

OPTN/UNOS Policy Oversight Committee
Report to the Board of Directors
June 22-23, 2009
Richmond, VA

Summary

I. Action Items for Board Consideration

- None

II. Other Significant Items

- The Committee is using a new “Policy Development Scorecard” that is intended to provide a consistent framework for reviewing policies, and is aligned with the OPTN Strategic Goals and the Committee’s policy review charge (Item 1, Page 3).
- The Committee supports the Kidney and Liver Committee’s proposal to establish minimum listing criteria for simultaneous liver-kidney candidates (Item 2, Page 3).
- The Committee supports the Liver and Intestine Committee’s proposal to create regional distribution of livers for Status 1 candidates. (Item 3, Page 4).
- The Committee supports the Liver and Intestine Committee’s proposal to create regional distribution of livers for MELD/PELD candidates. (Item 4, Page 5).
- The Committee supports the Liver and Intestine Committee’s proposal to standardize MELD/PELD exceptions. (Item 5, Page 6).
- The Committee supports the Thoracic Committee’s proposal to add the factors “current bilirubin” and “change in bilirubin” to the lung allocation score (LAS) (Item 6, Page 6).
- The Committee supports the Living Donor Committee’s proposal to modify the high risk donor policy to protect confidential health information. (Item 7, Page 7)
- The Committee supports the Membership and Professional Standards Committee’s proposal to modify the OPTN/UNOS Bylaws to clarify the process for reporting changes in key personnel. (Item 8, Page 7)
- The Committee supports the OPO Committee’s proposal to clarify, reorganize, and update Policy 5.0 (Item 9, Page 8)
- The Committee reviewed recommendations from the Living Donor Data Task Force (Item 15, Page 12)

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Edward R. Garrity, M.D., MBA, Chair

This report represents the deliberations of the Policy Oversight Committee during its February 5, 2009 meeting.

1. Policy Review Scorecard. Prior to the review of the public comment proposals, the Committee was given an overview of the scorecard and the modifications made to questions #9 and #10, which were slightly modified based on input from the Committee during its initial use of the scorecard. The use of the scorecard was initiated in 2008 and forms the basis for feedback to the Board of Directors and sponsoring Committees. The scorecard is also intended to streamline the Committee's very complex work and to lend transparency to the policy-making process. It uses a modified Stapel Scale, which is a type of itemized rating scale that is used to measure how closely a proposal meets each goal. Proposals receive a score ranging from -3 to +3 for each category listed. The scorecard is an important tool to generate discussion as the Committee reviews the policies as they pertain to the various questions. It was also noted that the scorecard can still be considered as being in the "testing" phase.

Members were reminded of the Committee's charge with regard to policy review, which is to review existing and proposed policies to determine that policy goals (1) are objective and measurable; (2) further the mission, strategic plan and long term goals of the OPTN and HHS program goals; and (3) are scientifically based.

The process for scoring the proposals was modified in order to better facilitate the review of the proposals. During its initial use, the scores were submitted during the meeting in order to get the members familiar with the process. Prior to the February 5, 2009 meeting, scorecards and finalized public comment proposals were distributed to the Committee members and scores were compiled prior to the meeting. Additionally, following the review of the proposals, it was suggested that the questions could be split into two categories: (1) how the proposal addresses the strategic goals and program goals; and (2) how well the policy was developed.

Review of Proposals Circulated for Public Comment, February 2009 (Scores Provided in Table 1)

2. Proposed to listing requirements for simultaneous liver-kidney transplant candidates. This proposal would set minimum criteria for candidates listed for simultaneous liver-kidney (SLK) transplantation. The intent of this proposal is first to identify candidates who are unlikely to regain renal function following liver transplantation. Once identified, this proposal would provide priority for these candidates to receive a SLK transplant. The goal of this proposal is to improve patient and renal graft survival following SLK transplant and hopefully reduce the number of SLKs.

