

**OPTN/UNOS Living Donor Committee
Report to the Board of Directors
June 23-24, 2014
Richmond, Virginia**

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

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This report reflects the work of the OPTN/UNOS Living Donor Committee between September 2013 and April 2014.

Action Items

1. Proposal to Require UNetsm Registration of all Living Donor Organ Candidates Prior to Transplant

Public Comment: September 6 – December 6, 2013

Under this proposal, all candidates for living donor transplants would be required to be added to the waiting list before their transplant. All living donor organ recipients are already reported to UNetsm and are charged a registration fee, just like candidates for deceased donor organs. Most transplant programs add living donor organ transplant candidates to the waiting list prior to the transplant procedure via Waitlistsm, while other programs report living donor organ transplant recipients via Tiedism after the transplant occurs. Patient safety benefits associated with registering a candidate prior to transplant include improved blood type verification prior to the transplant procedure, providing unique identifiers for comparing donor and candidate information, and the accrual of waiting time. Please note that this proposal would not change the registration fees paid to the OPTN Contractor.

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 (18-Yes, 0-No, 0-Abstain):

RESOLVED, that the modifications to Policy 3.4.C (Candidate Registration), as set forth in Exhibit B, are hereby approved, effective September 1, 2014.

2. Proposal to Establish Minimum Requirements for Living Liver Donor Follow-up

Public Comment: September 6 – December 6, 2013

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

Transplantation (AST), the American Society of Transplant Surgeons (ASTS), and the North American Transplant Coordinators Organization (NATCO) provided to the OPTN/UNOS Living Donor Committee.

The Committee considered and addressed all public comment received on this proposal which is provided in the briefing paper (**Exhibit B**). After modifying the original proposed policy language, the Committee voted in support of sending the proposal for consideration by the Board of Directors (19-Yes, 0-No, 0-Abstain):

RESOLVED, that the following new or modified Policies 14.1.B (Required Protocols for Liver Recovery Hospitals), 18.1 (Data Submission Requirements), 18.2 (Timely Collection of Data), 18.5 (Living Donor), 18.5.A (Reporting Requirements after Donation), 18.5.B (Reporting Requirements after Living Liver Donation), 18.5.B (Submission of Living Donor Death and Organ Failure), 18.5.C (Reporting of Non-transplanted Living Donor Organs), and 18.5.D (Reporting of Living Donor Organs Not Transplanted in the Intended Recipient) as set forth in Exhibit B are effective September 1, 2014.

FURTHER RESOLVED, that the following modification to Policy 18.5.A (Reporting Requirements after Donation), as set forth in lines 64, 71 and 79 in Exhibit B, are removed from policy and will be reinstated effective pending programming and notice to OPTN membership.

Committee Projects

3. **Modify Existing or Establish New Requirements for the Informed Consent of all Living Donors**

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

Project Board Review: *November, 2014*

This proposal would modify existing policy and establish new policy requirements for the psychosocial and medical evaluation of all types 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 Work Group 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) provided to the Living Donor Committee. Policy to standardize the medical evaluation of living kidney donors has already been established. This proposal reorganizes the section on medical and psychosocial evaluation of living donors so that there are general provisions that apply to all living donors and there are provisions that only apply to specific donors. This facilitates consistency across organs. It also provides a minimum framework for all living donors (including lungs, intestine and pancreata). The proposal establishes new provisions for medical and psychosocial evaluation of living liver donors. This proposal also modifies some elements of existing policy for the psychosocial and medical evaluation of living kidney donors.

While public comment is not yet complete, initial comments from committees and regions that have considered the proposal have been supportive. Public comment on

this proposal will conclude in June, 2014. The Committee will review and respond to public comment, and determine if the proposal should be sent for Board consideration.

For more information, see the full text of the proposal or refer to the Committee meeting summary from March 31, 2014 (**Exhibit C**).

4. Modify Existing or Establish New Requirements for the Psychosocial and Medical Evaluation of all Living Donors

Public Comment: March 14 – June 13, 2014

Project Board Review: *November, 2014*

This proposal would modify existing policy and establish new policy requirements for the psychosocial and medical evaluation of all types 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 proposals reorganizes the informed consent of living donors so that there are general provisions that apply to all living donors and there are provisions that only apply to specific donors. This facilitates consistency across organs. It also provides a minimum framework for all living donors (including lungs and pancreata). The proposal establishes new informed consent provisions for living liver donors. This proposal also modifies some elements of existing policy for the psychosocial and medical evaluation of living kidney donors and.

While public comment is not yet complete, initial comments from committees and regions that have considered the proposal have been supportive. . Public comment on this proposal will conclude in June, 2014. The Committee will review and respond to public comment, and determine if the proposal should be sent for Board consideration.

For more information, see the full text of the proposal or refer to the Committee meeting summary from March 31, 2014 (**Exhibit C**).

5. Require the Reporting of Aborted Living Donor Recovery Procedures

Public Comment: March 14 – June 13, 2014

Project Board Review: *November, 2014*

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 UNetSM 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 UNetSM Improving Patient Safety Portal. Additionally, the proposal would clarify current living donor adverse event reporting requirements by eliminating some redundant sections of policy.

While public comment is not yet complete, all general public, regional and other committee comments received to date have supported the proposal. Public comment on this proposal will conclude in June, 2014. The Committee will review and respond to public comment, and determine if the proposal should be sent for Board consideration.

For more information, see the full text of the proposal or refer to Committee meeting summary from March 31, 2014 (**Exhibit C**).

6. Clarify the Status of Domino Donors

Public Comment: Spring 2015

Project Board Review: *November, 2015*

There are inconsistent practices regarding whether domino donors are considered as living 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 development.

In response, the Living Donor Committee is leading this new area of work by forming a joint work group involving the Liver, Thoracic, and Operations and Safety Committees. UNOS staff representing these Committees has met to identify the policies that may need to be modified to address domino donation.

Based on a preliminary analysis, the work group may propose:

- Modifying Policy 1.2 (Definitions) to add a definition for domino donor
- Developing policy for domino liver donation similar to Policy 6.5.F (Allocation of Domino Donor Hearts)
- Modifying Policy 18.1 (Data Submission Requirements) to clarify a living donor follow-up form is not required for domino donors
- Modifying Policy 14 (Living Donation) to exclude domino donors where appropriate

The joint work group plans to provide draft policy language for the Liver, Thoracic, and Operations and Safety Committee to review during their fall 2014 full committee meetings.

7. New Requirements for the Transport of Living Donor Organs

Public Comment: To be Determined

Project Board Review: *To be Determined*

The Living Donor Committee first discussed this topic in May 2010 and determined that OPTN 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 proposal was approved by the Board 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 was not intended to address 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 a FMEA for its ABO Proposal, which was distributed for spring 2014 public comment, and FMEA was used 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. At this point, the Committee is investigating the availability of resources for and applicability of an FMEA for this project.

Committee Projects Pending Implementation

8. Modify the Patient Safety System for Living Donor Events

Public Comment: Spring 2010

Board Approval: *November 2010*

Projected Implementation: *To be Determined*

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 Clarify Requirements for Independent Living Donor Advocates at Living Kidney Donor Recovery Centers

Public Comment: Spring 2013

Board Approval: November 2013

Implementation Date: February 1, 2014

The proposal is intended to lead to increased standardization in Independent Living Donor Advocate (ILDA) practice among living kidney donor programs. 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 fall 2014 meeting.

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

Public Comment: Spring, 2012

Board Approval: November, 2012

Implementation Date: February 1, 2013

The project 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 fall 2014 meeting.

11. Proposal to Establish Minimum Requirements for Living Kidney Donor Follow-up

Public Comment: Spring, 2012

Board Approval: November, 2012

Implementation Date: February 1, 2013

The project intended to improve the collection of clinical and laboratory data for living kidney donors during the first two years post-donation. The Committee met on March 31, 2014 and received a very preliminary verbal report based six months post-donation follow-up data collected on a cohort who donated between February 1, 2013 and May 31, 2013. This report revealed a greater than 6% increase nationally (averaged across programs) in timely clinical data, and an 11% increase nationally in laboratory test data. Based on these preliminary data, clinical data submission rates have increased from 59% to 65%, on average across programs, and laboratory test data rates have increased from 48% to 59%.

12. Proposal to Establish Requirements for the Medical Evaluation of Living Kidney Donors

Public Comment: Spring, 2012

Board Approval: November, 2012

Implementation Date: 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 fall 2014 meeting.

Review of Public Comment Proposals

The Committee reviewed 5 of the 17 proposals released for public comment from March – June, 2014.

13. Proposal to Notify Patients Having an Extended Inactive Status (Transplant Coordinators Committee)

A member saw a potential loophole in the proposal that would allow a center to keep a patient inactive for 89 days and then activate the patient one day only to make them inactive again. This would allow the center to avoid sending the notifications as required by policy. The Committee supported this proposal by voice vote.

14. Proposal to Align OPTN Policies with the 2013 PHS Guideline for Reducing Transmission of Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV) Through Solid Organ (Ad Hoc Disease Transmission Advisory Committee)

A committee member noted that Hep B surface antibody testing is required in this proposal, but was not recommended by DTAC in the proposed infectious disease testing requirements in another proposal (Psychosocial and Medical Evaluation of all Living Donors) also distributed for public comment. This potential discrepancy has been reported to DTAC, and will be addressed during the post public comment period. The Committee supported his proposal by voice vote, with one member opposed.

15. Proposal to Allow Non-substantive Changes to OPTN Policies or Bylaws (Policy Oversight Committee)

A member suggested that there should be a public log of non-substantive changes to policy or bylaws. The Committee supported this proposal by voice vote.

16. Proposal to Clarify Data Submission and Documentation Requirements (Membership and Professional Standards Committee)

The Committee supported this proposal by voice vote.

17. Proposed ABO Blood Type Determination, Reporting, and Verification Policy Modifications (Operations and Safety Committee)

A member commented that any new ABO policy changes need to align with CMS requirements. A member questioned how frequently ABO mismatch problems occur and if the proposed new requirements add unnecessary excessive burden to transplantation. The Committee could not reach consensus on this proposal and referred the proposal back to subcommittee for further consideration.

Meeting Summaries

The committee held meetings on the following dates:

- December 12, 2013
- September 16, 2013
- March 31, 2014

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

**Proposal to Require UNetsm Registration of all Living Donor
Organ Candidates Prior to Transplant**

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BRIEFING PAPER**OPTN/UNOS**

Proposal to Require UNetsm Registration of all Living Donor Organ Candidates Prior to Transplant

Sponsoring Committee: Living Donor**Summary and Goals of the Proposal:**

Under this proposal, all candidates for living donor transplants would be required to be added to the waiting list before their transplant. All living donor organ recipients are already reported to UNetsm and are charged a registration fee, just like candidates for deceased donor organs. Most transplant programs add living donor organ transplant candidates to the waiting list prior to the transplant procedure via Waitlistsm, while other programs may report a living donor organ transplant recipient after the transplant occurs via Tiedism. Patient safety benefits associated with registering a candidate prior to transplant include improved blood type verification prior to the transplant procedure, providing unique identifiers for comparing donor and candidate information, and the accrual of wait time. Please note that this proposal would not change the registration fees paid to the OPTN contractor

Background and Significance of the Proposal:

UNOS conducts audits of designated programs with a living donor component for compliance with living donor policies. Citations of policy violation are commonly connected to Policies 3.1.2 (Transplant Center) (*Now Policy 5.5.A (Receiving and Accepting Organ Offers)*), 12.7.7 (Verification of Information Upon Receipt of Organ) (*Now Policy 5.6 (Blood Type Verification upon Receipt)*) and 12.7.9.1 (Living Donor Organs that Remain in the Same Recovery Facility as the Intended Candidate) (*Now Policy 16.1 (Organs not Requiring Transport)*). These policies address requirements involving:

- Unique recipient identifier verified after procurement and before transplantation
- Blood types of the donor and the recipient verified after procurement and before transplantation.

