donor’s recovery and could be identified as risks for poor psychosocial outcome.”

The proposals should further require disclosure of and evaluation for any known risks associated with pancreas, intestine, and lung donations.

These problems were likely the product of inattention to the inconsistencies within and between the two proposals. Otherwise, they would surely raise a chilling specter, imperiling the lives and bodily integrity of those persistently comatose, brain injured, and those with other severe cognitive or volitional impairments.

#### **Committee Response:**

The Living Donor Committee notes that many remarks from the representative of the National Catholic Partnership on Disability (NCPD) intertwine concerns about the informed consent proposal and the psychosocial and medical evaluation proposal.

The NCPD representative viewed the proposals as condoning future ability by medical science to engage in transplantation of organs that compromises donors' bodily integrity and are morally illicit. The Committee notes that the informed consent proposal (as well as the psychosocial and medical evaluation proposal) pertain to specific activities concerning living donors. The Committee notes that the policy has been now been revised to pertain specifically to solid organ living donors, (i.e., kidney, liver, pancreas, lung, intestine donors). The policy therefore does not pertain to any other types of donation. This modification to the proposal does not prohibit the donation of VCAs from living donors. It does, however, mean that living VCA donors will not have the same protections and oversight as other living donors.

The NCPD representative expressed concerns that the informed consent proposal and the psychosocial and medical evaluation proposal do not address specific issues in either the consent or evaluation process for donors providing tissue other than kidney or liver. The Committee considered but did not propose any additional requirements for the informed consent or evaluation of living lung, pancreas, or intestine donors (e.g., the disclosure of any known risks associated with these types of donation) because the volume of these types of donation is so low that it is not possible to specify any additional elements of informed consent and it is not possible to determine the value of any additional medical testing for such individuals. Given the low volumes, there are limited published data on these issues in such donors and there is unlikely to be a consensus conference for the development of expert opinion on best practices.

The NCPD representative also expressed concerns about the exclusion criteria for living donors included in the psychosocial and medical policy proposal. With regard to kidney donors, it is important to note that these criteria are already included in current policy. They derive from the recommendations of a Joint Societies Work Group composed of the transplant professional societies (American Society of Transplantation; American Society of Transplant Surgeons; North American Transplant Coordinators Organization) to the Living Donor Committee. However, under current policy, living liver donor recovery programs must develop and follow center-specific protocols for the evaluation of living liver donors. Furthermore, living lung, intestine, or pancreas donor programs are not required to develop or follow a center-specific protocol and are not subject to any OPTN requirement for the evaluation of living donors. Therefore, if the current proposal is not approved, living liver donor programs will continue to follow non-standardized requirements for living liver donors and programs that perform living lung, pancreas, and intestinal donation will not be required to follow any evaluation process for these categories of living donors.

As the Committee describes in response to public comment on the policy proposal on the medical and psychosocial evaluation, the policy proposal's list of exclusion criteria for donation are based on recommendations from a Joint Societies Work Group comprised of representatives from the transplant professional societies. It should be noted that existing and proposed policy address absolute contraindications to living donation. Living donor recovery hospitals may apply their own relative contraindications to approve or exclude potential living donors who are judged by the recovery hospital to be at too great a risk to reasonably be approved for donor surgery. These case-by-case decisions, made at most centers by multidisciplinary teams, cannot be precisely prescribed by any given national policy.

Moreover, OPTN policy cannot and does not address every issue of donor selection that clinical experts in transplant programs would understand, by virtue of their training and experience, are exclusions for donation. For example, it is not necessary for policy to state that chronic kidney disease in a potential donor is a contraindication to kidney donation. The Living Donor

Committee does not therefore accept the view that if a factor of condition is not explicitly excluded by policy then that factor or condition must be allowed under policy.

The NCPD representative emphasized a concern over the issue of a potential donor's mental capacity and why it would ever be permissible to allow an individual who is mentally incapable of providing informed consent to donate. The Joint Societies Work Group and the Committee recognized that, if one uses the yardstick of the best interests of the individual (in this case, the prospective donor), there have been situations where it has been judged with the courts or social services systems, as well as by the mental health and psychosocial experts on transplant teams, to be in the donor's best interest to allow that person to serve as a living donor. These cases have most often involved an adult child (the prospective donor) who relied on a parent for care, and the parent needed a transplant in order to continue to reasonably provide such care. These situations are extremely rare but, in the view of the Joint Societies Work Group and the Living Donor Committee, should not be ruled out automatically on the basis of OPTN policy. Rather, each center should be able to review all evidence in such circumstances.

Regarding the concern about coercion, as the Committee describes in response to public comment on the policy proposal on the medical and psychosocial evaluation, high suspicion of coercion would be an automatic rule-out but this does not preclude transplant programs from further investigation should they suspect any degree of coercion. In addition, this proposed policy notes that there must be a full assessment of whether the donor's decision to donate is free of inducement, coercion, and other undue pressure, in order to determine whether an individual is suitable for proceeding with living donation. Within the current proposal regarding informed consent, the living donor is required to sign a statement indicating that they are free from inducement or coercion.