The proposal was based on recommendations from two consensus conferences where the transplant community discussed trends in simultaneous liver-kidney transplantation (SLK), including incidences and outcomes. It was noted that the number of SLK transplants have increased from 82 in 1995 to 400 in 2006, and has increased four fold since the implementation of MELD in 2002. The proposal

contains criteria for chronic renal failure, acute renal failure, and metabolic diseases. It also contains a safety net provision for those who qualified for SLK initially and for those who did not qualify for SLK initially. The main issue is the appropriateness of when a patient on the liver transplant waiting list truly needs a kidney transplant since a lot of times their hepatorenal syndrome will reverse and their kidney function will return to normal. A review of the data also showed that there is a wide variety of philosophies amongst the regions, and particularly certain centers about when an end-stage liver disease patient needs a kidney transplant.

The Committee used the scorecard to assess this policy and the proposal received an overall score of 16.4. The proposal received average score of greater than 2 in the following categories: Best use of donated organs, statement of the problem, and evidence.

Committee Vote: 8 in favor, 0 opposed, and 0 abstentions.

3. Proposal to create regional distribution of livers for Status 1 liver candidates. This proposal will create regional distribution of livers for Status 1 candidates by eliminating “local” from the allocation algorithm. The intent of this proposal is to increase broader distribution and provide greater access to organs. There is currently broader distribution for pediatric liver donors and combined liver-intestines as well as several regions that share for Status 1 candidates.

Liver allocation policy has always granted priority to those candidates in highest urgent need of a liver transplant. Changes implemented in August 2005 were designed to ensure that the priority assigned to Status 1 candidates is reserved for those candidates with the most immediate need for a liver transplant. These changes more stringently defined Status 1 (A and B) for adult and pediatric liver transplant candidates. With these definitions in place, the Liver Committee began to investigate broader geographic distribution for the sickest candidates as the next logical step in the evolution of the liver allocation policy. This is consistent with the OPTN Final Rule, which states that one of the goals of developing equitable allocation policy is to distribute “organs over as broad a geographic area as feasible.” The Committee has already modified the liver allocation policy to address this goal. Recent changes included distributing pediatric livers regionally, “Share 15” and broader distribution for combined liver-intestine candidates. Several regions (1, 9, and 10) have had alternative allocation systems with regional distribution for Status 1 candidates in place for years.

One Committee member noted that this proposal is interesting because there has always been such a disparity between some local and regional areas and the assumption that large transplant programs would take over smaller ones. However, a proposal like this seems to imply that this sort of thinking is going away and the transplant community is getting together to do what is right for the patients, not necessarily for the individual transplant centers.

There was concern raised because the data presented showed that there were 5 incidences where Status 1 candidates got better without a transplant. If there are livers more readily available there might be cases where a transplant occurred when the candidate’s condition might improve. This feedback will be provided to the Liver and Intestine Committee.

The Committee used the scorecard to assess this policy and the proposal received an overall score of 20.3. The proposal received average score of greater than 2.5 in the following categories: Best use of donated organs, geographic equity, and assessment.

Committee Vote: 8 in favor, 0 opposed, and 0 abstentions.

4. Proposal to create regional distribution of livers for MELD/PELD candidates. This proposal will create regional distribution of livers for MELD/PELD candidates by eliminating “local” from the allocation algorithm. The intent of this proposal is to increase broader sharing and provide greater access to organs. It is similar to the proposal to create regional distribution of livers for Status 1 candidates where the intent is to distribute “organs over as broad a geographic area as feasible.” It was noted that both of the regional distribution proposals apply to adult donors only because the Pediatric Committee has worked hard over the last few years to make changes to the pediatric donor algorithm. The Liver and Intestine Committee has been involved in a series of changes over the past 10-15 years and these proposals are seen as the next step. Past changes include MELD/PELD, Share 15, Region 8 Sharing for M/P 29. The Committee evaluated the initial data from Region 8 and noted that there was no data to support a threshold of 29 so they decided to go directly to a regional distribution for all MELD/PELD scores.

One issue raised by the Committee was the variability of lab results, especially for INR (International Normal Ratio) and creatinine which are part of the labs results used to calculate the MELD score. In a way, the wider distribution of livers might be based on lab differences, not patient differences. If the liver transplant community is going to wider sharing, it would be important to come up with uniform standards for lab testing. It was noted by the SRTR that these differences exist at the local level just as they do at the regional level, but the main difference will be that the recipient pool will be larger at a regional distribution level. It was noted that there has recently been a push for more standardized testing, especially within the nephrology community for the testing for creatinine. Studies have shown that the INR values have varied widely in the past but that everyone has gone to an international protocol for INR within the past couple of years.

