

OPTN/UNOS POLICY OVERSIGHT COMMITTEE SUMMARY

I. Action Items for Board Consideration:

- The Board is asked to approve a resolution to establish a joint OPTN Committee to evaluate the use of living donor data. (Item 1D, page 5)
- The Board is asked to approve a resolution requesting that the OPTN undertake a study to address geographic disparities in organ allocation. (Item 2, page 6)

II. Other Significant Issues:

- The Committee supports the Pediatric Committee's proposed modifications to the Transplant Candidate Registration (TCR), Transplant Recipient Registration (TRR), and Transplant Recipient Follow-up (TRF) forms. (Item 1A, page 3)
- The Committee supports the Living Donor Committee's proposed modifications to Policies 7.1.5 (Reporting Definitions) and 7.3.2 (Submission of Organ Specific Transplant Recipient Registration Forms and Submission of Living Donor Registration Forms). (Item 1B, page 4).
- The Committee supports the Living Donor Committee's proposed modifications to policy 7.3.3 (Submission of Living Donor Death and Organ Failure Data), modified to limit the reporting requirement to two years post-donation. (Item 1C, page 4)
- The Committee supports the Living Donor Committee's proposed modifications to the Living Donor Registration and Follow-up forms. (Item 1D, page 5)
- The Committee is conditionally in support of the Organ Availability Committee's proposal for additional data elements on the Deceased Donor Registration form, with the request that the OAC define for each organ the clinical questions/hypotheses that will be answered using these data and provide a plan for use of the data. (Item 1E, page 5)
- The Committee supports the OPO Committee's request for additional data elements on the Deceased Donor Registration form. (Item 1F, page 6)
- The Committee has completed its review of Policy 3.11 (Intestinal Organ Allocation) and is near completion of its review of Policy 3.6 (Allocation of Livers). Recommendations will be provided to the Liver and Intestinal Organ Transplantation Committee. (Item 2, Page 6).
- The POC is in support of a policy that clarifies what should occur when a DCD donor converts to brain death, but felt that the Transplant Coordinators Committee should further examine the point in the process when the list cannot be re-run. (Item 3, page 8)
- The Committee is considering revisions to Policy 7.1.3 (Reporting Definitions) related to post-graft failure follow-up. (Item 4, page 9)

This page is intentionally left blank.

**REPORT OF THE
POLICY OVERSIGHT COMMITTEE TO THE
BOARD OF DIRECTORS
Richmond, VA
June 26, 2007
Janis M. Orlowski, M.D., Chair**

Framework for Committee Discussions

At the start of the May 17, 2007, meeting, Janis M. Orlowski, M.D., Committee chair, reviewed the charge to the Policy Oversight Committee (POC) and the OPTN President's Annual Goals for the POC (**Exhibit A**). Erick Edwards, PhD, reviewed progress made toward the HRSA program goals. The Committee was asked to keep these in mind during their deliberations.

1. Ad Hoc Data Management Committee (AHDMC) Recommendations. One of the Annual Goals set for the POC was to "establish and oversee the Ad Hoc Data Management Committee (AHDMC) charged with remaining data reduction and management tasks." The AHDMC was asked to:
 - Review requests for new data elements;
 - Revise data release policies;
 - Review of researcher requests for identified data; and
 - Follow-up on data reduction (e.g., malignancy).

The AHDMC was formed in early 2007, with Richard Pierson, M.D. and Felicia LeClere, Ph.D., representing the POC, and with representation from the Kidney, Pancreas, Liver, Thoracic, OPO, and Pediatric Committees. The AHDMC met on May 2 and May 14, 2007 (**Exhibit B**) to review six proposals that had been circulated for public comment in March 2007. The AHDMC reviewed each proposal for adherence to the OPTN Principles of Data Collection (PODC) that were approved by the Board. Dr. Pearson reviewed the AHDMC's recommendations for each of the six proposals.