Many programs are using the potential living donor transplant recipient's name as the unique identifier required to verify the correct organ for the correct recipient. This practice is problematic because in order to comply with policy, the unique identifier (potential recipient's name) must be recorded in the donor's medical record, which could violate provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA)¹. To avoid a potential HIPAA violation, some programs have used a non-unique label such as "Recipient ABO = X" for the documentation, but this places those programs at risk for a potential policy violation as it is not "unique".

In response to these challenges, the Committee considered how it might protect living donors and recipients through assurance of a documented process of recipient identification, and at the same time help programs maintain compliance with HIPAA requirements.

¹ <http://www.hhs.gov/ocr/privacy/>

The Committee began its work by reviewing existing Policy 3.2.1 (Mandatory Listing of Potential Recipients) (*Now Policy 3.4.C (Candidate Registrations)*), which requires all deceased donor organ recipients to be added to the waiting list prior to transplant.

The first step for adding any transplant candidate to the waiting list is UNetsm registration via Waitlistsm. The transplant program must complete all fields on the candidate registration form in order to add a candidate, however many of the fields are automatically populated with the hospital's listing defaults.

A poll of Committee members revealed that most transplant programs represented on the Committee already register their living donor transplant candidates in UNetsm prior to transplant. This anecdotal evidence was also supported by data (Table 1. Living Donor Recipient Waiting List Registration) in the Supporting Evidence section of this document, which reveals greater than ninety percent of living donor organ recipients are registered on the waiting list prior to transplant. Feedback from Committee members also suggested that the programs that register their candidates prior to surgery typically list their candidate as inactive or with stringent donor acceptance criteria, such as for only zero-mismatch offers, because the person's potential living donor has not yet been cleared for.

The Committee concluded that requiring living donor recipients to be registered on the waiting list, in addition to requiring living donors to be registered in UNetsm prior to surgery, could improve compliance with policies concerning verification of information at transplant and promote safety for both the living donor and living donor transplant candidate, while facilitating compliance with HIPAA.

The Committee identified numerous potential benefits associated with requiring living donor organ recipients to be registered in UNetsm prior to transplant. These include:

- Requiring double verification of the intended recipient's blood type in UNetsm before surgery;
- Standardizing transplant center practice for all transplant recipients, regardless of whether they receive a deceased donor or living donor organ;
- Providing a Waitlistsm ID as a unique recipient identifier for verification of information at transplant;
- Providing a Waitlistsm ID as a unique recipient identifier to help ensure anonymity of both the living donor and organ recipient when needed;
- Registering a potential living donor recipient could result in the candidate being offered a deceased donor organ (e.g., zero antigen mismatch) that may have better outcomes than the intended living donor's organ;
- Registering a potential living donor recipient could result in the candidate being offered a non-directed living donor organ through Policy 12.5.6 (Placement of Non-directed Living Donor Organs) (*Now Policy 14.7.B (Placement of Non-directed Living Donor Kidneys)*);
- Accruing waiting time if the living donor transplant does not occur, for candidates who meet the GFR/dialysis requirement to be on the waiting list; and
- Accruing waiting time if a living donor transplant results in immediate and permanent graft failure through Policy 3.2.4.2 (Waiting Time Reinstatement for Kidney Recipients) (*Now Policy 3.6.B.i (Non-function of a Transplanted Kidney)*).

- **Collaboration**

The Committee provided a draft of this proposal to the Kidney, Operations and Safety, Transplant Coordinators, and Transplant Administrators Committees during development and prior to the public comment period. The Kidney, Operations and Safety, and Transplant Coordinators Committees did not provide formal responses prior to this public comment period.

Some members of the Transplant Administrators Committee commented that the proposed policy would violate Policy 3.5.12 (Time of Waiting) (*Now Policy 8.3.A (The Point System for Expanded Criteria Donor Kidney Allocation)*) because some candidates would not meet the requirements for accruing waiting time. The committee determined that the proposal would not violate this policy. The Final Rule states that transplant hospitals should add individuals to the list “as soon as they are determined to be candidates for transplantation,” but there is no prescribed definition for determining who is suitable, and the decision to list a candidate for transplant is determined by the transplant hospital. Living donor transplant candidates can be listed preemptively and before requiring dialysis or having a glomerular filtration rate less than or equal to 20 ml/min, which is required to accrue waiting time points. Candidates who are listed preemptively can receive organ offers; however, they will be ranked low on the waiting list because they will not have accrued waiting time points.

- **Alternatives Considered**

The Committee considered a requirement to register all candidates for living donor organs by some specific time point prior to organ recovery or organ transplant.

Requiring registration prior to donor organ recovery would increase the safety of living donation by reducing the possibility of an unintended ABO mismatch and would match current CMS Conditions for Participation (48.92 (b) 2).

Ideally, candidates for living donor organs should be registered and added to the waiting list at least 10 business days prior to transplant to fulfill requirements in Policy 3.2.7 (Patient Notification) (*Now Policy 3.5 (Patient Notification)*). The Committee opined that such candidates should be registered in UNetsm as far in advance as possible, but it ultimately determined that the policy proposal should not mandate a timeline for completing the registrations.

- **Strengths and weaknesses:**

As proposed and if approved, the policy should help transplant hospitals show compliance with OPTN policies, while also avoiding HIPAA violations.

The proposed policy requirement would not lead to additional data collection or other additional work for the transplant program, as current policy mandates that all living donor organ recipients must be registered in UNetsm. Instead, under the proposal, the requirement for registration must be performed prior to transplant instead of after transplant.

The proposed policy requirement is not expected to increase fees paid to the OPTN or otherwise significantly increase hospital expenses. All living donor organ recipients are already required to pay a registration fee.

- **Description of intended and unintended consequences:**

As proposed, the policy should improve living donor and living donor candidate or recipient safety by:

- Requiring double verification of the intended recipient's blood type in UNetsm before surgery;
- Providing a Waitlistsm ID as a unique recipient identifier for verification of information at transplant;
- Providing a Waitlistsm ID as a unique recipient identifier to help ensure anonymity of both the living donor and organ recipient when needed

Adding a candidate to the waiting list while the living donor evaluation is still ongoing may result in the allocation of a deceased donor kidney to that candidate. This, in turn, may reduce the total number of deceased donor kidneys available for transplantation for those awaiting deceased donor organs.

Adding a candidate to the waiting list could increase the number of patient notification letters required under Policy 3.2.7 (Patient Notification) (*Now Policy 3.5 (Patient Notification)*). In 2012, 527 living kidney donor recipients (9.4%) were not registered in UNetsm prior to their transplant.

If a candidate does not want to consider accepting a deceased donor organ, the listing center should register the candidate in UNetsm prior to surgery and place the candidate in inactive status to exclude possible deceased donor organ allocation offers for the candidate.

Supporting Evidence and/or Modeling

In 2012, 527 living kidney donor recipients (9.4%) were not registered in UNetsm prior to transplant. During the same year, all living liver donor recipients were registered in UNetsm prior to transplant.

Table 1. Living Donor Recipient Wait List Registration at Transplant
 Recipients of Living Donor Kidneys and Livers
 January 1, 2001 – December 31, 2012

		Was Recipient on Waiting List at Transplant?				All	
		Not on Waiting List at Transplant		On Waiting List at Transplant			
		N	%	N	%	N	%
Transplanted organ	Year of Transplant						
Kidney	2001	2,585	42.8	3,460	57.2	6,045	100.0
	2002	2,501	40.1	3,740	59.9	6,241	100.0
	2003	2,494	38.5	3,976	61.5	6,470	100.0
	2004	2,253	33.9	4,394	66.1	6,647	100.0
	2005	1,966	29.9	4,606	70.1	6,572	100.0
	2006	1,692	26.3	4,743	73.7	6,435	100.0
	2007	1,417	23.4	4,626	76.6	6,043	100.0
	2008	1,108	18.6	4,860	81.4	5,968	100.0
	2009	1,002	15.7	5,385	84.3	6,387	100.0
	2010	810	12.9	5,467	87.1	6,277	100.0
	2011	616	10.7	5,154	89.3	5,770	100.0
	2012	527*	9.4	5,090	90.6	5,617	100.0
Liver	2001	38	7.3	486	92.7	524	100.0
	2002	8	2.2	355	97.8	363	100.0
	2003	9	2.8	313	97.2	322	100.0
	2004	6	1.9	317	98.1	323	100.0
	2005	2	0.6	321	99.4	323	100.0
	2006	3	1.0	285	99.0	288	100.0
	2007	7	2.6	259	97.4	266	100.0
	2008	7	2.8	242	97.2	249	100.0
	2009	1	0.5	218	99.5	219	100.0
	2010	1	0.4	281	99.6	282	100.0
	2011	0	0.0	247	100.0	247	100.0
	2012	0	0.0	246	100.0	246	100.0

*In 2012, there were 5617 recipients of living donor kidneys, and 527 of the recipients (9.4%) were not on the waiting list before their transplant. That same year, there were 88 programs that performed at least one living donor kidney transplant for a recipient who was not on the waiting list.

Based on OPTN data as of March 22, 2013; data subject to change based on future data submission or correction.

Expected Impact on Living Donors or Living Donation

The proposal is expected to improve the safety of living donation by improving the blood type verification process. Requiring all candidates to be registered prior to transplant requires two persons to separately and independently enter the candidate's blood type in UNetsm before transplant can occur.

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 HHS Program Goals and the OPTN/UNOS Strategic Plan Goals:

The proposal addresses the following HHS Program Goals:

- Patient Safety - by promoting safe, high-quality care for transplant candidates, transplant recipients, and living donors
- Operational Effectiveness - by identifying process and system improvements that best support critical network functions and working to disseminate them to all members who could benefit.

The proposal will address four of the OPTN/UNOS Strategic Plan Goals:

- Promote transplant patient safety by requiring double verification of the intended recipient's blood type in UNetsm before surgery and by accruing waiting time.
- Promote living donor safety by providing unique identifiers for verification of donor and recipient information.
- Promote the efficient management of the OPTN by standardizing transplant center practice for all transplant recipients, regardless of whether they receive a deceased donor or living donor organ.

The Committee's goals for these policy modifications meet provisions of the Final Rule as outlined in §121.5 Listing Requirements.

Plan for Evaluating the Proposal:

One year after policy implementation, the Committee will request a report on Living Donor Recipient Wait List Registration at Transplant to determine if all living donor transplant candidates were registered in UNetsm prior to transplant. Additionally, the Committee will consult UNOS staff to determine if there has been a reduction in violations involving Policies 3.1.2 (Transplant Center)

(Now Policy 5,5,A (Receiving and Accepting Organ Offers), 12.7.7 (Verification of Information Upon Receipt of Organ) (Now Policy 5.6 (Blood Type Verification upon Receipt)) and 12.7.9.1(Living Donor Organs that Remain in the Same Recovery Facility as the Intended Candidate) (Now Policy 16.1(Organs not Requiring Transport)).

Additional Data Collection:

This proposal would not require additional data collection.

Expected Implementation Plan:

Transplant hospital will be expected to register all transplant candidates before transplantation.

Communication and Education Plan:

The proposal would revise members' practices for a minority of living donor transplant candidates. While members' overall burden of work will not change while the benefits to patient safety may increase, and some members may need to change specific protocols to meet the policy's requirements. New work for members should be limited to an increase in the number of patient notification letters required under Policy 3.27 (Patient Notification) *(Now Policy 3.5 (Patient Notification))*. (In 2012, 527 living kidney donor recipients were not registered in UNetsm prior to their transplant).

Information about the new requirement would be included in an ongoing effort to provide educational programs to members regarding patient safety, with particular emphasis on practices at living donor transplant programs. The revised policy also would be incorporated into the OPTN Evaluation Plan, and education would accompany ongoing efforts to notify members of periodic updates to the plan.

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

- Policy notice
- System notice
- Member e-newsletter/member communications archive article

Compliance Monitoring:

This proposal will not change routine monitoring of living donor programs.