It was noted that the Liver Committee has been looking at “net benefit” vs. “net benefit plus regional distribution” and the latter shows a lot more impact than net benefit alone. However, since a proposal for a net benefit type liver allocation system is probably several years away, the Committee thought this would be an appropriate first step.

The data presented showed there would be a slight decrease in liver transplants in 9 of the 11 regions under a regional distribution system. Additionally, there was some concern about the increased cold ischemia time and the potential for organ wastage and that the estimates for both seemed a little low. It was noted that the cold ischemia time was based on current data and estimates for local distribution, regional distribution, and national distribution. Current cold ischemia time for regional distribution is estimated to be about one hour more than local. There was a comment made that there is a difference in the importance of cold ischemia time for livers and kidneys as compared to thoracic organs. An important factor on the outcomes is the age of the organ. Also, if an organ gets sent to a center some distance away and they are unable to use the organ for that recipient, shipping it back will significantly increase the cold ischemia time. The Policy Oversight Committee felt that more discussion needs to occur as to what happens in that situation in order to avoid organ wastage.

The Policy Oversight Committee has the following concerns:

- The data showing the predicted reduction in transplants in 9 of the 11 regions
- The variability in lab results (creatinine and INR)
- The merging of policy language if both regional distribution proposals (Status 1 and MELD/PELD) get approved
- The potential increase in cold ischemia time and organ wastage

The Committee used the scorecard to assess this policy and the proposal received an overall score of 19.2. The proposal received average score of greater than 2.3 in the following categories: Best use of donated organs, geographic equity, assessment, patient impact, and degree of criticality.

Committee Vote: 6 in favor, 2 opposed, and 0 abstentions.

5. Proposal to standardize MELD/PELD exception scores. This proposal will establish standard MELD/PELD Exception scores for certain diagnoses that will be used across all eleven UNOS regions. The purpose of this proposal is to provide more consistency in exceptional scores given to liver transplant candidates with the following diagnoses: Cholangiocarcinoma, Cystic Fibrosis, Familial Amyloid Polyneuropathy (FAP), Hepatopulmonary Syndrome, Portopulmonary Syndrome, and Primary Hyperoxaluria.

The MELD/PELD score is an estimate of a candidate's likelihood of dying on the waiting list within three months if they did not receive a transplant. The calculated lab score may not reflect some candidates' need for a transplant therefore transplant centers can request additional MELD/PELD exception points through the Regional Review Boards (RRBs). In 2006, members of the liver transplant community held a consensus conference¹ to further discuss 17 diagnoses and make recommendations for standardized criteria and exception points. The Liver and Intestine Committee formed a subcommittee in 2007 to review the recommendations from the conference and evaluate which diagnoses could be given standardized MELD/PELD scores without prospective RRB review.

There was concern about what a 10% increase means and it was noted that it is a 10% increase in mortality risk, not a 10% increase in the MELD/PELD score. For example, a 15% mortality risk translates to a MELD score of 22 and a 10% increase in mortality risk (25%) would increase the MELD score to 25. It was noted that this clarification could be added to the policy language prior to going to the Board for approval.

For cholangiocarcinoma, transplant centers will be required to submit a written protocol to the Liver and Intestine Committee for approval before they can submit an exception application for automatic approval. There was a concern about the burden on the Liver Committee to approve the protocols if a lot of centers wish to participate. It was noted that the Mayo Clinic has a well-recognized protocol for cholangiocarcinoma that others could utilize; however, the Committee did not want to force centers to use one particular protocol. Another comment was that Committee membership changes all the time so there might be variability in what gets approved. However, it was also noted that there is currently no criteria and all the cases are going to the RRBs.

The Committee used the scorecard to assess this policy and the proposal received an overall score of 16.9. The proposal received average score of greater than 2 in the following categories: statement of problem, evidence, and assessment.

Committee Vote: 8 in favor, 0 opposed, and 0 abstentions.