- A. Proposed Modifications to Data Elements for Pediatric Candidates and Recipients on UNetSM Transplant Candidate Registration (TCR), Transplant Recipient Registration (TRR) and Transplant Recipient Follow-up (TRF) Forms (Pediatric Transplantation Committee). During its first conference call, the AHDMC expressed concern that the quality of the data derived from the proposed extension of data collection could be compromised by inadequate follow-up for pediatric transplant recipients, who are at greater risk of being lost to follow-up than are adult recipients. This concern was partially allayed by the data provided by the OPTN, which indicates that the lost-to-follow-up rate to 5 years was no worse than 25% for any of the pediatric age intervals reported, and was less than 20% for most age ranges. The AHDMC submitted the following recommendation to the POC:

The Pediatric Transplantation Committee recommends that pediatric recipients be followed up using pediatric TRF forms for five years after transplant and a reduced pediatric TRF following the adult reduction process with seven additional data fields specifically related to pediatric concerns regarding growth and development until the pediatric recipients reach 25 years of age. The Pediatric Committee suggested that the growth and development of adolescents should be monitored through age 25 to assess the consequences of transplantation during childhood. The AHDMC suggests that this modification may have an impact on the quality of available data as the differential loss

to follow up in this age range (18-25) may be substantial, particularly for those patients whose transplants occurred in early childhood. In order to assess the impact of extending the period of pediatric follow up, the AHDMC recommends that this change should be implemented initially for a three year period, which corresponds with the current OMB requirements for form evaluation and expiration. Data should be assessed after a two year submission period to evaluate the impact of loss to follow up on the quality of the data obtained from pediatric transplant patients between ages 18-25. At this time, changes may be recommended for the next data collection form review period, to be submitted in March 2010.

A Committee member questioned the validity of the functional outcome measures included in the Pediatric follow-up form. Estella Alonzo, M.D., representing the Pediatric Transplantation Committee, stated that her Committee worked with a team of experts, including a pediatric neurocognitive development specialist, to develop tools to be used for cognitive and motor function. The information provided would not be as granular as information taken from actual patient testing or survey, but would help categorize patients that seemed to be at risk for problems. The AHDMC felt that these data elements had been carefully considered and would yield useful information. Representatives from the SRTR were involved throughout the process as these data elements were considered.

By a vote of 8 in favor, 0 opposed, and 1 abstention, the Committee supports the Pediatric Committee's proposed modifications to the Transplant Candidate Registration (TCR), Transplant Recipient Registration (TRR) and Transplant Recipient Follow-up (TRF) forms.

- B. Proposed Modifications to OPTN/UNOS Policy 7.1.5 (Reporting Definitions) and OPTN/UNOS Policy 7.3.2 (Submission of Organ Specific Transplant Recipient Registration Forms and Submission of Living Donor Registration Forms). The OPTN contract requires collection of information on all living donors at the time of donation and for at least two years after the donation. The Living Donor Committee has recommended that the two-year Living Donor Follow-up (LDF) form include the same data elements that are currently being collected at one-year post donation. The AHDMC discussed the proposal and recommended approval as written, stating that the proposed modification meets the OPTN Principles of Data Collection (criteria a, c, and d), and that no additional issues related to data acquisition or evaluation were identified.

By a vote of 12 in favor, 0 opposed, and 1 abstention, the Committee supports the Living Donor Committee's proposed modifications to Policies 7.1.5 and 7.3.2

- C. Proposed Modifications to OPTN/UNOS Policy 7.3.3 (Submission of Living Donor Death and Organ Failure Data). The Living Donor Committee proposed modifications to Policy 7.3.3 that would define living donor "native organ failure" as (1) placing living liver donors on the National Liver Transplant Waitlist and (2) living kidney donors requiring dialysis. This proposal also limits the reporting period to five years. The AHDMC discussed the proposal and recommended approval as written, stating that the proposed modifications meet the OPTN Principles of Data Collection (criteria a, c, and d), and no additional issues related to data acquisition or evaluation were identified.

The Committee supports the requirement for 72-hour reporting of serious adverse events. However, several members questioned what will be accomplished with the requirement for reporting out to five years post-donation. If the intent is, for example, to analyze the long-term consequences of organ donation, the policy would not address this issue. The Committee's

concerns were related to the quality and completeness of the data being collected. The Committee would support the proposal if the time frame for reporting is limited to 2 years, which is the current requirement for living donor follow-up.

