

**OPTN/UNOS POLICY OVERSIGHT COMMITTEE
SUMMARY**

I. Action Items for Board Consideration:

- The Board is asked to approve a recommendation that a limited set of data elements shall be required for validation of the Transplant Recipient Follow-up (TRF) form after 5 years post-transplant. This proposal was circulated for public comment in November 2006 and was widely supported. (Item 1, Page 3)

II. Other Significant Items:

- The Committee concluded that the modifications to Policy 3.5.9 (Minimum Information/Tissue for Kidney Offer) proposed by the Organ Availability Committee are not ready to be considered by the Board as currently written. However, the POC strongly recommends that the OAC put forward a proposal to standardize the biopsy technique that does not to mandate additional data collection. (Item 2, page 6)
- The Committee supports the modifications to Policy 5.0 (Standardized Packaging and Transporting of Organs and Tissue Typing Materials) proposed by the Operations Committee and finds them appropriate for Board consideration, with the request that that the portion of the policy dealing with interactions between a single operating room suite be stricken or changed. (Item 3, page 8)
- The Committee supports the modifications to Policy 3.1 (Organ Distribution: Definitions) proposed by the Operation Committee and finds them appropriate for Board consideration, with the request that the Operations Committee require verification of the unique linkage between the donor and the recipient. (Item 4, page 8)
- The POC unanimously supported the changes proposed by the Pediatric Committee, but asked the Pediatric Committee for a recommendation for length of follow-up for pediatric transplant recipients. The Pediatric Committee plans to issue this for public comment in March 2007. (Item 5, page 9)
- The Committee is developing a process for review of existing policies (Item 6, page 10).

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**REPORT OF THE
POLICY OVERSIGHT COMMITTEE TO THE
BOARD OF DIRECTORS
St. Louis, MO
March 23, 2007
Janis M. Orlowski, M.D., Chair**

Framework for Committee Discussions

At the start of the January 24, 2007 meeting, Janis M. Orlowski, M.D., Committee chair, reviewed the HRSA program goals, OPTN Strategic Plan goals, the OPTN President's Annual Goals for the Policy Oversight Committee (POC) and the Committee's charge (**Exhibit A**). The POC should conduct its business within the context of these factors. The primary goals set for the meeting were to: (1) approve the process for review of existing policies; (2) discuss the scorecard for policy proposals; (3) review Public Comment proposals; and (4) determine process for written recommendations from the POC to the Board. The Committee also received a series of effective questions that could be used to guide the discussions.

I. Action Items for Board Consideration:

1. Proposed Modifications to Data Elements on UNetSM Transplant Recipient Follow-up (TRF) Form. Dr. Orlowski reviewed the Committee's proposal for the data elements that would be retained on the TRF after five years post-transplant (**Exhibit B**). This proposal was in response a Board resolution approved in June 2006 stating that "the OPTN will address within six months what limited elements other than patient and graft survival will be required for follow up after five years." The proposal was circulated for public comment on November 19, 2006, and several individual, regional, and public comments had been submitted. The Kidney Transplantation Committee unanimously voted that creatinine be retained for all organs "due to its indicative value in organ failure." The numbers of dual organ and kidney-after-non-renal transplants are increasing, as immunosuppressive agents can cause kidney damage. Creatinine, as a measure of renal function, would be used to evaluate this trend and to assess to what extent future allocation systems should accommodate the need for dual transplants. The Thoracic Organ Transplantation Committee asked to retain data related to renal function for this reason as well. An initial motion to send the request back to the Kidney Transplantation Committee for further clarification with respect to the Principles of Data Collection was approved by a vote of 8 in favor, 0 opposed, and 1 abstention.

Following this vote, Committee members noted that this request would only apply to pancreas, liver and intestine recipients, as the proposal already included creatinine for kidney, kidney-pancreas, and thoracic organs. Peter Stock, M.D., chair of the Pancreas Transplantation Committee, stated that this data element should be added for pancreas-alone transplants for policy development and ensuring patient safety. The question being asked in the pancreas transplant community is whether pre-uremic diabetic patients are being harmed by receiving a pancreas-alone transplant, in that they risk developing kidney failure as a direct result of the immunosuppression. Another Committee member stated that creatinine should be collected for liver transplant recipients, as cardiovascular morbidity and longevity correlate with renal function.