Policy Proposal:

RESOLVED, that Policy 3.4.C (Candidate Registration) is modified as set forth below, effective September 1, 2014.

Policy 3.4.C Candidate Registration

Recipients of deceased and living donor organs must be registered as candidates on the waiting list prior to their transplant.

Transplant programs must complete all candidate ~~additions~~ registrations, modifications, and removals in the waiting list.

Public Comment Responses:**1. Public Comment Distribution**

Date of distribution: 9/6/2013

Public comment end date: 12/6/2013

Public Comment Response Tally					
Type of Response	Response Total	In Favor	In Favor as Amended	Opposed	No Vote/ No Comment/ Did Not Consider
Individual	48	38 (92.6%)	0 (%)	3 (7.32%)	7
Regional	11	11(100%)	0 (%)	0 (%)	0
Committee	19	6(100%)	0 (%)	0 (%)	13

2. Primary Public Comment Concerns/Questions

There was limited concern that the proposal could reduce the number of living donors if candidates for living donor organs received and accepted a deceased donor organ offer after being placed on the waitlist and before their scheduled living donor transplant.

In response to these concerns, a new inactive reason was added to WaitlistSM effective 3/26/14. The new option 'Candidate for living donor transplant only', was added to the list of available inactive reason codes in Waitlist for temporarily inactive candidates. This information is captured under the Organ Information section of the Add and Edit Candidate Information pages. This change applies to all organ types.

3. Regional Public Comment Responses

Region	Meeting Date	Motion to Approve as Written	Approved as Amended (see below)	Meeting Format
1	9/30/2013	17-0-0		In person
2	10/25/2013	28-0-0		In person
3	12/6/2013	17-0-0		In person
4	12/6/2013	21-0-0		In person
5	12/12/2013	22-0-3		In person
6	10/04/2013	40-13-9		In person
7	11/22/2013	22-1-0		In person
8	12/06/2013	23-0-1		In person
9	10/23/2013	21-0-0		In person
10	10/18/2013	24-0-0		In person
11	12/6/2013	19-1-0		In person

Region 6: Although the region approved the proposal, the pediatric program opposed the change because they do not list their candidates prior to transplant when the candidate has a living donor. They are concerned that if they change their policy to list the candidates with living donors and there is a delay in the living donor evaluation, they will get pressure from families and physicians to accept a deceased donor kidney. There was also concern that listing the candidates will further decrease the number of living donor transplants for their pediatric recipients.

Committee Response:

The Living Donor Committee appreciates this response and will consider the region's comments. Effective 3/26/14, a new option will be added to the list of available Inactive Reason codes in Waitlist for Temporarily Inactive candidates. The new option will be 'Candidate for living donor transplant only' and will prevent all deceased donor organ offers.

4. Committee Public Comment Responses

Membership and Professional Standards Committee:

The Committee supported this proposal as written.

Committee Response:

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

Operations and Safety Committee:

The Operations and Safety Committee considered this proposal at their December 3, 2013 conference call meeting. One Committee member commented on how to list but yet respect the wishes of candidates, such as pediatric ones, not wanting deceased donor offers. It was shared that while these persons can be listed as a "7" currently, the Living Donor Committee is working to modify the system to allow registration for living donor organs only. It is hoped that this option will be available before this proposal goes before the OPTN/UNOS Board of Directors.

One Committee member mentioned considering other impacts such as selection criteria (e.g. age) if protocols differ between deceased and living transplant programs and awareness that other requirements, such as patient notifications, will now apply to living donors. An anecdote was shared where a deceased donor offer was accepted instead of the planned living donor, yet the organ quality may not have been the same. This highlighted the need to think through all possible consequences and operational changes while recognizing the overall benefits from the proposal.

The Committee voted to support this proposal (12 in favor, 0 opposed, 0 abstentions)

Committee Response: The Living Donor Committee appreciates this response. Effective 3/26/14, a new option will be added to the list of available Inactive Reason codes in Waitlist for Temporarily Inactive candidates. The new option will be "Candidate for living donor transplant only" and will prevent all deceased donor organ offers.

Pediatric Transplantation Committee:

Along with a request that the Living Donor Committee analyze this policy's impact on living donation in pediatric patients throughout the post-implementation evaluation of this proposal, the

Committee supported a motion to approve the proposal as written (10- support, 1- oppose, 0- abstentions).

Some Committee members were concerned that this proposal may yield decreased living donation in children. Ultimately, the Committee agreed that these proposed policies would yield safer living donor transplants and that its concerns about decreased living donation in children cannot necessarily be supported with data at this time. Stemming from those concerns, the Committee suggested additional guidance regarding best practices for framing the discussion of living donation transplants versus deceased donation transplants would be helpful for transplant providers.

Committee Response:

The Living Donor Committee appreciates this response and the support for the policy proposal. The Committee will consider the recommendations from the Pediatric Transplantation Committee.

Effective 3/26/14, a new option will be added to the list of available Inactive Reason codes in Waitlist for Temporarily Inactive candidates. The new option will be “Candidate for living donor transplant only” and will prevent all deceased donor organ offers.

Policy Oversight Committee (POC):

Committee Response:

The POC reviewed the proposal pre public comment.

Thoracic Organ Transplantation Committee:

The Committee did not voice concerns or questions about the proposed policy, and voted in favor of it.

Transplant Administrators Committee:

The Committee voted unanimously in support of a motion to approve the proposal as written (15 support, 0 oppose, 0 abstentions).

Committee Response:

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

Transplant Coordinators Committee:

The Committee voted in support of the proposal (Support 14, Oppose 0, Abstain, 1). The following issues were addressed:

- There is a misconception that if a candidate isn’t registered then you don’t pay the fee, but you do.
- The fee will be the same as for those listed on the deceased donor list.
- The timeframe to register a candidate will be left up to the transplant center.
- The center pays the fee to register a candidate.

Committee Response:

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

5. Individual Public Comment Responses

Comment 1:

vote: Oppose

Date Posted: 09/06/2013

A recipient who is fortunate enough to have a living donor should not be forced to list for a deceased organ, nor should the center be required to undergo the effort to list such a patient if that patient clearly has no intent to accept a deceased donor organ should one be offered.

Committee Response:

The background material of the proposal explains that the proposal will improve patient safety by improving the ABO verification process for living donors and their organ recipients. Most centers already register their living donor transplant candidates prior to transplant. Centers will have the option of inactivating the candidate in UNetsm and excluding any deceased donor organ offers by selecting “candidate for living donor transplant only”

Comment 2:

vote: Oppose

Date Posted: 09/06/2013

We are strongly opposed to this proposed requirement. It will discourage altruistic living donation, and likely result in the deaths of many patients.

Committee Response:

The background material of the proposal explains that the proposal will improve patient safety by improving the ABO verification process for living donors and their organ recipients. There is no evidence that the proposal would discourage altruistic living donation or result in patient deaths. Most centers already register the living donor transplant candidates prior to transplant. Centers will have the option of inactivating the candidate in UNetsm and excluding any deceased donor organ offers by selecting “candidate for living donor transplant only.”

Comment 3:

vote: Support

Date Posted: 10/18/2013

At MCV Hospitals starting Jan 1998, Region 11 Directors were informed in writing and at Liver Program Directors meeting that all Living donor liver Recipients would be activated on UNOS liver list before initiating liver donor evaluation completion to ensure that there would be no controversy on equity for a liver in Region 11 in case rescue with a Deceased donor (DDLTL) was needed and to ensure that appropriateness of listing followed the Norm for DDLTL. This holds true for living kidney donors and the LDLTL practice at VCU has been a >100 fold positive factor for providing deceased donor organs back to the regions recipients who are not blessed with having a living organ donor.

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

Comment 4:*vote: Support**Date Posted: 09/10/2013*

I agree with the proposal that waitlisting donors prior to donation will improve ABO verification prior to the procedure.

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

Comment 5:*vote: Support**Date Posted: 09/16/2013*

I strongly support this proposal, and hope that leads to mandatory lifetime followup of all living donors and living donor candidates, past, present, and future, among minimum standards for transplant centers.

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

Comment 6:*vote: Support**Date Posted: 12/06/2013*

NATCO supports this proposal as written.

Committee Response: The Living Donor Committee appreciates NATCO's response and the organization's support for the proposal.

Comment 7:*vote: Support**Date Posted: 11/30/2013*

The American Nephrology Nurses' Association supports this proposal without revisions.

Committee Response: The Living Donor Committee appreciates this response from the American Nephrology Nurse's Association and the organization's support for the proposal.

Comment 8:*vote: Support**Date Posted: 12/04/2013*

The National Kidney Foundation supports the proposal to require living donor transplant candidates to be added to the waiting list prior to the transplant. In addition to the benefits discussed in this policy proposal, the proposal allows candidates to accrue time on the waiting list, which is important in case the living donation is unable to proceed. The proposal also enables living donor candidates to be considered for zero antigen mismatch deceased donor organ and waiting time will also be reinstated in case of graft failure.

Committee Response: The Living Donor Committee appreciates this response from the National Kidney Foundation and the organization's support for the proposal.

Post Public Comment Consideration:

The Committee determined the proposal did not require modification based on public comment.

The original proposed policy language sent for public comment was modified to integrate it into the plain language policy rewrite approved by the Board in November 2013, and which took effect on February 1, 2013.

Proposal to Establish Minimum Requirements for Living Liver Donor Follow-up

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Proposal to Establish Minimum Requirements for Living Liver Donor Follow-up**Living Donor Committee****Summary and Goals of the Proposal:**

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

Background and Significance of the Proposal:

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

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

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

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

In September 2007, the Committee sponsored and the Board approved new bylaws which required transplant centers:

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

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

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

- Determine a minimum threshold for categorizing living donors as "lost to follow-up" on LDF forms;
- Strengthen reporting requirements so that 6 month, one-year, and two-year LDF forms are submitted at appropriate times; and
- Commit to an annual review of the status of LD follow-up.

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

- Enforce a minimum standard for submission of complete LDF forms.
- Require, as prescribed in existing policies, that LDF forms must be submitted at six months, one year, and two years after donation, and that the data submitted reports reflect an accurate and up-to-date donor status.
- Investigate any living donor transplant program that categorizes more than 10 percent of its donors as "lost to follow-up."
- State that the absence of additional funding specific to living donor follow-up is not an acceptable excuse for failing to complete the follow-up forms. Transplant centers should consider living donor follow-up as a mandatory component after transplantation.
- Support educational efforts to improve living donor follow-up data submission.
- Support the concept that completion of LDF forms and categorizing donors "as lost to follow-up" will become a metric for evaluating living donor programs in the future.

In addition and concurrent with the work done by the Living Donor Committee, in June 2007, the OPTN/UNOS Board approved a resolution from the Policy Oversight Committee in support of this effort stating that, "Resolved, that a joint OPTN committee be established to evaluate the use of living donor data." As a result, the Living Donor Data Task Force (LDDTF) was established in late 2007. The LDDTF was asked to take an objective look at the various needs for living donor follow-up data and to propose an appropriate approach for each need. Final recommendations for consideration by the Board of Directors included the following:

- As currently collected, the OPTN data are incomplete beyond the point when the discharge form is submitted (up to six weeks post donation, but much earlier for most donors) and therefore useless making conclusions about living donor safety or related research.
- There exists strong support for the following:
 - 1) Using the OPTN data supplemented by data from the Social Security Death Master File (SSDMF) and the National Death Index (NDI) as the mechanism for tracking short- and long-term deaths.
 - 2) Requiring center reporting and completion of data through a limited time interval (discharge through 6-12 months), with the duration depending on whether funding is made available to the centers.

- 3) Developing a self-reporting mechanism for donors of a longer duration than that required of centers.

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

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

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

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

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

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

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

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

The Joint Societies Steering Committee formed a JSWG which previously provided recommendations for living kidney donor consent, medical evaluation, and follow-up policies. New policy requirements for living kidney donors follow-up were considered and approved by the OPTN/UNOS Board of Directors on November 12, 2012, and they became effective on February 1, 2013.