By a vote of 13 in favor, 0 opposed, and 1 abstention, the Committee supports the Living Donor Committee's proposed modifications to policy 7.3.3 (Submission of Living Donor Death and Organ Failure Data), modified to limit the reporting requirement to two years post-donation.

- D. Proposed Modifications to the UNetSM Living Donor Registration (LDR) and Living Donor Follow-up (LDF) Forms. The Living Donor Committee has proposed to add one new data element to the LDF form and three new data elements to the LDR form that would document attempts follow living donors. The AHDMC discussed the proposal and recommended approval as written. The proposed modification meets the OPTN Principles of Data Collection (criteria a, c, and d), and no additional issues related to data acquisition or evaluation were identified.

By a vote of 13 in favor, 0 opposed, and 0 abstentions, the Committee supports the Living Donor Committee's proposed modifications to the Living Donor Registration (LDR) and Living Donor Follow-up (LDF) forms.

Committee members stated that the OPTN should develop plan for how living donor data are to be used, the hypotheses to be investigated, and the endpoints for analysis. For example, the OPTN may need long-term national statistics for informed consent, and/or institution-specific live donor transplant outcomes. The OPTN needs to determine the best way to answer these questions in the short and long-term. The Committee recommends the following resolution for consideration by the Board of Directors:

**** RESOLVED, that a joint OPTN Committee be established to evaluate the use of living donor data.**

Committee Vote: 13 in favor, 0 opposed, 0 abstentions.

- E. Proposed Modifications to Data Elements on UNetSM Deceased Donor Registration (DDR) Form. The Organ Availability Committee (OAC) proposed the addition of several data elements to the Deceased Donor Registration (DDR) form that would provide more specific details on the recovery process for individual donation after cardiac death (DCD) donors. There are not currently enough data collected on DCD donors to determine best practices or to correlate specific features of the donor or recovery procedure with outcomes. The AHDMC agreed unanimously that collecting serial vital sign data at 5 minute intervals would be appropriate, in accordance with standard anesthesia monitoring guidelines for intraoperative care, for all elements except urine output. For measurement of urine output, the AHDMC unanimously agreed that it was appropriate to measure total urine output once over the duration of the case. Both of these modifications were recommended by the OAC representative on the conference call. The AHDMC recommended approval of the proposal with the above change, noting that the proposed modification meets the OPTN Principles of Data Collection (criteria a, c, and d).

Committee members agreed that there are important questions that need to be answered regarding DCD donors, and that data need to be collected. There are substantial differences between OPOs with respect to use of DCDs and recovery and acceptance practices. One Committee member noted that acceptance decisions are often made based on anecdotal information because there are no data available. The Committee asked that the OAC define the specific clinical

questions/hypotheses that the OAC is hoping to answer, for each organ, and map the data elements requested to specific scientific questions.

By a vote of 13 in favor, 0 opposed, and 0 abstentions, the Committee is conditionally in support of the Organ Availability Committee's request for additional data elements on the DDR, with the request that the OAC define for each organ the clinical questions/hypotheses that will be answered using these data and outline a plan for use of the data.

- F. Proposed Imminent Neurological and Eligible Death Definition Data Elements. The OPO Committee is requesting the addition of data elements intended to enhance understanding of all imminent neurological and eligible deaths. During the AHDMC conference call, it was noted that the proposal appeared to apply to all vented patients. The AHDMC commented that it would be an overwhelming data burden on the OPO if they had to report all vented referrals because many vented patients may not die, or may die weeks after inappropriateness or refusal for organ donation has been determined. The number of these referrals is very significant as compared to those patients that meet imminent neurological death criteria, as precisely and appropriately defined in the proposal. Further, the AHDMC agreed that in the category listed as "Consented/Non-consenting, Imminent Neurological Death", the "Date and time of pronouncement of death," should be changed to: "Date and time of death, if known." These modifications were recommended by the OPO Committee representative on the conference call. The AHDMC recommended approval of the proposal with the above changes, stating that the proposed modification meets the OPTN Principles of Data Collection (criteria a, c, and d).