Committee members discussed the use of OPTN data as a general research tool, with concerns expressed that this function of the dataset is being abandoned. For example, the creatinine data can be used to better understand the natural history of transplantation by following renal function in non-

uremic diabetic pancreas transplants recipients. This type of analysis on a small subset of transplant recipients is best done using registry data. While it is very important to be able to justify the addition of elements to the database, the Committee should be equally focused on asking whether it is safe to remove elements from the database, which was not the case in the data reduction project. There is a tension between collection of data that may enhance the transplant community's knowledge of transplantation and the cost and burden to the centers. To accommodate the need for data for these purposes, the OPTN may need to explore funding for targeted, time-limited data collection efforts.

Subsequent to these discussions, a motion was made to support the Kidney Transplantation Committee's request, citing development of allocation policies and institutional performance as relevant principles for data collection, e.g., to assess whether a center has a high rate of renal failure in the long term. The Committee approved a motion to retain creatinine for all organs after 5 years post-transplant by a vote of 9 in favor, 3 opposed, and 0 abstentions.

The Committee discussed the appropriate length of post-transplant follow-up. The Board resolution from June 2006 specifically referred to "follow up after five years." However, the AST/ASTS Task Force recommended that the full set of data be collected for only three years, and a reduced dataset thereafter. Center performance is currently measured at up to three years post-transplant. An additional two years may have value in evaluating small programs, a concept that is being considered by the Membership and Professional Standards Committee (MPSC). Furthermore, center performance is not the only use of OPTN data. The Committee discussed how the Committee might systematically understand whether five years of post-transplant data is "better" than three years of data, although the answer would depend on what the data are being used for. For now, the Committee recommends that the OPTN collect the full set of data (post data reduction) for five years, but will reassess that decision as part of the annual data review process.

UNOS staff noted that the primary cause of graft failure was not included in the proposal for all organ types, and the Committee agreed that this oversight should be corrected.

Review of Public Comment

As of January 19, 2007, the deadline for comment submission, 49 responses had been submitted to UNOS regarding this policy proposal. Of these, 40 (81.6%) supported the proposal, 3 (6.1%) opposed the proposal, and 6 (12.2%) had no opinion. Of the 43 who responded with an opinion, 40 (93.0%) supported the proposal and 3 (7.0%) opposed the proposal. The three individual comments submitted via the OPTN and UNOS websites were in support of the proposal. All 11 regions were in support of the proposal.

The Committee discussed several letters received in response to the public comment proposal. The National Kidney Foundation submitted a letter requesting additional data capture, which the Committee referred to the Kidney Committee. A letter from Wyeth expressed concern that "the ability of the transplant community to assess the impact of immunosuppressive regimen modification and long-term patient outcome measures will be severely limited by these pending changes to the UNOS data collection methodology." The Committee referred this letter to the Ad Hoc Data Management Committee. Finally, the Committee briefly reviewed a letter from the National Association of Transplant Coordinators (NATCO) that contained two questions relating to malignancy data. The POC has stated that it will reassess the collection of malignancy data in a year, pending analyses conducted by the Scientific Registry of Transplant Recipients (SRTR) contractor.

Comments from AST/ASTS Task Force

Dr. Orlowski noted a letter from the presidents of AST and ASTS regarding their concerns about the data reduction process that was discussed at the December 2006 Board meeting (**Exhibit C**). The AST and ASTS requested that the Board formally adopt principles of data collection. The Board approved a revised version of the principles of data collection during the December 2006 meeting. The Committee reviewed a letter from Sue McDiarmid, M.D., OPTN/UNOS President, in response to the AST/ASTS letter that promised that the POC would meet annually to “address the progress of the data submission modification and make adjustments as necessary” (**Exhibit D**).

Long-term Collection of Malignancy Data

As noted above, the Board approved the following resolution in June 2006:

***FURTHER RESOLVED**, that collection of post-transplant malignancy data shall be limited to tumor types, site, and cancer diagnosis date, pending distribution of appropriate notice and programming in UNetSM, if and as applicable. Collection of these data will be reevaluated by the Policy Oversight Committee and Board in two years.*

Because of this resolution, the POC chose not to address this Liver and Intestinal Organ Transplantation Committee’s request for retention of “presence and type of malignancy” at this time. These data will remain on the forms until the SRTR completes its assessment of (1) the value of collecting these data in terms of quantifying cancer risk and incidence and (2) how long these data should be collected.