Similarly, for this proposal a Joint Societies Policy Steering Committee formed a JSWG to develop policy recommendations for living liver donor follow-up which met beginning August 7, 2012. This JSWG included four members of the Living Donor Committee.

The JSWG was directed to address:

- The level of specificity to be required in the OPTN/UNOS policy
- Specific policy provisions, differentiating between what would be required and what would be optional or recommended
- The evidence basis for each recommendation (which may consist of data in published literature, or generally accepted medical practice)
- How frequently the requirements should be reevaluated for currency
- Possible pertinent comments on cost implications for members, patients, OPTN/UNOS
- Identification of key policy components for assessing policy compliance by the members

The JSWG met by teleconference over several months and provided proposed recommendations for living liver donor policies to the leadership of the parent transplant societies (AST, ASTS, and NATCO) on December 1, 2012.

The leadership of the parent societies responded to the JSWG recommendations regarding the:

- Need clearly delineate between recommendations and policy requirements and to provide rationale for why some items are considered recommendations while others are proposed policy;
- Need to provide a mechanism for donors to “opt-out” of post donation follow-up;
- Need to address how abnormal lab results (e.g. false positive tests) may lead to additional diagnostic procedures with their attendant risks to the living liver donor.

The JSWG considered the feedback from the parent transplant societies and subsequently modified their living liver donor policy recommendations.

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 policy development.

After these preliminary recommendations were formally approved by two of the three parent societies (NATCO and ASTS), the Committee considered the policy recommendations in the development of these proposed policy requirements for the follow-up of living liver donors.

The Committee met by teleconference on June 18, 2013 to consider if this proposal should be considered for public comment. Several Committee members were concerned that the proposal would not require the reporting of living liver donor laboratory data at two years post-donation. After a lengthy discussion, the Committee ultimately supported sending the proposal for public comment.

- ***Collaboration:***

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

- ***Alternatives considered:***

The Committee supported the specific data elements for follow-up recommended by the JSWG.

The JSWG recommended against a requirement to report living liver donor laboratory data (total bilirubin, alanine aminotransferase, alkaline phosphatase and a platelet count) at two years post-donation. The final JSWG recommendations included:

- Complications, if any, following living liver donation are most likely to occur and be identified in the early phases of recovery. Therefore, obtaining clinical information and laboratory data through the 1 year follow-up time point is considered essential for optimal donor care.
- Abnormalities in liver function tests can be expected in up to 4% and 8% of asymptomatic non-donors¹ and liver donors, respectively, which are of uncertain significance. This may trigger additional diagnostic procedures with their attendant risks to the living liver donor.
- The recommended clinical and laboratory parameters are based on the best available published data to date and ..., are believed by the Work Group to be minimally necessary to monitor donor safety.

The opinions of Committee members were split regarding a requirement for the collection and reporting of living liver donor laboratory data at two years. Some members opined that although published literature may not support collection of living liver donor laboratory data at two years post-donation, not including a two-year reporting requirement might be viewed negatively during public comment. After a lengthy debate, the Committee ultimately supported the JSWG recommendation against requiring reporting living liver donor laboratory data at two years post-donation with agreement to reconsider the issue after public comment.

- ***Strengths and weaknesses***

There remains some opposition to requiring recovery centers to perform any living donor follow-up. Some members of the transplant community argue that short-term living donor follow-up is not useful, is an unfunded mandate, and that short-term follow-up cannot be obtained because donors do not want to participate in follow-up.

The proposal does not address living donor follow-up beyond two years post-donation.

The proposal would lead to the standardization of requirements for living liver donor follow-up. The proposed requirements for living liver donor follow-up are similar to existing policy requirements for living kidney donor follow-up.

The proposal does not address follow-up reporting for other types (e.g., lung, intestine, and pancreas) of living donors.

The proposal would require reporting of some clinical and laboratory data that cannot be captured on the Living Donor Follow-up (LDF) form, and those required elements could not be reported until the LDF form can be updated and related programming can be completed.

- ***Description of intended and unintended consequences:***

The proposal creates the need to eliminate existing OPTN policy requirements that liver recovery hospitals must develop, and once developed, must comply with written protocols for the submission of required follow-up forms at 6 months, one-year, and two-years post-donation. Under this proposal, this

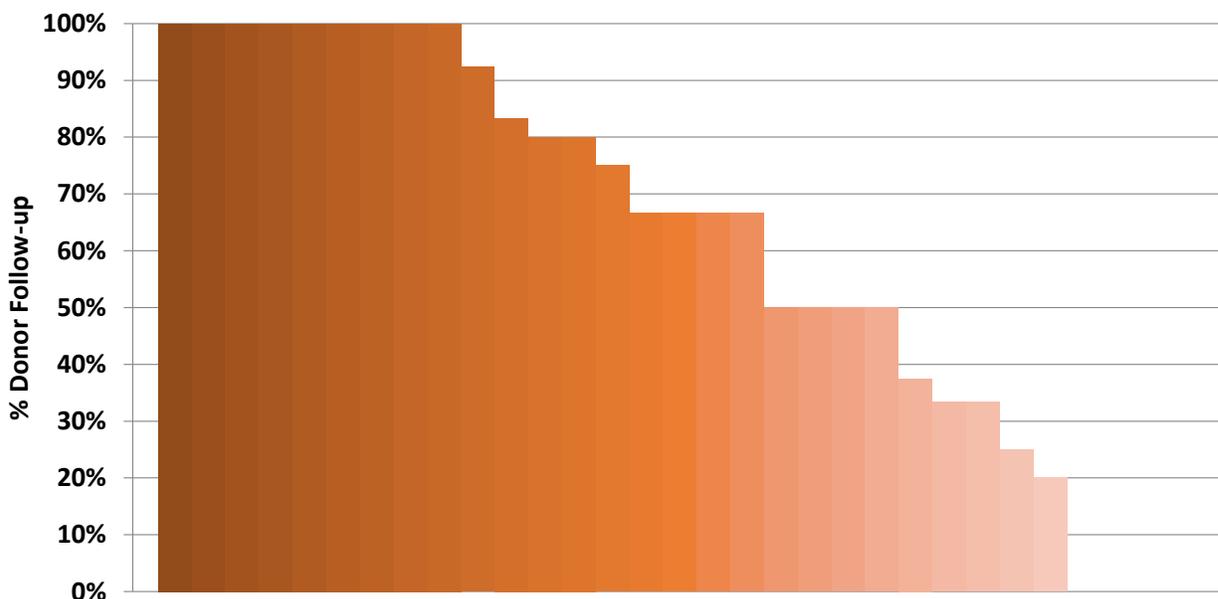
policy requirement would be superseded by new policy requirements for collecting specific living donor follow-up at required reporting intervals.

Supporting Evidence and/or Modeling:

**Table 1. Living Liver Donors in the US
January 1, 2005 – December 31, 2012**

Year of Donation	Transplanted Living Donor Livers
2005	323
2006	288
2007	266
2008	249
2009	219
2010	282
2011	247
2012	246
2013	252

Figure 1. Percent of Living Liver Donors with a 6-Month LDF with Timely and Complete Laboratory Data, by Program



Note: Each bar represents 1 program. Includes living liver donors who donated between 1/1/13 and 7/31/13. 4 programs (blank area on right side of graph) reported timely and complete lab values for 0% of their donors.

Data subject to change based on future data submission or correction.

Expected Impact on Living Donors or Living Donation

Living liver donors will be expected to participate in follow-up at required post-operative reporting periods (6, 12, and 24 months). Requiring transplant programs that recover living donor livers to report accurate and current follow-up information for at least 80% of their liver donors at the required reporting intervals should result in more complete and useful data on living donors.

Expected Impact on Specific Patient Populations

There should be no direct impact on the candidate pool. However, the proposal has the potential to affect all living liver donors. In 2012, there were 246 living liver donors. At least 80% of the liver donors at each program will need to be followed at the program or have their required follow-up reported back to the program for submission on the LDF form.

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

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

Plan for Evaluating the Proposal:

- ***What questions or hypotheses are guiding the evaluation of the proposal?***

Will overall living donor follow-up reporting improve if programs are required to report accurate and current follow-up information on 80% of living liver donors at the required reporting intervals?

- ***Policy Performance Measures:***

The Committee will monitor the aggregate and center-specific percentage of follow-up.

- ***Time Line for Evaluation:***

Annually, for three years beginning 2015, the Committee will monitor the percentage of living liver donors at each recovery hospital for whom the required follow-up elements have been reported.

Additional Data Collection:

The proposal does not require immediate changes to the OPTN data collection system. However, several elements of the proposed required reporting cannot be captured on the current Living Donor Follow-up (LDF) form, including:

Loss of medical, health, or life insurance due to donation
 Platelet count
 Incisional hernia related to donation

Modification of the LDF and required related programming to facilitate reporting these elements is expected to be completed by March 2015, and would require new data collection after this date.

Expected Implementation Plan:

Living donor recovery hospitals will continue to report living donor follow-up at six months, 1 year, and 2 years from the date of donation. If approved, the proposal would not require programming in UNetSM prior to implementation. However, several elements of the required reporting cannot be captured on the current Living Donor Follow-up (LDF) form. Modifying the LDF form to capture these additional elements at some point in the future would create a need for additional programming.

It may be helpful for living donor programs to understand the anticipated timeline for this policy proposal. If the policy proposal is approved by the Board in June 2014, the policy would be expected to take effect in September 2014. As proposed, the new reporting requirement would apply only to living liver donors who donate beginning in September 2014. For these donors, living donor recovery hospitals would first be required to report under the new requirements for living donor follow-up beginning in March 2015 (when the six-month LDF forms are due for donors who donated in September 2014). The first cohort of donors to be reviewed will include donors who donate between implementation (September 2014) and March 2015. The six-month LDFs for the last donor in this cohort will be due in September 2015. Transplant programs must submit LDFs to the OPTN within 60 days of form generation, so no program could be out of compliance with the new policy before May 2015.

Communication and Education Plan:

While the proposal would newly apply to hospitals performing living liver donor transplantation, its general scope is similar to previously enacted requirements for living kidney donor transplantation. Communication and education efforts would thus focus on the specific details of the new requirements and support members who may need to revise their individual protocols, including peer-based best practice recommendations.

Information about the new requirements would be included in an ongoing effort to provide educational instructional programs to members regarding patient safety, with particular emphasis on practices at living donor transplant programs. The revised policy also would be incorporated into the OPTN Evaluation Plan, and education would accompany ongoing efforts to notify members of periodic updates to the plan.

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

- Policy notice
- System notice
- UNOS Update article
- Member e-newsletter/member communications archive article
- Notification to a listserv group for transplant administrators

Compliance Monitoring:

At Living Donor recovery hospitals, site surveyors will review a sample of living liver donor medical records, and any material incorporated into the medical record by reference, to verify that data reported through UNetSM is consistent with source documentation, including the:

- Presence of supporting documentation in the donor chart for answers to each of the following:
 - Most recent donor status since [date of last follow-up form submission]
 - Working for income
- Presence of supporting documentation in the donor chart when any of the following are answered on the LDF:
 - Cause of death
 - If [not working for income], not working due to
- Presence of supporting documentation in the donor chart when any of the following are answered "yes" on the LDF:
 - Donor readmitted since last LDF form was submitted?
 - Liver complications
 - Loss of medical (health, life) insurance due to donation*
- The lab values entered on the LDF for
 - Alanine aminotransferase
 - Alkaline phosphatase
 - Total bilirubin
 - Platelet count*

- Review aggregate data derived from UNetSM to verify that the recovery hospital's submitted data met the required thresholds for:
 - Completeness
 - Timeliness of donor status and clinical information, based on the reported date last seen

At Living Donor recovery hospitals, site surveyors will also review a sample of living donor medical records, and any material incorporated into the medical record by reference, to verify that the recovery hospital's submitted data met the required thresholds for timeliness of liver laboratory data, by verifying that there is documentation that the following reported values were collected within 60 days before or after the form due date:

- Alanine aminotransferase
- Alkaline phosphatase
- Total bilirubin
- Platelet count*

Policy Proposal:

New Policy and Policy Modification

RESOLVED, that the following new or modified Policies 14.1.B (Required Protocols for Liver Recovery Hospitals), 18.1 (Data Submission Requirements), 18.2 (Timely Collection of Data), 18.5 (Living Donor), 18.5.A (Reporting Requirements after Donation), 18.5.B (Reporting Requirements after Living Liver Donation), 18.5.B (Submission of Living Donor Death and Organ Failure), 18.5.C (Reporting of Non-transplanted Living Donor Organs), and 18.5.D (Reporting of Living Donor Organs Not Transplanted in the Intended Recipient) as set forth below is effective September 1, 2014.