By a vote of 13 in favor, 0 opposed, and 0 abstentions, the Committee is in favor of the OPO Committee's request for additional data elements on the DDR, as modified.

2. Review of Existing Policies. The POC is required to "establish a process for examining existing and proposed OPTN policies, and ensure that allocation policies meet certain performance-improvement standards." The process for review of policies was also an Annual Goal for the Committee. Policies 3.6 (Allocation of Livers) and 3.11 (Intestinal Organ Allocation) have been assigned to Committee members for review. The reviewers are asked to review the policies with the following in mind:

- What is the function of the policy/section?
- Does the policy present a clear statement of what is to be accomplished (e.g. maximize the person-years of life gained, reduce waitlist deaths, etc). ?
- Is the policy clearly worded and/or appropriately organized?
- Is the policy in keeping with current medical/technological practice?
- Other comments/concerns?

The UNOS Policy Analyst assigned to the sponsoring Committee is responsible for providing the history/background of the policy, including the intended goal(s) of the policy, the data used to justify the policy change, the metric(s) to be used to assess the policy, and any assessment of the policy after implementation. The Committee liaisons will ask the sponsoring committee to address any clinical questions that are identified. Once the sponsoring Committee has reviewed the POC's input, the Policy Analysts will rewrite the policy language as appropriate.

Committee reviewers Simon Horslen, M.D. and Melissa Gardiner reviewed the intestine policy (**Exhibit C**). Dr. Horslen noted that the function of the intestine policy is to equitably allocate organs to individuals in need of isolated intestine transplantation and as a cross-reference to the liver

allocation policy for individuals listed for combined liver and intestine transplantation. The policy does not present a clear statement of what is to be accomplished. Dr. Horslen felt that the policy could be better worded, and Ms. Gardiner felt that some of the sections were confusing and should be reworded. Regarding the current clinical practice, Dr. Horslen stated that Policy 3.11.4 (Combined Intestine-Liver Organs Candidates) should be revised, and provided comments regarding potential revisions. Some issues noted:

- Status 1 is not clearly defined.
- Waiting time does not transfer from Status 2 to Status 1.
- The policy is not in keeping with current practice.

Committee members also urged that the Liver Committee continue to address the high mortality rates of small children awaiting combined liver-intestine candidates. Size matching for children under the age of 2 years of age could be considered. The Committee agreed by unanimous vote to send these comments to the Liver and Intestinal Organ Transplantation Committee for its review.

Drs. Roberts, Pomfret, Wynn, and Orlowski reviewed the existing Liver allocation policies. Dr. Pomfret addressed the exceptions to the MELD/PELD score, which includes pediatric candidates with metabolic diseases and hepatoblastomas, candidates with hepatocellular carcinoma (HCC), and “other exceptional cases” such as hepatopulmonary syndrome and familial amyloidosis. Dr. Pomfret provided several comments about these policies:

- There is a loophole in the process if an appeal to the RRB is entered on day 20 or 21 that allows candidates to receive a higher score without approval of the RRB.
- The recommendations of the MESSAGE conference held in 2006 should be incorporated into the policies for exceptions. This conference produced detailed evidence-based guidelines and criteria for candidates with specific exceptional case diagnoses.
- Policies 3.6.4.3 (Pediatric Liver Transplant Candidates with Metabolic Diseases) and 3.6.4.4.1 (Pediatric Liver Transplant Candidates with Hepatoblastoma) are fine as written.
- Policy 3.6.4.4 (Liver Transplant Candidates with Hepatocellular Carcinoma (HCC)) could be clarified, as ultrasound is mentioned as an acceptable candidate assessment modality but it is not acceptable by itself for receiving the exception points.
- The HCC criteria are being reassessed by the Liver Committee.