Executive Summary

The Executive Summary for this proposal can be found as **Exhibit B, Attachment 1**.

Final Proposal

In summary, the POC supports the proposal it submitted for public comment on November 19, 2006, with the following exceptions/additions:

- The POC recommends that creatinine should be retained on all follow-up forms after 5 years post-transplant; and
- Primary cause of graft failure should be retained on all follow-up forms after 5 years post-transplant.

Subsequent to consideration of public comment, the Committee recommends the following resolutions for consideration by the Board of Directors:

**** RESOLVED**, that the data elements listed in Table 1 below shall be required for validation of the Transplant Recipient Follow-up (TRF) form for adult recipients after 5 years post-transplant, pending distribution of appropriate notice and programming in UNetSM, if and as applicable. This resolution is intended not to supersede but to complement previous actions taken by the Board regarding OPTN Data Reduction in June 2006.

Table 1. List of Data Elements That Would be Retained on the TRF After 5 years¹

<p>Follow-up Elements Common to All Organs</p> <p><u>Demographics</u>: Zip code and State <u>Provider/Donor Information</u>: Follow-up center (for logistical purposes only) <u>Patient Status</u>: Date last seen, or retransplanted, died, primary cause of death <u>Other Information</u>: Graft status, Date of graft failure, <u>Most recent serum creatinine</u></p> <p>Follow-up Elements: Liver Contributory causes of graft failure</p> <p>Follow-up Elements: Intestine Primary cause of graft failure</p> <p>Follow-up Elements: Kidney Primary cause of graft failure</p> <p>Follow-up Elements: Kidney-Pancreas Primary cause of graft failure Contributory causes of graft failure (pancreas)</p> <p>Follow-up Elements: Pancreas <u>Primary cause of graft failure</u> Contributory causes of graft failure</p> <p>Follow-up Elements: Thoracic <u>Primary cause of graft failure</u> Bronchiolitis Obliterans Syndrome (Lung forms only) Coronary Artery Disease (Heart forms only) Renal dysfunction (Yes/No) (All Thoracic forms) If renal dysfunction, creatinine > 2.5 mg/dl If renal dysfunction, chronic dialysis If renal dysfunction, renal transplant</p>
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Committee vote: 11 in favor, 0 opposed, 1 abstention.

II. Other Significant Items:

2. Proposed Modifications to Policy 3.5.9 (Minimum Information/Tissue for Kidney Offer)². Committee members Ray Gabel and Peter Stock, M.D. reviewed this proposal from the Organ Availability Committee (OAC). The intent of the proposal is to standardize biopsies and biopsy reporting data for all extended criteria donor (ECD) kidneys. The technique for the kidney biopsy and the rationale for utilizing this technique were very clearly stated. By standardizing the technique for kidney biopsy, it is hoped that the data will be used to more reliably determine the quality of the

¹ With the exception of malignancy data (tumor type, site, and date), which will be retained until the POC revisits these data elements pending SRTR analyses.

² Note: A summary of the recommendations for Items 2-4 is also contained in Table 2, found on page 9.

ECD kidneys. In the past, there has been no correlation between biopsy results and outcomes for ECD kidneys. One reason for this is that biopsies are not being done in a standard fashion. Dr. Stock noted that the reporting mechanism needs to be better defined. The stated goal of the proposal is to decrease the discard rate of deceased donor kidneys. However, the primary metric identified to assess the goal should be clarified – for example, is the metric the OPO’s ability to obtain biopsy data for every kidney, or the number of ECDs that are discarded before and after the policy?

Alan B. Leichtman, M.D., SRTR representative to the Committee, cited findings from an SRTR study indicating that frozen initial biopsies correctly predicted (1) the percent of glomerular obsolescence only 45% of the time; (2) the degree of arteriosclerosis 35% the time; (3) tubular interstitial fibrosis/atrophy 40% of the time; and (4) vessel hyalinosis 60% of the time. Furthermore, wedges can yield a range of results for glomerulosclerosis depending on how the wedge is cut.