6. Proposal to add the factors "current bilirubin" and "change in bilirubin" to the lung allocation score (LAS). The LAS prioritizes candidates who are 12 years of age or older on the lung transplant waiting list. This proposal adds the following two factors to the waitlist survival model in the LAS: 1) "current bilirubinA (for all candidates);" and 2) "change in bilirubin" (for candidates in diagnosis

¹ MELD Exception Study Group (MESSAGE) – Conference held March 2, 2006 in Chicago, Illinois.

Group BB only). Analyses revealed the association between high bilirubin levels and waitlist mortality. The association between current bilirubin of at least 1.0 mg/dL and waiting list mortality has statistical significance. An increase in a lung transplant candidate's bilirubin level of 50% or more during a six-month period, when the higher bilirubin value is at least 1.0 mg/dL, increases a diagnosis Group B candidate's risk for dying on the waiting list. This association between change in bilirubin of at least 50% and waiting list mortality for candidates in diagnosis Group B (largely candidates diagnosed with pulmonary hypertension (PH)) has statistical significance. The Thoracic Committee anticipates that this policy modification will reduce lung transplant waitlist mortality, and create a more clinically comprehensive waitlist survival model that increases the sensitivity of the LAS in predicting a candidate's medical urgency for a lung transplant.

The Policy Oversight Committee reviewed an earlier version of this proposal which did not get submitted for public comment as planned in October 2008. The Thoracic Committee has since reviewed additional data and added "current bilirubin" to the proposal. There was a question raised about whether a certain score denotes the same mortality risk today as it did in 2007? It was noted that the patients being transplanted are sicker than they were before and a concern of the Thoracic Committee was that there would be an increase in futile transplants. However because LAS, unlike MELD/PELD, is an urgency and benefit system that has been neutralized that quite a bit. Also, the patients are getting transplanted much faster which has significantly reduced live donor lung transplant to where they are only done for kids or very sick patients. There is one exception and that is the group B patient – their mortality rate on the waiting list appears to be twice as high as it use to be but the absolute number being transplanted remains about the same.

The Committee used the scorecard to assess this policy and the proposal received an overall score of 15.8. The proposal received average score of greater than 2 in the following categories: statement of problem and evidence.

Committee Vote: 8 in favor, 0 opposed, and 0 abstentions.

7. Proposal to modify the high risk donor policy to protect confidential health information. Living donor confidentiality is of paramount importance. If the current policy is applied to potential living donors, they might not be offered an opportunity to discontinue the donation process rather than have their high risk status disclosed. This proposal will clarify that this policy only applies to deceased donors.

The Living Donor Committee thought this proposal was pretty straight forward and serves as another example of trying to deal with living donor issues within the current deceased donor policies. Current policy requires transplant centers to inform potential organ recipients about any high risk behavior (as defined by the CDC guidelines) by the donor. The concern from the Living Donor Committee was that it does not specifically apply to living donors. The Committee is modifying the policy to provide potential living donors an opportunity to discontinue the evaluation or donation process rather than have their health information disclosed to other institutions or individuals.

The Committee used the scorecard to assess this policy and the proposal received an overall score of 10.2. The proposal received average score of greater than 2 in the following category: statement of problem.

Committee Vote: 8 in favor, 0 opposed, and 0 abstentions.

8. Proposal to modify the OPTN/UNOS Bylaws, to clarify the process for reporting changes in key personnel. This proposal to change the bylaws will clarify when notification of changes in key

personnel should be submitted and will further clarify the expectation that member institutions that cannot comply should voluntarily inactivate or withdraw the affected transplant program. This proposed language places greater emphasis on the submission of complete applications. Additionally, it clarifies the steps that will be taken if the member fails to inform the OPTN contractor of key personnel changes.

Key personnel are defined as primary surgeons, primary physicians, and primary lab directors. The primary focus of this proposal is on the primary surgeon and physician language in the bylaws which has not been very descriptive in the past and has led to many years of dealing with applications that are incomplete. The Membership Department has made numerous changes to all the applications over the years to be very explicit, with detailed directions and checklists of what documents need to be supplied – and we still continue to get applications that are incomplete and it has a significant impact on staff resource time trying to follow-up with the centers than they do with the completed applications that are ready to be processed. In order to take these applications through the process more efficiently, the MPSC thought that changes to the bylaws would more clearly define the process.