Dr. Wynn reviewed portions of the policy related to medical urgency (Status 1A/1B and MELD/PELD) and MELD/PELD recertification, as well as review of 1A/1B listings and listing accuracy. His comments were as follows:

- The terms CVVH and CVVD should be replaced with continuous renal replacement therapy (CRRT).
- The section stating how to apply to the RRB is duplicated in the adult and pediatric sections; this could be placed in a separate section describing exceptions. This was also poorly worded, with one sentence having 137 words.
- There are some inconsistencies in the Status 1A/1B requirements for adults and children.

Dr. Roberts reviewed several sections and provided the following comments:

- Allocation sequence (Policy 3.6): The section “Allocation Sequence for Candidates with PELD or MELD Scores Less Than or Equal to 6 (All Donor Livers)” should be eliminated. Data regarding the frequency of transplants of adult and pediatric patients in this range should be examined.

- Preliminary Stratification (3.6.1). The policy is redundant and should be eliminated.
- Blood Type Similarity Stratification/Points (3.6.2). This policy is poorly written and very confusing to read. The Liver Committee should consider allowing blood type A₂ livers to be transplanted in non-Status 1 blood type O or B candidates. The use of points for blood type compatibility for Status 1A/1B candidates should be reconsidered.
- Time Waiting (3.6.3). This policy should be reworded.
- Combined Liver-Intestine Candidates (3.6.4.7). No suggested changes.
- Allocation of livers for other methods of hepatic support (3.6.10). This policy should be reworded, as DonorNet® has eliminated the need for the organ center to do the placement.
- Allocation of livers for segmental transplantation (3.6.11). This policy should be reworded.

Regional Differences in Allocation

The Committee noted that MELD/PELD exceptions are handled differently by the Regional Review Boards (RRBs), and that, in some regions a patient may require several extensions (with increases in MELD/PELD scores) before getting transplanted while others may get transplanted earlier and at lower MELD/PELD scores. These differences based on geography should be addressed by the OPTN. One of the allocation performance goals of the Final Rule is “Distributing organs over as broad a geographic area as feasible.” The implementation of the MELD/PELD score and broader sharing for higher scores has lessened geographic differences with respect to the severity of illness at transplant. The distribution issues have been “set aside” during the deliberations over the kidney allocation system until the mechanism for allocation (net benefit) has been determined. However, the measurements of disparity must be clearly defined, (e.g., are waiting times to transplant an appropriate measure, or are transplant rates a better measure of geographic equity for kidneys?). The Committee recommends the following resolution for consideration by the Board of Directors:

**** RESOLVED, that the OPTN undertake a study to address geographic disparities in organ allocation.**

Committee Vote: 10 in favor, 0 opposed, 0 abstentions.

The POC will also consider geographic differences as a part of its review of policies.

3. Reallocation of Organs When a Donor Converts from DCD to Brain Death. The Transplant Coordinators Committee (TCC) has proposed changes to Policy 3.3.6 (Center Acceptance of Organ Offers) that address re-allocation of organs when a donor converts from a DCD to brain death. In October 2006, the POC asked “that the TCC begin to collect data regarding those cases when a DCD donor deteriorated to brain death, document the circumstances under which they occur, and determine if there is a time point after which reallocation should not occur.” The TCC began a survey in February 2007. In response to concerns arising from a potential inconsistency between allocation policies in the case of DCD donation, the Board approved the following in March 2007:

RESOLVED, that until the Board reconsiders policies regarding reallocating organs when a DCD donor progresses to brain death, the Board will not consider reallocation to be a violation of OPTN policy, effective March 23, 2007.

During the April 2007 meeting, the TCC proposed the following amended language:

3.3.6 Center Acceptance of Organ Offers. If an organ is offered and accepted without conditions, the Host OPO and ~~recipient~~ candidate’s transplant center shall be bound by

this transaction unless there is mutual agreement on an alternative allocation of the organ. This policy shall not apply in the case of a DCD donor who deteriorates to brain death after an initial offer has been made. In this instance, the match must be re-run and organs must be allocated according to policies 3.5 - 3.11 to the highest ranked transplant candidates. Additionally, OPOs are encouraged to initiate allocations of organs that may have been ruled out due to the donor's DCD status (i.e. heart, lungs, pancreas). In circumstances where an organ is not re-allocated despite the donor deteriorating from a DCD donor to a brain dead donor, the host OPO is responsible for submitting documentation explaining the event. These circumstances include:

- 1) lack of donor family approval and consent
- 2) donor instability
- 3) the situation occurs within four hours of the scheduled operating room recovery time.