Other Committee members discussed the problem that, while reliable biopsies are predictive of outcome, many biopsies are not reliable. Dr. Orłowski cited a study conducted by Gift of Life in Chicago that compared frozen biopsies to H&Es. The study group found that it is not practical to get an H&E or PAS³ before transplant. The study found that fresh frozen biopsies are an inaccurate way to make a decision because these over-reported sclerosis and did not adequately reflect arterial disease. Committee members noted that the requirement for biopsies may have unintended consequences, in that it may cause good organs to be discarded if the biopsy is inaccurate. However, ECD kidneys that are not biopsied are more likely to be discarded. Some Committee members felt that the transplant center and OPO should decide on a local approach to this issue. It was noted that this is research conducted at a national policy level, and that other options might include regional projects or a Committee sponsored variance with a study design and strict protocols, which would allow OPOs to opt in. The data could better be tracked by the transplant centers with an expert reading the biopsy, rather than at the OPO prior to allocation. Some OPOs may not have the ability to comply with this proposal.

Initially, when considering this proposal, members of the Committee opposed recommending it to the Board. As the Committee discussed the policy, the debate turned to how the policy could be improved so that it could be recommended to the Board. Committee members felt that, while they did not support the proposal in its current form, it could be easily modified. For example, if the goal of the proposal is to standardize how biopsies are to be performed, then the OAC should put forward a proposal to standardize how biopsies are to be done. If the intent is to implement a data collection mechanism for scientific study, then the OAC could put forward a proposal for that purpose. Committee members felt that there was a disconnect between the purpose of the policy and what it would do if implemented, and that better clarification of exact goals of the proposal is needed. The role of the POC is to assure that there is compelling evidence that the proposed policy will meet its goal(s). The Committee felt that what is needed is a proposal that states how a biopsy should be performed under ideal circumstances. Whenever possible, OPOs should strive to achieve this standard. The POC approved the following motion by unanimous vote:

Motion: The modifications to Policy 3.5.9 (Minimum Information/Tissue for Kidney Offer) proposed by the Organ Availability Committee are not ready to be considered by the Board as currently written. However, the POC strongly recommends that the OAC put forward a proposal to standardize the biopsy technique that does not mandate additional data collection.

Committee vote: 11 in favor, 0 opposed, 0 abstentions.

³Hematoxylin and eosin (H&E) and periodic acid-Schiff (PAS) stains.

3. Proposed Modifications to Policy 5.0 (Standardized Packaging and Transporting of Organs and Tissue Typing Materials). Committee member Simon Horslen, M.D., reviewed this proposal from the Operations Committee. The proposal addresses live donor organ packaging and transport. The purpose is to improve safety and standardization of organ handling, and is meant to support live donor transplantation and make it safer. The Committee reviewed the comments from the regions, noting that Regions 4, 5, 7, 8, 9 and 10 approved an amended version of the proposal.

The proposal states that “Some type of label must accompany the donor organ, and documentation must be present in both the donor and recipient charts.” Committee members questioned how a label would be applied when the organ is being transported in a basin from one room to another within the same OR suite, as there is no paperwork that would accompany a sterile basin. Committee members suggested that perhaps this should only apply to organs that will be packaged and shipped. Committee members questioned what a “time out” would accomplish, although the “time out” period is recommended, not mandated. It was further suggested that the following sentences should be stricken: “Some type of label must accompany the donor organ and documentation must be present in both the donor and recipient charts. A “time out” prior to leaving the donor operating room and an additional “time out” upon arrival in the candidate operating room are recommended.” Committee members agreed that when a live or deceased donor organ leaves an OR suite it should be packaged in the approved way, and that a process must be in place when an organ goes between one room and another in the same suite, but that the Host OPO and/or transplant center should standardize the procedure within their center. One member suggested that the Operations Committee consider labeling of pumped kidneys as well. The POC approved the following motion by unanimous vote:

Motion: The modifications to Policy 5.0 (Standardized Packaging and Transporting of Organs and Tissue Typing Materials) proposed by the Operations Committee are supported by the POC and are appropriate for Board consideration, with the request that that the portion of the policy dealing with interactions between a single operating room suite be stricken or changed.