As set forth in line 29 below, is effective immediately and will be reinstated effective pending programming and notice to OPTN membership.

FURTHER RESOLVED, that the following modification to Policy 18.5.A (Reporting Requirements after Donation), as set forth in line 30 below, is effective immediately.

14.1.B Required Protocols for Liver Recovery Hospitals

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

Liver recovery hospitals must document that all phases of the living donation process were performed in adherence to the hospital's protocols.

18.1 Data Submission Requirements

OPOs must provide donor information required for organ placement to the OPTN Contractor in an electronic data format as defined and required by the computer system. Deceased donor information required for organ placement must be submitted prior to organ allocation.

Members must report data to the OPTN using standardized forms. *Table 18-1* shows the member responsible for submitting each data form and when the Member must submit the following materials to the OPTN Contractor.

Table 18-1: Data Submission Requirements

The following member:	Must submit the following materials to the OPTN Contractor:	Within:	For the following groups:
Histocompatibility Laboratory	<i>Donor histocompatibility (DHS)</i>	30-days after the OPO submits the deceased donor registration	For each donor typed by the laboratory
Histocompatibility Laboratory	<i>Recipient histocompatibility (RHS)</i>	<i>Either of the following:</i> <ul style="list-style-type: none"> • 30-days after the transplant hospital removes the candidate from the waiting list because of transplant • 30-days after the transplant hospital submits the <i>recipient feedback</i> 	For each transplant recipient typed by the laboratory
OPOs, all	<i>Death notification records (DNR)</i>	30-days after the end of the month in which a donor hospital reports a death to the OPO or the OPO identifies the death through a death record review	For all imminent neurological deaths and eligible deaths in its DSA
OPOs, all	<i>Monthly Donation Data Report: Reported Deaths</i>	30-days after the end of the month in which a donor hospital reports a death to the OPO	For all deaths reported by a hospital to the OPO
Allocating OPO	<i>Potential transplant recipient (PTR)</i>	30-days after the match run date by the OPO or the OPTN Contractor	For each deceased donor organ that is offered to a potential recipient

The following member:	Must submit the following materials to the OPTN Contractor:	Within:	For the following groups:
Host OPO	<i>Deceased donor feedback</i>	5 business days after the procurement date	
Host OPO	<i>Deceased donor registration (DDR)</i>	30 days after the <i>deceased donor feedback</i> form is submitted and disposition is reported for all organs	For all deceased donors and authorized but not recovered potential deceased donors

Recovery Hospitals	<i>Living donor feedback</i>	The time prior to donation surgery	For each potential living donor organ recovered at the hospital
Recovery Hospitals	<i>Living donor registration (LDR)</i>	60 days after the Recovery Hospital submits the <i>living donor feedback</i> form	For each living donor organ recovered at the hospital
Recovery Hospitals	<i>Living donor follow-up (LDF)</i>	See Policy 18.5.A: Reporting Requirements after Donation 60 days after the six-month, 1- year, and 2-year anniversary of the donation date	For each living donor organ recovered at the hospital
Transplant hospitals	<i>Organ specific transplant recipient follow-up (TRF)</i>	1. 30-days after the six-month and annual anniversary of the transplant date until the recipient's death or graft failure 2. 14-days from notification of the recipient's death or graft failure	For each recipient followed by the hospital
Transplant hospitals	<i>Organ specific transplant recipient registration (TRR)</i>	60-days after transplant hospital submits the <i>recipient feedback</i> form	For each recipient transplanted by the hospital
Transplant hospitals	<i>Liver Post-Transplant Explant Pathology</i>	60-days after transplant hospital submits the <i>recipient feedback</i> form	For each liver recipient transplanted by the hospital
Transplant hospitals	<i>Recipient feedback</i>	24-hours after the transplant	For each recipient transplanted by the hospital
Transplant hospitals	<i>Recipient malignancy (PTM)</i>	30-days after the transplant hospital reports the malignancy on the <i>transplant recipient follow-up</i> form	For each recipient, with a reported malignancy, that is followed by the hospital

The following member:	Must submit the following materials to the OPTN Contractor:	Within:	For the following groups:
Transplant hospitals	<i>Transplant candidate registration (TCR)</i>	30-days after the transplant hospital registers the candidate on the waiting list	For each candidate on the waiting list or recipient transplanted by the hospital

18.2 Timely Collection of Data

Members must collect and submit timely information to the OPTN Contractor. Timely data on recipients and living donors is based on recipient or living donor status at a time as close as possible to the specified transplant event anniversary. *Table 18-2: Timely Data Collection* sets standards for when the member must collect the data from the patient.

Table 18-2: Timely Data Collection

Information is timely if this Member:	Collects this information for this form:	Within this time period:
Transplant hospital	<i>Organ specific transplant recipient registration (TRR)</i>	When the transplant recipient is discharged from the hospital or six-weeks following the transplant date, whichever is first
Recovery hospital	<i>Living donor registration (LDR)</i>	When the living donor is discharged from the hospital or six-weeks following the transplant date, whichever is first
Recovery hospital	<i>Living donor follow-up (LDF)</i>	within the 60-days prior to or after the form due date

18.5 Living Donor Data Submission Requirements

The follow up period for living donors will be a minimum of two years.

The OPTN Contractor will calculate follow-up rates will be calculated separately, and at least annually, for the submission of the six-month, one-year, and two-year LDF forms.

Living donor follow-up reporting requirements do not apply to any transplant recipient whose replaced or explanted organ is donated to another candidate.

18.5.A Reporting Requirements after Living Kidney Donation

The follow up period for living donors will be a minimum of two years.

The recovery hospital must report accurate, complete, and timely follow up data for donor status and clinical information using the LDF form for at least:

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

The recovery hospital must report accurate, complete, and timely follow up kidney laboratory data using the LDF form for at least:

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

Required kidney Donor Status and Clinical Information includes all of the following:

1. Patient status
2. Working for income, and if not working, reason for not working
3. Has the donor been readmitted since last LDR or LDF form was submitted?
4. Kidney complications
5. Maintenance dialysis
6. Donor developed hypertension requiring medication
7. Diabetes
8. Cause of death, if applicable and known

Required Kidney Laboratory Data includes all of the following:

1. Serum creatinine
2. Urine protein

The OPTN Contractor will calculate follow up rates separately, and at least annually, for the submission of the six-month, one-year, and two-year LDF forms.

18.5.B Reporting Requirements after Living Liver Donation

The recovery hospital must report accurate, complete, and timely follow-up data using the LDF form for living liver donors who donate after September 1, 2014, as follows:

1. Donor status and clinical information for 80% of their living liver donors.
2. Liver laboratory data for at least:
 - 75% of their living liver donors on the 6 month LDF
 - 70% of their living liver donors on the one year LDF

Required liver donor status and clinical information includes all of the following:

- Patient status
- Cause of death, if applicable and known
- Working for income, and if not working, reason for not working
- Loss of medical (health, life) insurance due to donation
- Hospital readmission since last LDR or LDF was submitted
- Liver complications, including the specific complications
 - Abscess
 - Bile leak
 - Hepatic resection
 - Incisional hernias due to donation surgery
 - Liver Failure
 - Registered on the liver candidate waiting list

Required liver laboratory data includes all of the following:

- Alanine aminotransferase
- Alkaline phosphatase
- Platelet count
- Total bilirubin

18.5.BC 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.CD 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.

18.5.DE 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.

Public Comment Responses:

1. Public Comment Distribution

Date of distribution: 09/06/2013

Public comment end date: 12/06/2013

Public Comment Response Tally					
Type of Response	Response Total	In Favor	In Favor as Amended	Opposed	No Vote/ No Comment/ Did Not Consider
Individual	47	35 (74.47%)	0(%)	4(8.51%)	8 (17.02%)
Regional	11	10 (91%)	1 (9%)	0 (%)	0
Committee	19	4(%)	0(%)	0 (%)	14*

*Several committee submitted comment but provide results of voting on the proposal.

2. Regional Public Comment Responses

Region	Meeting Date	Motion to Approve as Written	Approved as Amended (see below)	Meeting Format
1	9/30/13	18-0-0		In person
2	10/25/13	25-0-0		In person
3	12/6/13	17-0-0		In person
4	12/6/13	21-1-0		In person
5	12/12/13	18-3-7		In person
6	10/4/13	57-0-0		In person
7	11/22/13	7-9-2	20-0-2	In person
8	12/6/13	24-1-0		In person
9	10/23/13	22-0-0		In person
10	10/18/13	20-0-4		In person
11	12/6/13	19-1-0		In person

Region 5:

Members of the region were very concerned that the living donor committee has not conducted an analysis of the socio-economic distribution of donor follow-up rates. They discussed that several areas of Region 5 have a large lower income patient population. In these areas it is often a challenge to show the donor the value of taking a day off work (with no pay) or to seek out a primary care physician if they do not have one post donation. All centers agreed that 100% follow-up is the goal but that even the proposed goal is not obtainable in certain patient populations. Instituting this type of requirement could mean that centers will turn away donors that may be less likely to complete follow-up although the proposal does not correlate high reporting rates with better outcomes. Several centers requested that the living donor committee re-look at the post

donation follow-up “opt out” for donors. They are in agreement that this option would require a signature for the donor stating that they were opting out of post donation follow-up.

Committee Response: The Living Donor Committee appreciates this response. The required follow-up threshold under this proposal were recommended by a Joint Societies Work Group composed of representatives from AST, ASTS, and NATCO.

Under the proposed thresholds up to 20% of a programs living liver donors may elect not to participate or “opt out” of follow-up.

The Living Donor Committee previously developed a resource titled: Guidance for Developing and Implementing Procedures to Collect Post-Donation Follow-up Data form Living Donor (2013). The document has be offered to the primary transplant administrator at all living donor programs on two previous occasions and promoted in UNOS publications and through the Transplant Coordinators and Transplant Administrators Listservs on multiple occasions. The resource is available on the OPTN web site.

This resource was developed based on interviews with living donor programs already exceeding the thresholds for living donor follow-up that would be required under this proposal. The Committee interviewed a variety of programs, including both large and small volume programs and programs in urban and rural setting. This research did not specifically consider if socio-economics might influence rates of follow-up, but could be investigated in the future. Living donor transplant programs can use this resource as a “toolbox” when developing or modifying protocols for follow-up with their living donors. The toolbox may be useful for LDF data collection specifically as well as for general issues of maintaining contact with donors after donation.

Region 7:

Amendment: That the question “working for income” be stricken from the required fields.

The region was very supportive of requiring a threshold for follow-up and overall felt that 80% is low. They were concerned that what the threshold does not take into consideration the distinct difference between programs who have 90% of their information on 75% of their forms and those that 20% of the information on 75% of the forms. They felt that the current proposal does not provide a mechanism for those higher % centers to receive that “credit”.

The region requested that the entire form (not just the required elements) be reviewed by the LDC since many of the current questions do not have significant value to LD outcome research. Centers should only be focusing their energy on completing and submitting elements that are of importance to the transplant community.

Committee Response:

The Living Donor Committee appreciates this response. The required follow-up threshold under this proposal were recommended by a Joint Societies Work Group composed of representatives from AST, ASTS, and NATCO.