Elizabeth Pomfret, M.D., noted that the programs in Region 1 have agreed that once the recovery team is *en route* to the donor hospital then the list will not be re-run. However, recovery practices may vary from DSA to DSA, so this practice may not apply in all areas. A requirement for 4 hours may not apply to a small region such as New England. In cases when the donor and recipient are in the same hospital, there is no “travel time” required for the recovery team.

The Committee is in support of a policy that clarifies what should occur when a DCD converts to brain death, and made the following observations for the TCC to consider:

- Some DCD donors can be expected due to their clinical course to deteriorate to brain death. That situation presents the opportunity for more organs to be procured. The POC advises that OPOs utilize that period of time to see if the donor makes the transition from DCD to brain death. This may also allow for allocation to more urgent patients
- There should be a definite point when the list cannot be re-run. For some OPOs, it may be the recovery team going out, but for others that may not be an “event,” so this may require a specific time frame related to the operating room.

The policy should also include a statement of purpose, such as to increase number of organs available per donor and/or to allocate organs to more urgent patients. A suggestion to reword the policy to “DCD donor in whom brain death is declared after an initial offer has been made,” was supported by the Committee. It was noted that patients should be informed that a DCD offer might not result in transplant.

The Committee was reminded that circumstances 1-3 listed in the proposed policy simply define when the OPO must provide documentation as to why the organ was not re-allocated, however; Committee members felt that this would likely dictate clinical practice.

4. Proposed Revisions to Policy 7.1.3 (Reporting Definitions). In June 2006, the Board approved the Committee’s recommendation to modify Policy 7.1.3. The intent was to discontinue follow-up after graft failure for kidney or kidney-pancreas recipients. However, the proposal as worded would require that all patients must now be followed until death. The SRTR was asked to define a time frame for follow-up post-graft failure for kidney, pancreas, kidney-pancreas, and perhaps intestine recipients.

Robert Merion, M.D., Clinical Transplant Director of the SRTR, provided an update to a previous analysis of ascertainment of death after graft failure (**Exhibit D**). For the 4,008 kidney transplants

performed in 2004, 202 were reported as having died on the day the graft failed, and 200 of those deaths were found using a source other than the OPTN data. Of the 55 recipients that were reported to have died within the first week after graft failure, all were found using a source other than OPTN data, and of the 579 reported as having died between the first week and 1 year, only 3 were identified in the OPTN database only. Similar results were found for liver, lung, heart, pancreas, and intestine recipients. Thus, there are very few deaths after graft failure that are only known through OPTN data (i.e., cannot be found from another source). For liver recipients, graft failure is defined as either re-transplant or death, so graft failure should be captured by one of these two events. However, in 79 cases, graft failure is recorded but there is no record of a death or re-transplant. These anomalies were also seen for lung and heart recipients, and the SRTR will work with the OPTN to resolve these anomalies. The follow-up form is still needed to collect data for deaths on the day of graft failure. The Committee will address any necessary changes to the policy language during the July 2007 meeting.

5. Review of Existing Policies. Dr. Orłowski reviewed the role of the POC in policy review, which is to determine:

- If the policy's goals are objective and measurable;
- That the goals further the mission, strategic plan and long term goals of the OPTN and HHS Organ Transplantation performance goals; and
- That the goals are scientifically based.