Committee vote: 12 in favor, 0 opposed, 0 abstentions

4. Proposed Modifications to Policy 3.1 (Organ Distribution: Definitions). Committee members Cedric Sheffield, M.D., and Melissa Gardiner reviewed this proposal, which was in response to an incident that was reported to the MPSC regarding an incorrect, but ABO-identical organ placement error. The transplant center identified that the following situations contributed to the error:

- Both kidneys and both candidates were of the same blood group;
- Both kidneys arrived within two hours of each other; and
- There was a lack of communication of the UNOS Donor ID numbers in the operating room.

The Operations Committee put forward the policy proposal to prevent such errors, and to improve patient safety by requiring verification of UNOS Donor ID number of all organs prior to transplant. All 11 Regions were in favor of the proposal, with some proposing amendments.

Dr. Sheffield raised the concern that the opportunity for error occurs because there is not a unique relationship between the intended recipient and the UNOS donor ID number, and suggested that three components are necessary for safety:

1. Confirmation of recipient identification and blood type;
2. Confirmation of donor ID number and compatible blood type; and
3. An association between the recipient (name and perhaps unique identifier number) and donor organ Donor ID number). This would require those in the operating room to know, confirm,

and document the results of the offer/acceptance process. Thus kidney A would be known to be for recipient A and kidney B would be known to be for recipient B.

Committee members were informed that, when DonorNet[®] goes on-line, the linkage between donor and recipient will be clear. However, there was still concern about what happens to that linkage when the organ does not go into the intended recipient but into a back-up recipient. The POC approved the following motion by unanimous vote:

Motion: The modifications to Policy 3.1 (Organ Distribution: Definitions) proposed by the Operations Committee are supported by the POC and are appropriate for Board consideration, with the request that the Operations Committee require verification of the unique linkage between the donor and the recipient.

Committee vote: 11 in favor, 0 opposed, 0 abstentions.

Table 2. Summary of Proposals Reviewed by the POC, January 24, 2007

Policy Proposal	Sponsoring Committee	Public Comment	POC: Submit to Board?	POC Comments
Policy 3.5.9 (Minimum Information/Tissue for Kidney Offer))	Organ Availability	11/2006	No	The POC strongly recommends that the OAC put forward a proposal to standardize the biopsy technique that does not mandate additional data collection.
Policy 5.0 (Standardized Packaging and Transporting of Organs and Tissue Typing Materials	Operations	11/2006	Yes	The POC requests that that the portion of the policy dealing with interactions between a single operating room suite be stricken or changed.
Policy 3.1 (Organ Distribution: Definitions).	Operations	11/2006	Yes	The POC requests that the Operations Committee require those in the OR to verify the unique linkage between the donor and the recipient.

5. Pediatric Data Forms Revisions. Dr. Horslen, vice chair of the Pediatric Transplantation Committee, reviewed a proposal from that Committee regarding changes to data collection forms for pediatric candidates and recipients. Pediatric data elements were not included in the Data Reduction project undertaken by the POC in 2006 and approved by the Board in June 2006. The Pediatric Committee reviewed the changes made to the adult forms, and agreed with all of the deletions except for those pertaining to long term growth and development. The Committee asked how long pediatric patients would be followed using the pediatric follow-up form. Some Pediatric Committee members would like for patients transplanted as pediatrics to be followed until age 24 or 25, but recognize that this may be difficult logistically. However, if a patient is transplanted at age 5, it does not make sense to stop follow-up at age 10, as many feel that pediatric patients should be followed at least through

puberty. The POC unanimously supported the changes proposed by the Pediatric Committee, but asked for a recommendation for length of follow-up for pediatric transplant recipients. The Pediatric Committee plans to issue this for public comment in March 2007.