The Living Donor Follow-up (LDF) form is an OMB (Office Management and Budget) form. Any changes to the form would require OMB approval so the question regarding working for income cannot arbitrarily be removed from the form. The Committee agrees that the LDF forms need

updating and will propose changes to the LDF form through the public comment process during the future.

Region 10:

The region commented that they felt that 80% was a very low threshold. They requested that the committee consider starting the requirement at 80% with a plan to escalate the threshold over time.

Committee Response:

The Living Donor Committee appreciates this response and will consider the Region's comments.

3. Committee Public Comment Responses

Liver and Intestinal Organ Transplantation Committee:

Committee members asked about the thresholds for follow-up and reimbursement for follow-up laboratory values. The thresholds were recommended by the JSWG-L, and are less stringent than those in place for kidney, in that no laboratory values are required after one year. This recommendation was based on the fact that donation-related complications for liver primarily occur in the early post-donation period. The proposed policy does not include any provisions for payment or reimbursement, but would not require patients to report to the center in order to obtain the laboratory values. Concerns that some donors may not be able to afford or wish to comply with follow-up laboratory tests were expressed. The proposal does not include a provision for "good faith attempts" at follow-up, although this was discussed within the JSWG-L. The ASTS Living Donor Committee is developing a set of tips to help centers comply with these policies. The Committee will need to collaborate with the Living Donor Committee and the Membership and Professional Standards Committee (MPSC) as the policies are finalized and implemented.

Committee Response: The Living Donor Committee appreciates this response. As noted in the Liver Committee response the proposed required follow-up threshold under this proposal were recommended by a Joint Societies Work Group composed of representatives from AST, ASTS, and NATCO and would allow for 20% of a center's living liver donors not to participate in follow-up and therefore provides leeway for "good faith attempts" and for liver living donors who may initially commit to participate in follow-up but later fail to do so.

The Living Donor Committee developed a resource titled: Guidance for Developing and Implementing Procedures to Collect Post-Donation Follow-up Data form Living Donor (2013). The document has been offered to the primary transplant administrator at all living donor programs on two previous occasions and promoted in UNOS publications and through the Transplant Coordinators and Transplant Administrators Listservs on multiple occasions. The resource is available on the OPTN web site.

This resource was developed based on interviews with living donor programs already exceeding the thresholds for living donor follow-up that would be required under this proposal. Living donor transplant programs can use this resource as a "toolbox" when developing or modifying protocols for follow-up with their living donors. The toolbox may be useful for LDF data collection specifically as well as for general issues of maintaining contact with donors after donation. Based on this research many living donor recovery hospitals cover all costs associated with donor follow-up to encourage follow-up.

Membership and Professional Standards Committee:

The MPSC agreed that the proposal to amend the bylaws was acceptable. They did ask if the question regarding the living donor's working status was still relevant since their pre-donation work status is unknown? Dr. Thomas indicated he would take that comment back to Living Donor Committee since the field is on current form.

Committee Response:

The Living Donor Committee appreciates the MPSC's review of the proposal. The donor's pre-donation work status should be determined based on the psychosocial evaluation and requirement to provide an independent donor advocate.

Minority Affairs Committee:

Following brief review and discussion of the proposal, the committee did not identify an inherent minority impact resulting from the proposal. It was noted; however, that the proposal had the potential to make living donor follow up requirements comparable to the kidney donor follow up requirements. Payment for follow up was still identified as an area of concern since living donors traveling from out of the state and out of the country to donate are often members of minority groups.

Operations and Safety Committee:

The Operations and Safety Committee considered this proposal at their December 3, 2013 teleconference meeting. One question was raised regarding how much of the data being requested was on the current follow-up form. The response was that all required data elements in the proposal are on the current form with one exception, loss of insurance due to donation. This field will not be required until the form is updated.

The Committee voted to support this proposal (12 in favor, 0 opposed, 0 abstentions)

Committee Response: The Living Donor Committee appreciates this response. There is a new problem with this proposal that was not identified until the post public comment period. In addition to the Living Donor Follow-up (LDF) form not containing a field for reporting loss of insurance due to donation, the form also does not contain a field for reporting the platelet count. Incisional hernia related to donation would be required reporting under the proposal and it could be reported as an "other" complication on the LDF form but a specific field for this required element would be preferable.

A plan to add the loss of insurance question to the LDF form has been formulated. That plan has now been modified to also address adding fields for collecting the platelet count and incisional hernias related to donation. If this proposal is approved by the OTPN/UNOS Board it would only apply to living liver donors who donate after September 1, 2014 and six month follow-up forms for those donors would not be due until March 2015. Any changes to the LDF form will require OMB approval. The timeline for revising the LDF form and the associated IT programming has yet to be determined. Reporting platelet count and incisional hernias related to donation will not be required until the LDF form can be updated to capture this information.

Pediatric Transplantation Committee:

The Committee voted unanimously in support of a motion to approve the proposal as written (11 support, 0 oppose, 0 abstentions). Additionally, the Committee stated that the required follow-up labs in this proposal are not very sensitive measures and it was curious what the OPTN intend to

monitor with these data. The Committee recommended additional member guidance be provided regarding what these lab data are intended to measure, what transplant programs doing living liver donor follow-up should be considering when analyzing these results, and what these transplants programs should do in response to irregular or unexpected living liver donor follow-up lab results.

Committee Response:

The Living Donor Committee appreciates this response and will consider the Pediatric Committee's recommendations.

The OPTN will monitor new required follow-up labs to help determine the short-term risk of living liver donation.

The Living Donor Committee previously proposed developing a resource which would provide guidance to transplant programs regarding abnormal lab results during living donor follow-up, however that project was not approved.

Thoracic Organ Transplantation Committee:

One member raised a question regarding the cost involved in following up with donors that are not "in the care" of the hospital any longer. However, the Committee noted it seems unethical to imply that the hospital does not care about the donor after they have donated. By performing living donor transplants, the hospital therefore takes on the responsibility of following up with donors. A committee member also asked about the challenges of hospital compliance versus patient compliance with follow-up policies. The Committee noted that due to this persistent problem, the Living Donor Committee did not require one-hundred percent compliance with living donor follow-up. Rather, the hospital must meet a threshold, and can provide rationale for not being able to follow up with certain donors. Lastly, a Committee member asked whether there was a way to determine the cause of death for a donor. If the living donor dies within the two-year window post-transplant, the hospital must report how the donor died.

After discussion, the Committee voted in favor of the proposal: 20-supported; 0-opposed; and 0-abstained.

Committee Response: The Living Donor Committee appreciates this response.

As noted in the this response the proposed required follow-up threshold under this proposal were recommended by a Joint Societies Work Group composed of representatives from AST, ASTS, and NATCO and would allow for 20% of a center's living liver donors not to participate in follow-up and therefore provides leeway for "good faith attempts" and for liver living donors who may initially commit to participate in follow-up but later fail to do so.

The Living Donor Committee developed a resource titled: Guidance for Developing and Implementing Procedures to Collect Post-Donation Follow-up Data form Living Donor (2013). The document has be offered to the primary transplant administrator at all living donor programs on two previous occasions and promoted in UNOS publications and through the Transplant Coordinators and Transplant Administrators Listservs on multiple occasions. The resource is available on the OPTN web site.

This resource was developed based on interviews with living donor programs already exceeding the thresholds for living donor follow-up that would be required under this proposal. Living donor transplant programs can use this resource as a "toolbox" when developing or modifying

protocols for follow-up with their living donors. The toolbox may be useful for LDF data collection specifically as well as for general issues of maintaining contact with donors after donation. Based on this research many living donor recovery hospital cover all costs associated with donor follow-up to encourage follow-up.

Per policy, the recovery hospital is only required to report a living donor death during the first two years post donation if the hospital becomes aware of the donor death.

Transplant Administrators Committee:

The Committee voted unanimously in support of a motion to approve the proposal as written (15 support, 0 oppose, 0 abstentions).

Committee Response:

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

Transplant Coordinators Committee:

The Committee discussed the proposal and had a split vote (Support 5: Oppose 5: Abstain 5). Issues that were addressed included:

- If a center is not compliant, there is uncertainty at the current time if this will be considered by the MPSC. It will most likely be based on how many programs are not compliant. The LDC will not be involved in that decision.
- This proposal will establish thresholds at 75%. Currently, you can submit blank forms and be compliant under current policy. These are recommendations taken directly from the Joint Society Working Group.
- Research is in the process of automating the ability for programs to determine their compliance. Program Specific Reports are expected for living donor programs to report follow up rates. The SRTR is finalizing the content and complication rate but haven't decided what will be included; however, the goal is to have something prepared in March or June for programs to provide feedback.
- The thresholds for kidney are not higher than for liver.
- The liver committee takes the position that priority points are going to be designated because livers are allocated according to urgency. The Liver Committee prefers to use the regional review board process to determine if you move up the list if you donate a segment of your liver.

Committee Response:

The Living Donor Committee appreciates the Transplant Coordinator's Committee review of the proposal.

4. Individual Public Comment Responses

Comment 1:

vote: Oppose

Date Posted: 09/11/2013

This policy, as written, will present many challenges for the transplant centers who will be required to complete this follow-up. With changes in health care reform and donors traveling long distances, it will be out of the control of transplant centers to ensure routine follow-up. We would recommend that the committee consider a self-reported system that would include routine surveys being sent directly to donors from UNOS inquiring about current healthcare status. This may require additional demographic information (email addresses) that is collected at time of Living Donor registration.

Committee Response: The proposed threshold for follow-up in the proposal area based on recommendations from a Joint Societies Work Group comprised of representatives from NATCO, AST, and ASTS, and under the proposal up to 20% of a recovery hospitals living liver donor will not need to receive or participate in follow-up.

The Living Donor Committee previously developed a resource titled: Guidance for Developing and Implementing Procedures to Collect Post-Donation Follow-up Data form Living Donor (2013). The document has be offered to the primary transplant administrator at all living donor programs on two previous occasions and promoted in UNOS publications and through the Transplant Coordinators and Transplant Administrators Listservs on multiple occasions. The resource is available on the OPTN web site, It was developed based on interviews with living donor programs already exceeding the thresholds for living donor follow-up that would be required under this proposal. Living donor transplant programs can use this resource as a “toolbox” when developing or modifying protocols for follow-up with their living donors. The toolbox may be useful for LDF data collection specifically as well as for general issues of maintaining contact with donors after donation.

Comment 2:

vote: Oppose

Date Posted: 09/06/2013

While I agree with follow-up for living donors to assess their progress there has to be some financial arrangement to be able to perform a minimum number of tests. I have met with my senior management, hospital compliance and even the hospital lawyer regarding the transplant program "paying for the tests" and still there has not been a solution. Some of my donors do not have any insurance coverage and even if they did they will surely be co-pays etc. for the testing. Also, in my experience, some donors simply do not wish to have follow-up and calling writing doesn't seem to make any difference. So, it seems rather punitive to me to ask the transplant programs to cover this financially and then be "blamed" if they cannot get the donors to respond. Have a national policy on number of times we contact them, write to them. Based on the number of donors annually, a letter from UNOS would also help the cause. But the financial has to be settled rather than expecting the transplant centers to cover the post donor expense. There also has to be better collaboration with CMS as both are federal agencies and UNOS and CMS should be working together rather than apart. So in summary, I am in favor of follow-up for donors post donation as we should take responsibility for the people who make this great sacrifice to make sure we truly "do no no harm". But do not expect the donors to pay for everything or the transplant programs once they have made their donation.

Committee Response: The proposal does not address who should be responsible for the cost of living donor follow-up.

The proposed threshold for follow-up in the proposal area based on recommendations from a Joint Societies Work Group comprised of representatives from NATCO, AST, and ASTS, and under the proposal up to 20% of a recovery hospitals living liver donor will not need to receive or participate in follow-up.