The Committee has been developing a Policy Evaluation Scorecard to be used as a tool for reviewing new proposals. The concept of a scorecard was included in OPTN contract proposal as a way to enhance feedback to the Board of Directors and sponsoring committees. The scorecard will also provide consistent ranking of policies across meetings and reviewers. A subcommittee met in January, and its initial proposal was presented to Committee in January. A revised proposal was developed for presentation at the May meeting. The scorecard categories include:

1. Positive impact on the OPTN Program Goals and Strategic Plan
2. Positive impact on a high proportion of candidates and/or recipients (to include Improvement in Patient Safety)
3. OPTN/SRTR contractor cost/risk Factor
4. Member cost
5. Cost Reduction/Efficiency Gain to OPTN (Members or Staff)
6. Policy Easy to Understand/Accessible
7. Serves a special or disenfranchised group

All seven items will be ranked using the same score (0 to 5), where 0 equals low/costly and 5 equals high/efficient. The first two items would receive a weight of 3 while the rest would receive a weight of 1. The intent is to balance the ranking based on the most important categories versus other factors that are important but do not carry the same weight as the program goals and impact on patients. The Committee will begin to use this for new proposals, which can be modified as necessary.

Committee members questioned how costs and risks to the OPTN and members would be assessed. The UNOS Information Technology department is developing a detailed risk-benefit scorecard for its projects that can be used as input into the scorecard. Furthermore, the Transplant Administrators Committee could serve as a resource for member costs, which could be broken into specific categories (i.e., increased data entry and/or collection, requirements for laboratory tests, etc.). Committee members noted that it might be useful for a proposal to receive a preliminary score early

in development, so that a Committee might reconsider spending time on a proposal that does not further any of the goals of the organization.

The Role and Timing of the POC in Policy Review

One of the Annual Goals set for the Committee was to discuss the role and timing of the POC in policy review. The Committee has been kept up-to-date regarding the proposed revisions to the kidney allocation system, which are undergoing discussion by the Kidney Committee and the community. In most cases, the Committee has reviewed proposals as they are circulated for public comment. However, if the POC has substantive comments back to the Committee on the proposal, there may be a problem with timing in terms of the proposal going to the Board. One tool available to the Committee is the “Policy Tracker,” which summarizes all of the proposals currently in development, ranging from concepts to proposals that have been circulated for public comment. This tool is posted on the POC’s external SharePoint™ Site.

6. Vice-Chair Reports. The Vice-chairs of the Kidney Transplantation, Liver and Intestinal Organ Transplantation, Minority Affairs, OPO, Pancreas Transplantation, Pediatric Transplantation, and Thoracic Organ Transplantation Committees reported on the policy proposals that their Committees are considering (**Exhibit E**).

Policy Oversight Committee

05/17/2007

NAME	POSITION	
Janis Orłowski MD	Chair	X
Ray Gabel	At Large	by telephone
Melissa Gardiner	At Large	
Rainer W. Gruessner M.D.	At Large	X
Simon Horslen MD	At Large	by telephone
Maryl Johnson MD	At Large	X
Jack Kalbfleisch Ph.D.	At Large	
Felicia LeClere Ph.D.	At Large	
Jeffrey Orłowski MS, CPTC	At Large	X
Richard Pierson III, MD	At Large	by telephone
Elizabeth Pomfret MD, PhD	At Large	X
John Roberts MD	At Large	X
Bruce Schmeiser Ph.D.	At Large	
Cedric Sheffield MD	At Large	by telephone
Peter Stock MD, PhD	At Large	X
Judy Jones Tisdale PhD	At Large	by telephone
Winfred Williams MD	At Large	X
James Wynn MD	At Large	X
Janet Shaftel RN, BSN	BOD - Liaison	
Christopher McLaughlin	Ex Officio	
Robert Merion MD	SRTR Liaison	X
Invited Guests		
Estella Alonso, MD	Pediatric Transplantation Committee	
Stuart Sweet, MD	Pediatric Transplantation Committee	
UNOS Staff		
Ann Harper	Policy Analyst/Committee Liaison	X
Deanna Sampson Esq.	Director, Evaluation and Quality, Committee Liaison	X
Erick Edwards Ph.D.	Assistant Director, Research	X
Mary D. Ellison, PhD, MSHA	Assistant Executive Director, Federal Affairs	
Berkeley Keck, RN, MPH	Assistant Executive Director, Information Technology	