6. Process for Review of Existing Policies. The Committee considered the proposed process for review of existing policies (**Exhibit E**). This review is a requirement of the OPTN contract as well as one of the OPTN President's Annual Goals set for the POC. Committee members John Roberts, M.D., and Elizabeth Pomfret, M.D., were asked to review the Liver allocation policy, beginning with the sections on the use of waiting time and blood type compatibility in the allocation algorithm, using a proposed review template. These sections of policy were selected for the trial review because it was thought that they would be simple to review. However, the reviewers found that these policies were much more complicated than anticipated, as the goals are not easily determined in some cases, and the policies were interlinked. The reviewers found that Policy 3.6.3 was poorly written and very confusing to read. Policy 3.6.2 states the policy for ABO compatibility, which is different for Status 1A/1B candidates versus MELD/PELD candidates. The Status 1 policy was not changed when the MELD policy was implemented, so this is a remnant from a prior policy era. Candidates in Status 1A/1B are ranked based on a combination of points for waiting time (0-10) plus points for blood type compatibility (0-10). Thus, a candidate who has waited longest in that Status could potentially receive an offer for an ABO compatible donor ahead of a candidate who is of identical blood type to the donor but has only been in that status a short time. This policy was more appropriate prior to the redefinition of Status 1, when patients could potentially stay in Status 1 for a long time. The policy may still apply for Status 1B, which applies to chronically ill pediatric patients, but Status 1A patients, who are in fulminant hepatic failure, should not more than a week in that status. When this policy was originally put into place, outcomes for recipients of compatible blood type livers were likely worse than for identical blood type livers. This may no longer be the case, and so the original goals of the policy may no longer apply.

UNOS staff noted that the existence of variances, exceptions, etc., which are located in other parts of the policy, also make it difficult to understand how the match is constructed from reading the policies in isolation. The Committee recommended that the Policy Analysts at UNOS should be responsible for providing the background for the policy, including the intent as stated by the Committee, the analyses used to support the policy at the time, interaction with other policies, etc. Once the POC formulates its recommendations, those will go back to the sponsoring Committee. The Policy Analysts will also take the lead in rewriting the policies as appropriate. The recommendations should be well-summarized for the Committees.

Committee members suggested that the Committee review existing policies on a "higher level" than the process for newly proposed policies, perhaps addressing questions such as :

- Does the policy state the intended goal/purpose?
- Is it being monitored to assess if it is meeting that goal?
- Is this policy relevant to what we are currently doing/ Does it still fit within the policy now?
- Does the policy meet the performance measures from the OPTN Final Rule?
- Does it appear to contribute to the goals of the OPTN?
- Is it possible to determine the effect of modifying the policy?

The review should utilize the Policy Development Checklist. Drs. Roberts and Pomfret will continue their review of the liver allocation policy, and Dr. Orłowski will make further assignments for policy review.

7. Scorecard Subcommittee Report. In the OPTN contract proposal, UNOS proposed that

“...to guide the Committee’s deliberations, UNOS proposes an evaluation scorecard for the policy or the proposal. The measures could include factors such as whether adequate research has been conducted; whether the proposal is written in easily understood, unambiguous terms; whether alternate systems were considered; and whether the performance measures are adequate for future evaluation of a proposal’s success once adopted. The evaluation scorecard would also form the basis for feedback to the Board of Directors and sponsoring Committees.”

The POC created a Subcommittee to begin this work. The POC Scorecard Subcommittee met on January 4, 2007 and January 19, 2007. The deliberations of the January 4 teleconference call are included in **Exhibit F**. During the January 18, 2007 call, the Subcommittee reviewed two scorecards that had been created for the purposes of discussion (**Exhibit G**).

The Subcommittee found the first scorecard example to be simpler, but the second differentiated the program and strategic plan goals and included a method for assigning points. Committee members felt that advancement of the program and strategic goals should be weighted heavily. Committee members discussed whether policies that relate to patient safety would be adequately addressed. However, a policy that affects patient safety may likely impact a large group of patients and would receive points for that aspect. For example, the double verification policy for ABO would potentially affect the entire waiting list. Jeff Orłowski, Subcommittee chair, recommended that the Committee approve a model that they could begin to use and modify if necessary. The scorecard is for use by the Committee, so it must meet the Committee’s needs. The Committee is also free to change the scorecard if it is not working as intended. It was recommended that the sponsoring Committee should fill out the scorecard, rather than the POC, as part of the process to forward items to the POC. The sponsoring Committee will be more familiar with the potential impacts of the proposed policy and better able to provide the information. The Subcommittee will meet one more time to finalize the scorecard.