The proposed changes will make it clear to the transplant centers when they must notify the OPTN contractor about changes in key personnel and clarify that institutions that cannot comply with the bylaw should voluntarily inactivate or withdraw the affected program. It places greater emphasis on the submission of a completed application and it clarifies the steps that will be taken if the member fails to notify the OPTN contractor of the change in key personnel. As currently written, the bylaws do not force a center to inactivate a program if a primary surgeon or physician leaves, therefore allowing transplants to continue. The proposed changes will make it clear that the expectation is for the institution to inactivate the membership. It was noted that in some instances, transplant programs will inactivate their wait list but not their membership.

There was a concern about the new bylaw language because it states that transplant programs must submit a complete change in personnel application “at least 30 days prior” to the end of an individual’s active participation in the program. The reason being that other circumstances might come up where a key staff member might leave unexpectedly. The Committee thought that modifying the language to include language like “at least 30 days before or no later than 30 days after” would prevent any confusion.

There was a question raised about what happens to the living donor program if the transplant program is inactivated. It was noted that living donor programs have a separate application process, but if the program loses one of their key personnel they would have to inactivate the living donor part of the transplant program until a replacement is approved.

The Committee used the scorecard to assess this bylaw change and the proposal received an overall score of 10.1. The proposal received average score of greater than 2 in the following categories: patient safety and transplantation oversight.

Committee Vote: 8 in favor, 0 opposed, and 0 abstentions.

9. Proposal to clarify, reorganize and update Policy 5.0 – Standardized Packaging, Labeling and Transporting of Organs, Vessels and Tissue Typing Materials. The proposed modifications to Policy 5.0 will clarify the policy requirements, eliminate redundancy and provide guidance to OPOs and Transplant Centers when packaging, labeling and shipping organs, vessels and tissue typing materials. The entire contents of the policy have been reorganized in order to promote clarity. Types of organ packaging are defined, labeling and documentation requirements are clearly delineated for solid

organs, tissue typing materials and vessels. Vessel recovery and storage requirements are listed, as is transportation responsibilities for renal, non renal and tissue typing materials. The goal is to prevent organ wastage, to define terms and responsibilities to promote safe and efficient packaging and labeling, and to clearly list the requirements for recovering, storing and using vessels in solid organ transplant recipients. The responsibility for packaging and labeling deceased donor organs is assigned to the Host OPO while the responsibility for packaging and labeling living donor organs is assigned to the Transplant Center.

The Department of Evaluation and Quality (DEQ) provided the OPO Committee with information about various types of policy violations and the primary reason in most instances was that the policy language was outdated or in need of clarification. UNOS staff completely reorganized the policy and provided clarification to make them easier to understand. The intent of making these changes to be consistent with current practice regarding labeling of organs, packaging and labeling of vessels and tissue typing materials.

There was some concern from a Committee member about the requirements for certain containers. Some OPOs are requiring the use of containers that do not make it practical for transport. The requirements for commercial transport of organs are understandable, but when the transplant team procures the organ(s) they should be allowed to transport the organs based on their own practice and judgement. It was noted that the policy changes will allow for more options when using containers for transport.

The Committee used the scorecard to assess this policy and the proposal received an overall score of 14.2. The proposal received average score of greater than 2 in the following categories: patient safety/transplantation oversight and statement of problem.

Committee Vote: 8 in favor, 0 opposed, and 0 abstentions

Table 1	Simultaneous Liver-Kidney Criteria	Status 1 Liver Distribution	MELD/PELD Liver Distribution	Standardized MELD/PELD Exceptions	Bilirubin to LAS
Patient Safety and Transplantation Oversight	1.5	2.1	1.5	1.9	1.6
Best Use of Donated Organs	2.2	2.7	2.4	1.9	1.8
Geographic Equity	1.1	2.8	2.7	1.5	1.1
Maximum Capacity	1.1	0.6	0.5	0.4	0.7
Operational Effectiveness	0.6	0.9	0.4	0.5	0.8
Statement of the problem	2.2	2.2	2.5	2.6	2.3
Evidence	2.1	2.2	2.3	2.2	2.1
Assessment	1.9	2.5	2.3	2.1	2
Patient Impact	1.8	2.1	2.3	1.9	1.6