The Living Donor Committee previously developed a resource titled: Guidance for Developing and Implementing Procedures to Collect Post-Donation Follow-up Data form Living Donor (2013). The document has be offered to the primary transplant administrator at all living donor programs on two previous occasions and promoted in UNOS publications and through the Transplant Coordinators and Transplant Administrators Listservs on multiple occasions. The resource is available on the OPTN web site.

This resource was developed based on interviews with living donor programs already exceeding the thresholds for living donor follow-up that would be required under this proposal. Living donor transplant programs can use this resource as a “toolbox” when developing or modifying protocols for follow-up with their living donors. The toolbox may be useful for LDF data collection specifically as well as for general issues of maintaining contact with donors after donation.

Comment 3:

vote: Support

Date Posted: 09/17/2013

As the living liver donor policies begin their approval process, it has come to my attention that there are no provisions/definitions included to handle domino transplants (situations where a liver is transplanted into a recipient, whose own liver then goes to another recipient, usually in situations where underlying liver disease involves an enzyme defect). clearly these types of "donors" cant be followed as donors, since they will get a new liver with its own set of potential problems/complications/outcomes. Additionally, should these "donors" undergo medical evaluation and informed consent as for a standard living liver donor? may need to adjust current policy proposals, or develop new hybrid proposal to cover this situation.

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

The Committee is planning to propose clarifications to existing policy to address domino liver donation.

Comment 4:

vote: Support

Date Posted: 10/22/2013

Concerns about compliance with follow up by donor.

Committee Response: The Living Donor Committee appreciates this support for the proposal.

Comment 5:

vote: Support

Date Posted: 09/16/2013

I strongly support this proposal, and hope that this minimal first step, which is merely parity with the already approved minimum followup for living kidney donors, leads to mandatory lifetime

followup of all living donors and living donor candidates, past, present, and future, as a condition of remaining a transplant center.

Committee Response: The Living Donor Committee appreciates this support for the proposal.

Comment 6:

vote: Support

Date Posted: 11/22/2013

I support the proposal but how does the cmt expect transplant centers to reliably track down these patients in order to get "meaningful" information?

Committee Response: The Living Donor Committee appreciates this support for the proposal.

The Living Donor Committee previously developed a resource titled: Guidance for Developing and Implementing Procedures to Collect Post-Donation Follow-up Data form Living Donor (2013). The document has be offered to the primary transplant administrator at all living donor programs on two previous occasions and promoted in UNOS publications and through the Transplant Coordinators and Transplant Administrators Listservs on multiple occasions. The resource is available on the OPTN web site.

This resource was developed based on interviews with living donor programs already exceeding the thresholds for living donor follow-up that would be required under this proposal. Living donor transplant programs can use this resource as a "toolbox" when developing or modifying protocols for follow-up with their living donors. The toolbox may be useful for LDF data collection specifically as well as for general issues of maintaining contact with donors after donation.

Comment 7:

vote: Support

Date Posted: 12/06/2013

NATCO supports this proposal as written.

Committee Response: The Living Donor Committee appreciates NATCO's response and the organization's support for the proposal.

Comment 8:

vote: Support

Date Posted: 12/05/2013

The National Kidney Foundation supports this proposal. However, we believe there should lifetime follow-up to collect data on the health status, including kidney function, of living kidney donors. While current evidence shows that living donation does not change life expectancy and does not appear to increase the risk of kidney failure, additional data collection on the long-term outcomes for living donors is needed. Some studies show that living donors may have an increased risk of developing high blood pressure. Lifetime follow-up and data collection on the health status of donors, including blood pressure, is helpful information that may be used in the future to inform potential living donors.

Committee Response: The Living Donor Committee appreciates NKF's response and the organization's support for the proposal. The Committee will consider the comments submitted.

Post Public Comment Consideration:

New policy requirements for living kidney donor follow-up were approved by the OPTN/UNOS Board of Directors on November 12, 2013, and became effective on February 1, 2014. These new requirements include reporting if the donor “loss of medical (health, life) insurance due to donation.” However, this element cannot be reported using the current LDF form and updates to the form to capture this element and related required programming are not expected to be complete until March 2015. In response, on April 9, 2014, the Executive Committee of the Board, approved removing this required data element from current policy until the LDF form and required programming is completed.

During this same meeting, the Executive Committee approved an additional change to living kidney donor follow-up policy. Prior to action by the Executive Committee, living kidney donor follow-up policy required living kidney donor recovery hospitals to report if a living *donor has been readmitted since the last LDF form was submitted*. Prior to modification to the policy if a living donor was readmitted between initial discharge and the first six months post donation it would not need to be reported because policy only requires reporting since the last LDF form was submitted.

The Executive Committee approved updated to policy to require the living kidney donor recovery hospital to report if a donor has been readmitted since the last *LDR* (submitted at discharge) *or LDF* (submitted at six months, one-year and two years post donation) was submitted to distinctly require reporting any readmission between discharge and the first six months post donation (see the Policy Notice from April 17, 2014 available at http://optn.transplant.hrsa.gov/ContentDocuments/Policy_Note_04-10-2014.pdf.)

These policy changes to living kidney donor follow-up are now reflected in the living liver donor follow-up policy proposal to be considered by the Board.

Post public comment changes included modifying the proposal to fix a problem with Policy 18.1 (Data Submission Requirements) inadvertently introduced during the plain language policy rewrite approved by the Board in November 2013.

Another post public comment change involved integrating the policy language into the new plain language version of policy (approved by the Board in November 2013 and effective February 1, 2014). A crosswalk reflecting all post public comment changes to the proposal is provided as **Appendix A**.