8. Process for Written Recommendations to the Board. The OPTN contract states that “the contactor shall be responsible for presenting written recommendations from the POC to the Board of Directors and the Project officer on a semiannual basis. All members of the POC shall be responsible for signing the written recommendations and an opportunity shall be provided for members to present dissenting views.” The Committee voted unanimously to recommend that the “Policy Tracker,” which includes a summary of the POC’s recommendations, should be circulated for all members to sign on a semiannual basis.

9. Ascertainment of Death after Graft Failure. As part of the Data Reduction project, the Board approved a modification to Policy 7.1.3 in June 2006 that would eliminate the requirement to follow patients after their graft has failed. During the August 16, 2006, Committee meeting, Erick Edwards, Ph.D., UNOS Assistant Director of Research, noted that the policy as revised implies that all patients should be followed until death, whereas the intent was to discontinue follow-up once the graft has failed for kidney or kidney-pancreas recipients. At the time, the Committee agreed that the policy for kidney, pancreas, and kidney pancreas transplants, and perhaps isolated intestine transplants, should be different from liver and thoracic transplants. The SRTR was asked to propose a time frame for follow-up post-graft failure. During the October 16, 2006, meeting, the Committee reviewed data prepared by the SRTR regarding follow-up ascertainment of death after graft failure. An updated analysis was presented during the January 2007 meeting. The SRTR determined the number of deaths after graft failure for 2000-2005 that could only be found using OPTN data. For liver and kidney, there were 51 and 38 deaths found only within the OPTN, most of which were reported to the OPTN within a year after graft failure. For heart recipients, 16 deaths were found only in the OPTN,

and 15 of those were reported within 21 days of the graft failure. The SRTR plans to look at subgroups of the data (e.g., pediatric patients, those patients with out social security numbers). The SRTR will make a more formal report during the May 2007 meeting.

10. KARS Update. The Committee continues to review progress made towards a revised kidney allocation system. Several Committee members also serve on the Kidney Allocation Review Subcommittee (KARS), which will be hosting its first public forum in Dallas on February 8, 2007. The Committee will review the report from the forum and subsequent meeting when it is available.

**Policy Oversight Committee
January 24, 2007
Chicago, IL**

Committee Members in Attendance

Janis M. Orlowski, M.D.	Chair
Elizabeth A. Pomfret, M.D., Ph.D.	Vice chair, Liver and Intestinal Organ Transplantation Committee
Peter G. Stock M.D., Ph.D.	Vice chair, Kidney Transplantation Committee
Maryl Johnson, M.D.	Vice chair, Thoracic Organ Transplantation Committee
Simon Horslen, M.D.	Vice chair, Pediatric Transplantation Committee
Ray Gabel (via teleconference)	Vice chair, Patient Affairs Committee
Jeffrey P. Orlowski, M.S., CPTC	Vice chair, OPO Committee
Melissa Gardiner	At-large
John P. Roberts, M.D. (via teleconference)	At-large
Judy Jones Tisdale, Ph.D.	At-large
Winfred W. Williams, M.D.	At-large
James J. Wynn, M.D.	At-large
Cedric D. Sheffield, M.D.	At-large, Minority Affairs Committee
Ginny McBride, R.N.,M.P.H,CPTC	OPTN Project Officer, Ex Officio, non-voting
Alan Leichtman, M.D.	SRTR, Ex Officio, non-voting
Robert Wolfe, Ph.D.	SRTR, Ex Officio, non-voting

Committee Members Unable to Attend

Jack D. Kalbfleisch Ph.D.	At large
Felicia B. LeClere, Ph.D.	At-large
Richard N. Pierson III, M.D.	At-large
Bruce W. Schmeiser, Ph.D.	At-large
James F. Burdick, M.D.	Director, Division of Transplantation, Ex Officio, non-voting
Gregory Fant, Ph.D., MACE, FRIPH	SRTR Project Officer Ex Officio, non-voting

Staff in Attendance

Erick Edwards, Ph.D.	Assistant Director, Research
Mary D. Ellison, Ph.D., M.S.H.A.	Assistant Executive Director for Federal Affairs
Ann M. Harper	Research/Policy Analyst, Staff Liaison to Committee
Berkeley Keck	Assistant Executive Director, IT
Deanna Sampson, J.D.	Director, Evaluation and Quality, Staff Liaison to Committee