Degree of Criticality	1.9	2.2	2.3	1.9	1.8
Total	16.4	20.3	19.2	16.9	15.8

Table 1 (continued)

	High Risk Donor Policy	Reporting Changes in Key Personnel	Clarify, reorganize, and update Policy 5.0
Patient Safety and Transplantation Oversight	1.4	2.1	2.3
Best Use of Donated Organs	0.3	0	1.5
Geographic Equity	0.1	-0.2	0
Maximum Capacity	0.6	0.1	0.8
Operational Effectiveness	0.5	0.9	1.4
Statement of the problem	2.1	1.7	2.2
Evidence	1.5	1.3	1.1
Assessment	1	1.5	1.4
Patient Impact	1.3	1.2	1.9
Degree of Criticality	1.4	1.5	1.6
Total	10.2	10.1	14.2

Review of Proposals in Development (for June 2009 public comment period)

10. Proposed changes to Policy 7.3.2 (Submission of Organ-Specific Transplant Recipient Registration Forms and Submission of Living Donor Registration Forms) (Living Donor Committee)

At the November 17-18, 2008 Board of Directors Meeting, the Board approved changes to Policy 3.3.7 (Center Acceptance and Transplant of Organs from Living Donors) which requires that transplant programs only accept and transplant living donor organs recovered at other OPTN centers. The proposed changes to Policy 7.3.2 will shift the responsibility of submitting living donor follow-up (LDF) forms to the living donor organ recovery transplant center. The draft of the proposed language is listed below:

7.3 SUBMISSION OF ORGAN-SPECIFIC TRANSPLANT RECIPIENT REGISTRATION FORMS AND SUBMISSION OF LIVING DONOR

REGISTRATION FORMS

- 7.3.1** The Thoracic, Kidney, Liver, Pancreas and Intestinal Transplant Recipient Registration Forms must be submitted to the OPTN within 60 days of the form generation date. Transplant Centers must complete the form when the transplant recipient is discharged from the hospital or six weeks following the transplant date, whichever is first
- 7.3.2** Living Donor Registration Forms (LDR) must be submitted to the OPTN within 60 days of the form generation date. ~~Recipient~~ Living donor organ recovery transplant centers must complete the LDR form when the donor is discharged from the hospital or by six weeks following the transplant date, whichever is first. The living donor organ recovery recipient transplant center must submit LDR forms for each living donor at six months, one year and two years from the date of donation.

The Policy Oversight Committee agreed that the proposed changes seem reasonable and will review the proposal again once it gets distributed for public comment.

Other Discussion Items

11. OMB Forms Submission Process. UNOS Research Staff provided the Committee with an overview of the upcoming process for reviewing the OMB (Office of Management and Budget) forms. The current forms expire in November 2010 so the various Committees will be starting their reviews soon. The forms will be reviewed to assess whether important variables are missing, need clarification, or are no longer needed. Any proposed additions of data elements must adhere to the Principle of Data Collection and Operational Guidelines. The Ad Hoc Data Management Group will review all proposed changes and forward their recommendations to the POC. All the recommendations from the various committees will be combined into a single proposal that will go out for public comment in late summer of 2009. Anticipated implementation following HRSA/OMB approval is November 2010.

12. Update from Kidney Forum. Kenneth Andreoni, MD, vice chair of the Kidney Transplantation Committee, provided an update on the Kidney Forum held on January 26, 2009 in St. Louis, Missouri. The Committee discussed the possible components of a new kidney allocation system (KAS) and how to put them together. The components discussed were:
 - **Waiting Time**: Currently, waiting time starts with the initiation of dialysis or a creatinine clearance less than or equal to 20 ml/min. Time spent on dialysis allows candidates to gain priority over the period they receive this treatment, adding the essential element of justice into the allocation system.
 - **Donor Profile Index (DPI)**: This will provide a continuous measure of organ quality based on clinical information. DPI increases individual autonomy by providing a better metric for deciding which organs are appropriate for which candidates. This would replace the current SCD (standard criteria donor) and ECD (expanded criteria donor).
 - **Life Years from Transplant (LYFT)**: Determines the estimated survival that a recipient of a specific donor kidney may expect to receive versus remaining on dialysis. LYFT is primarily a measure of utility. Overall there was a concern about the predictive value of this was not good. What the Committee was trying to determine other methods of

outcome measurement and how they can use it potentially or not in allocation.