Appendix A

Language Sent for Public Comment	Plain Language Rewrite	Proposed Integration for Board Consideration																		
<p>12.8.3 Reporting Requirements</p> <p>Transplant centers that recover living donor organs must submit Living Donor Follow-up (LDF) forms for each living donor at six months, one year, and two years from the date of donation.</p> <p><u>Living donor follow-up data collected within 60 days of the six-month, one-year, and two-year anniversary of donation is considered timely.</u></p> <p><u>Follow-up rates will be calculated separately, and at least annually, for the submission of the six-month, one-year, and two-year LDF forms.</u></p>	<p>18.2 Timely Collection of Data Members must collect and submit timely information to the OPTN Contractor. Timely data on recipients is based on recipient status at a time as close as possible to the specified transplant event anniversary. <i>Table 18-2: Timely Data Collection</i> sets standards for when the member must collect the data from the patient.</p> <p>Table 18-2: Timely Data Collection</p> <table border="1" data-bbox="506 856 1016 1031"> <thead> <tr> <th data-bbox="506 856 695 1031">Information is timely if the Member</th> <th data-bbox="695 856 883 1031">Collects this information for this form:</th> <th data-bbox="883 856 1016 1031">Within this time period</th> </tr> </thead> <tbody> <tr> <td data-bbox="506 1062 695 1499">Transplant hospital</td> <td data-bbox="695 1062 883 1499"><i>Organ specific transplant recipient registration (TRR)</i></td> <td data-bbox="883 1062 1016 1499">When the transplant recipient is discharged from the hospital or six-weeks following the transplant date, whichever is first</td> </tr> <tr> <td data-bbox="506 1530 695 1898">Recovery hospital</td> <td data-bbox="695 1530 883 1898"><i>Living donor registration (LDR)</i></td> <td data-bbox="883 1530 1016 1898">When the living donor is discharged from the hospital or six-weeks following the transplant date,</td> </tr> </tbody> </table>	Information is timely if the Member	Collects this information for this form:	Within this time period	Transplant hospital	<i>Organ specific transplant recipient registration (TRR)</i>	When the transplant recipient is discharged from the hospital or six-weeks following the transplant date, whichever is first	Recovery hospital	<i>Living donor registration (LDR)</i>	When the living donor is discharged from the hospital or six-weeks following the transplant date,	<p>18.2 Timely Collection of Data Members must collect and submit timely information to the OPTN Contractor. Timely data on recipients <u>and living donors</u> is based on recipient <u>or living donor</u> status at a time as close as possible to the specified transplant event anniversary. <i>Table 18-2: Timely Data Collection</i> sets standards for when the member must collect the data from the patient.</p> <p>Table 18-2: Timely Data Collection</p> <table border="1" data-bbox="1045 848 1555 1022"> <thead> <tr> <th data-bbox="1045 848 1234 1022">Information is timely if the Member</th> <th data-bbox="1234 848 1422 1022">Collects this information for this form:</th> <th data-bbox="1422 848 1555 1022">Within this time period</th> </tr> </thead> <tbody> <tr> <td data-bbox="1045 1052 1234 1488">Transplant hospital</td> <td data-bbox="1234 1052 1422 1488"><i>Organ specific transplant recipient registration (TRR)</i></td> <td data-bbox="1422 1052 1555 1488">When the transplant recipient is discharged from the hospital or six-weeks following the transplant date, whichever is first</td> </tr> <tr> <td data-bbox="1045 1499 1234 1898">Recovery hospital</td> <td data-bbox="1234 1499 1422 1898"><i>Living donor registration (LDR)</i></td> <td data-bbox="1422 1499 1555 1898">When the living donor is discharged from the hospital or six-weeks following the transplant date,</td> </tr> </tbody> </table>	Information is timely if the Member	Collects this information for this form:	Within this time period	Transplant hospital	<i>Organ specific transplant recipient registration (TRR)</i>	When the transplant recipient is discharged from the hospital or six-weeks following the transplant date, whichever is first	Recovery hospital	<i>Living donor registration (LDR)</i>	When the living donor is discharged from the hospital or six-weeks following the transplant date,
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<p><u>12.8.3.1 Living Kidney Donor Reporting Requirements</u></p> <p>The transplant center must report accurate, complete, and timely follow-up data for Donor Status and Clinical Information using the Living Donor Follow-up (LDF) form for at least:</p>	<p>Recovery hospital <i>Living donor follow-up (LDF)</i> whichever is first within the 60-days prior to or after the form due</p> <p>18.5 Living Donor</p> <p>18.5.A Reporting Requirements after Donation</p> <p>The follow up period for living donors will be a minimum of two years.</p> <p>The recovery hospital must report accurate, complete, and timely follow up data for donor status and clinical information using the LDF form for at least:</p> <ul style="list-style-type: none"> • 60% of their living kidney donors who donate between February 1, 2013 and December 31, 2013 • 70% of their living kidney donors who donate between 	<p>Recovery hospital <i>Living donor follow-up (LDF)</i> whichever is first within the 60-days prior to or after the form due</p> <p>18.5 Living Donor <u>Data Submission Requirements</u></p> <p><u>The follow up period for living donors will be a minimum of two years.</u></p> <p><u>The OPTN Contractor will calculate Ffollow-up rates will be calculated separately, and at least annually, for the submission of the six-month, one-year, and two-year LDF forms.</u></p> <p><u>Living donor follow-up reporting requirements do not apply to any transplant recipient whose replaced or explanted organ is donated to another candidate.</u></p> <p>18.5.A Reporting Requirements after Living Kidney Donation</p> <p>The follow up period for living donors will be a minimum of two years.</p> <p>The recovery hospital must report accurate, complete, and timely follow up data for donor status and clinical information using the LDF form for at least:</p> <ul style="list-style-type: none"> • 60% of their living kidney donors who donate between February 1, 2013 and December 31, 2013
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<ul style="list-style-type: none"> • 60% of their living kidney donors who donate between February 1, 2013 and December 31, 2013 • 70% of their living kidney donors who donate between January 1, 2014 and December 31, 2014 • 80% of their living kidney donors who donate after December 31, 2014. <p>The transplant center must report accurate, complete, and timely follow-up Kidney Laboratory Data using the LDF form for at least:</p> <ul style="list-style-type: none"> • 50% of their living kidney donors who donate between February 1, 2013 and December 31, 2013 • 60% of their living kidney donors who donate between January 1, 2014 and December 31, 2014 • 70% of their living kidney donors who donate after December 31, 2014. <ul style="list-style-type: none"> • Donor Status and Clinical Information <ul style="list-style-type: none"> • Patient status • Cause of death, if applicable and known • Working for income, and if not working, reason for not working • Loss of medical (health, life) insurance due to donation • Has the donor been readmitted since last LDF 	<p>January 1, 2014 and December 31, 2014</p> <ul style="list-style-type: none"> • 80% of their living kidney donors who donate after December 31, 2014 <p>The recovery hospital must report accurate, complete, and timely follow up kidney laboratory data using the LDF form for at least:</p> <ul style="list-style-type: none"> • 50% of their living kidney donors who donate between February 1, 2013 and December 31, 2013 • 60% of their living kidney donors who donate between January 1, 2014 and December 31, 2014 • 70% of their living kidney donors who donate after December 31, 2014 <p>Donor Status and Clinical Information:</p> <ol style="list-style-type: none"> 1. Patient status 2. Working for income, and if not working, reason for not working 3. Loss of medical (health, life) insurance due to donation 4. Has the donor been readmitted since last LDF form was submitted? 5. Kidney complications 6. Maintenance dialysis 7. Donor developed hypertension requiring medication 8. Diabetes 9. Cause of death, if applicable and known <p>Kidney Laboratory Data:</p> <ol style="list-style-type: none"> 1. Serum creatinine 2. Urine protein <p>The OPTN Contractor will calculate follow up rates separately, and at least annually, for the submission of the six-</p>	<ul style="list-style-type: none"> • 70% of their living kidney donors who donate between January 1, 2014 and December 31, 2014 • 80% of their living kidney donors who donate after December 31, 2014 <p>The recovery hospital must report accurate, complete, and timely follow up kidney laboratory data using the LDF form for at least:</p> <ul style="list-style-type: none"> • 50% of their living kidney donors who donate between February 1, 2013 and December 31, 2013 • 60% of their living kidney donors who donate between January 1, 2014 and December 31, 2014 • 70% of their living kidney donors who donate after December 31, 2014 <p><u>Required kidney Donor Status and Clinical Information includes all of the following:</u></p> <ol style="list-style-type: none"> 1. Patient status 2. Working for income, and if not working, reason for not working 3. Loss of medical (health, life) insurance due to donation 4. Has the donor been readmitted since last <u>LDR</u> or LDF form was submitted? 5. Kidney complications 6. Maintenance dialysis 7. Donor developed hypertension requiring medication 8. Diabetes 9. Cause of death, if applicable and known <p><u>Required Kidney Laboratory Data includes all of the following:</u></p>
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<p>form was submitted?</p> <ul style="list-style-type: none"> • Kidney complications • Maintenance dialysis • Donor developed hypertension requiring medication • Diabetes <p>• Kidney Laboratory Data</p> <ul style="list-style-type: none"> • Serum creatinine • Urine protein <p>Living donor follow-up data collected within 60 days of the six-month, one-year, and two-year anniversary of donation is considered timely.</p> <p>Follow-up rates will be calculated separately, and at least annually, for the submission of the six-month, one-year, and two-year LDF forms.</p> <p><u>12.8.3.2 Living Liver Donor Reporting Requirements</u></p> <p><u>This subsection applies only to living liver donors who donate on or after September 1, 2014.</u></p> <p><u>The transplant center must report accurate, complete, and timely follow-up data for Donor Status and Clinical Information using the Living Donor Follow-up (LDF) form for at least 80% of their living liver donors.</u></p>	<p>month, one-year, and two-year LDF forms.</p>	<ol style="list-style-type: none"> 1. Serum creatinine 2. Urine protein <p>The OPTN Contractor will calculate follow up rates separately, and at least annually, for the submission of the six-month, one-year, and two-year LDF forms.</p> <p><u>18.5.B Reporting Requirements after Living Liver Donation</u></p> <p><u>The recovery hospital must report accurate, complete, and timely follow-up data using the LDF form for living liver donors who donate after September 1, 2014, as follows:</u></p> <ol style="list-style-type: none"> 3. <u>Donor status and clinical information for 80% of their living liver donors.</u> 4. <u>Liver laboratory data for at least:</u> <ul style="list-style-type: none"> • <u>75% of their living liver donors on the 6 month LDF</u> • <u>70% of their living liver donors on the one year LDF</u> <p><u>Required liver donor status and clinical information includes all of the following:</u></p> <ul style="list-style-type: none"> • <u>Patient status</u> • <u>Cause of death, if applicable and known</u> • <u>Working for income, and if not working, reason for not working</u> • <u>Loss of medical (health, life) insurance due to donation</u> • <u>Hospital readmission since last LDR or LDF was submitted</u> • <u>Liver complications, including the specific complications</u> <ul style="list-style-type: none"> ○ <u>Abscess</u> ○ <u>Bile leak</u> ○ <u>Hepatic resection</u> ○ <u>Incisional hernias due to donation surgery</u>
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<p><u>The transplant center must report accurate, complete, and timely follow-up Liver Laboratory Data using the LDF form for at least:</u></p> <ul style="list-style-type: none"> • <u>75% of their living liver donors on the 6 month follow-up form for donors</u> • <u>70% of their living liver donors on the one-year follow-up form for donors</u> <p><u>Donor Status and Clinical Information includes all of the following fields:</u></p> <ul style="list-style-type: none"> • <u>Patient status</u> • <u>Cause of death, if applicable and known</u> • <u>Working for income, and if not working, reason for not working</u> • <u>Loss of medical (health, life) insurance due to donation</u> • <u>Hospital readmission since last LDF was submitted</u> • <u>Liver Complication</u> <ul style="list-style-type: none"> ○ <u>Bile leak</u> ○ <u>Hepatic resection</u> ○ <u>Abscess</u> ○ <u>Liver failure</u> ○ <u>Registered on the liver candidate waiting list</u> ○ <u>Incisional hernia due to donation surgery</u> <p><u>Liver Laboratory Data includes all of the following fields:</u></p>	<p>14.1.B Required Protocols for Liver Recovery Hospitals Liver recovery hospitals must develop and comply with written protocols to address all phases of the living donation process.</p> <p>Specific protocols must include the evaluation, pre-operative, operative, and post-operative care, and submission of required follow up forms at 6 months, one-year, and two-years post-donation.</p> <p>Liver recovery hospitals must document that all phases of the living donation process were performed in adherence to the hospital’s protocols. This documentation must be maintained by the recovery hospital</p> <p>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:</p> <ol style="list-style-type: none"> 1. Promoting the best interests of the potential living donor 2. Advocating for the rights of the living donor 	<ul style="list-style-type: none"> ○ <u>Liver Failure</u> ○ <u>Registered on the liver candidate waiting list</u> <p><u>Required liver laboratory data includes all of the following:</u></p> <ul style="list-style-type: none"> • <u>Alanine aminotransferase</u> • <u>Alkaline phosphatase</u> • <u>Platelet count</u> • <u>Total bilirubin</u> <p>14.1.B Required Protocols for Liver Recovery Hospitals Liver recovery hospitals must develop and comply with written protocols to address all phases of the living donation process.</p> <p>Specific protocols must include the evaluation, pre-operative, operative, and post-operative care of the living liver donor, and submission of required follow up forms at 6 months, one-year, and two-years post-donation.</p> <p>Liver recovery hospitals must document that all phases of the living donation process were performed in adherence to the hospital’s protocols.</p> <p>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:</p> <ol style="list-style-type: none"> 1. Promoting the best interests of the potential living donor 2. Advocating for the rights of the living donor
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<ul style="list-style-type: none"> • <u>Total bilirubin</u> • <u>Alanine aminotransferase</u> • <u>Alkaline phosphatase</u> • <u>Platelet count</u> <p>12.11 Required Protocols for Liver Recovery Hospitals Liver recovery hospitals must demonstrate that they have the following protocols:</p> <p>(i) Living Donation Process: Liver recovery hospitals must develop, and once developed must comply with written protocols to address all phases of the living donation process. Specific protocols shall include the evaluation, pre-operative, operative, and post-operative care <u>of the living liver donor, and submission of required follow-up forms at 6 months, one year, and two year post donation.</u></p> <p>Liver recovery hospitals must document that all phases of the living donation process were performed in adherence to the center's protocol. This documentation must be maintained and made available upon request.</p>	<p>3. Assisting the potential donor in obtaining and understanding information about the:</p> <ol style="list-style-type: none"> a. Consent process b. Evaluation process c. Surgical procedure d. Benefit of follow up e. Need for follow up 	<p>3. Assisting the potential donor in obtaining and understanding information about the:</p> <ol style="list-style-type: none"> a. Consent process b. Evaluation process c. Surgical procedure d. Benefit of follow up e. Need for follow up
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<p>(ii) Independent Donor Advocate: Liver recovery hospitals must develop, and once developed, must comply with written protocols for the duties and responsibilities of the Independent Donor Advocate that include, but are not limited, to the following elements:</p> <p>(1) a description of the duties and primary responsibilities of the IDA to include procedures that ensure that the IDA:</p> <p>(a) promotes the best interests of the potential living donor;</p> <p>(b) advocates the rights of the living donor; and</p> <p>(c) assists the potential donor in obtaining and understanding information regarding the:</p> <ul style="list-style-type: none"> (i) consent process; (ii) evaluation process; (iii) surgical procedure; and (iv) benefit and need for follow-up. 		
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OPTN/UNOS Living Donor Committee
Meeting Summary
March 31, 2014
Chicago, Illinois

Christy Thomas, MB, FRCP, FASN, FAHA, Chair
Sandra Taler, MD, Vice Chair

Discussions of the full committee on March 31, 2014 are summarized below and will be reflected in the committee's next report to the OPTN/UNOS Board of Directors. Meeting summaries and reports to the Board are available at <http://optn.transplant.hrsa.gov>.

Committee Projects

1. Proposal to Require UNetsm Registration for all Living Donor Candidates Prior to Transplant

The Committee considered public comment received regarding this proposal. Based on public comment, the Committee did not modify the proposed policy language and supported sending the proposal for Board consideration.

2. Proposal to Establish Minimum Requirements for Living Liver Donor Follow-up discussed

The Committee considered public comment received regarding this proposal. The Committee approved minor changes to the proposed policy language and approved sending the proposal for Board consideration.

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

This policy proposal is currently distributed for public comment. The Committee reviewed a presentation providing an overview of the proposal that will be used at regional meetings.

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

This policy proposal is currently distributed for public comment. The Committee reviewed a presentation providing an overview of the proposal that will be used at regional meetings.

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

This proposal is currently distributed for public comment. The proposal is on the consent agenda for regional meetings.

Implemented Committee Projects

6. Brief Update on Living Kidney Donor Follow-up Policy

New policy requirements for living kidney donor follow-up took effect on February 1, 2013. The Committee heard a preliminary report on current living kidney donor follow-up rates.

Review of Public Comment Proposals

7. Proposal to Notify Patients Having an Extended Inactive Status

The Committee supported this proposal.

8. Proposal to Align OPTN Policies with the 2013 PHS Guidelines for Reducing Transmission of Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C (HCV) Through Solid Organ Transplantation

The Committee supported this proposal.

9. Proposal to Clarify Data Submission and Documentation Requirements

The Committee supported this proposal.

10. Proposal to Allow Non-Substantive Changes to the OPTN Policies and Bylaws

The Committee supported this proposal.

11. Proposed ABO Blood Type Determination, Reporting, and Verification Policy Modifications

The Committee could not reach consensus on this proposal and referred it back to subcommittee for consideration.

Other Significant Items

12. New Research – Former Living Kidney Donors who Develop ESRD: What we Need to Know

Drs. Lainie Ross and Richard Thistlewaite attended the Committee meeting and provided an overview of their current research with living kidney donors who have developed end stage kidney disease.

13. Emerging Data on ESRD after Living Kidney Donation: Implications for Informed Consent Policy

Dr. Krista Lentine provided an overview on new research revealing an increased risk of end stage kidney disease in living kidney donors.

14. Status of Committee Projects

The Committee Chair led a review of current and proposed Committee projects.

Upcoming Meeting(s)

- September 8, 2014 (Chicago, Illinois)