The Kidney Committee will take the feedback from the forum and discussions from the subsequent Committee meeting to determine the next steps to take in the review process.

13. Policies Relating to Multiorgan Transplants. The Committee briefly discussed this issue which has been raised by numerous Committees. Previous discussions have determined that the policies (primarily 3.9.3) are difficult to understand, and also use words such as of “may,” “should,” and “recommended,” which make them more confusing. UNOS staff has recommended that the best way to address this issue is to form a joint subcommittee with representation from numerous Committees. The Committee chair and UNOS staff will meet via conference call to determine the appropriate path forward.
14. Update on Policy Rewrite Project. UNOS staff provided a brief overview of the policy rewrite project. The primary goals of the project are to ensure the intent of the policies are clearly articulated and easy to understand, the requirements for compliance are clear, and the structure and format are uniform across all the policies. The next step includes the formation of an internal working group made up of experienced individuals from various departments. These include Policy, Membership, Regional Administration, DEQ, Research, Communications, IT, Professional Services and the Organ Center. There will also be an external advisory group that will work with and complement the Policy Oversight Committee in reviewing, editing, and providing expertise. The POC and all Committees will be actively involved in this process which is anticipated to take approximately 18 months to 2 years to complete.
15. Update from the Living Donor Data Task Force (LDDTF). Robert Gaston, MD, chair of the Living Donor Data Task Force, gave the Committee an update on the work this group. The group was formed following a Policy Oversight Committee resolution to the Board of Directors in June 2007. The charge was to identify specific needs for living donor data and propose an approach appropriate for each need. The goals include ensuring donor safety during the entire process, better understanding the long-term impacts on health and quality of life, and enhancing the informed consent process. The task force has finalized a “consensus report” (**Exhibit A**) and Dr. Gaston will provide a full report to the Board of Directors during its June 2009 meeting.

**Attendance at the February 5, 2009 meeting of the
OPTN/UNOS Policy Oversight Committee
Chicago, IL**

Member	Position	Attended
Edward Garrity Jr., MD, MBA	Chair	X
Kenneth Andreoni, MD	At-Large	By Telephone
Mark Barr, MD	At-large	X
Lori Brigham, MBA	At-large	X
David Campbell, MD	At-large	X
Laura Ellsworth, MBA	At-large	X
Dixon Kaufman, MD, PhD	At-large	-
Mary Kelleher, MS, CIP	At-large	X
Henry Randall, M.D.	At-large	X
W. Kenneth Washburn, MD	At-large	-
Janis Orłowski, MD	Ex-Officio	X
Monica Lin, PhD	Ex-Officio	By Telephone
Robert Walsh	Ex-Officio	By Telephone
Robert Gaston, MD	Chair, LDDTF	By Telephone
UNOS Staff in Attendance		
Erick Edwards, PhD	Assistant Director, Research	X
Mary D. Ellison, PhD, MSHA	Assistant Executive Director, Federal Affairs	X
Robert Hunter	Policy Analyst/Liaison	X
Karl J. McCleary, PhD, MPH	Director, Policy, membership, and Regional Administration	X
Sally Aungier	Liaison, MPSC	By Telephone
Lee Bolton, MSN, ACNP	Liaison, Living Donor Committee	By Telephone
Vipra Ghimire, MPH, CHES	Liaison, Thoracic Committee	By Telephone
Elizabeth Sleeman, MHA	Liaison, Pancreas Committee	By Telephone
Franki Chabalewski, RN, MS	Liaison, OPO Committee	By Telephone
Ann Harper	Liaison, Liver/Intestine Committee	By Telephone
SRTR Staff in Attendance		
Alan Leichman, MD	SRTR Representative	X
Robert Wolfe, MD	SRTR Representative	X