OPTN/UNOS PANCREAS TRANSPLANTATION COMMITTEE
SUMMARY

I. Action Items For Board Consideration

- The Board is asked to approve a white paper on reimbursement for islet cell transplantation that the Pancreas Transplantation Committee prepared in collaboration with the American Society of Transplant Surgeons. The paper will be sent to the Centers for Medicare and Medicaid Services with the approval of UNOS, the ASTS, and other relevant organizations in the islet transplant community. (Item 1, Page 3)

II. Other Significant Issues

- The Committee reviewed data on the recovery of deceased donor pancreata. The Committee also formed a subcommittee to review a survey to be sent to OPO Executive Directors to determine the factors and practices that influence the recovery and transplantation of whole organ pancreata. (Item 3, Page 5)

- The Committee considered surgical pancreas recovery standards. (Item 4, Page 6)

- The Committee was updated on the activities of the Tiered Acceptance/ DSA Task Force and formed a subcommittee to recommend characteristics to be included in profiles for pancreas and kidney-pancreas donors. (Item 5, Page 6)

- The Committee reviewed a letter referred by the MPSC from a program director whose program was under review for inactivity. The Committee sent a memorandum to the MPSC advising that the kidney payback system may be a legitimate factor in the program's inactivity. (Item 6, Page 6)

- The Committee formed a subcommittee to review the pancreas alternative allocation systems. (Item 8, Page 7)

- The Committee discussed the request from the MPSC and formed a subcommittee to work with the SRTR to develop an outcome review model for pancreas transplant centers. (Item 11, Page 7)

This page is intentionally left blank.

REPORT OF THE
OPTN/UNOS PANCREAS TRANSPLANTATION COMMITTEE
TO THE
BOARD OF DIRECTORS

Los Angeles, CA
September 17-18, 2007

Rainer W. G. Gruessner, MD, Chair
Dixon B. Kaufman, MD, PhD, Vice Chair

This report includes items addressed by the Pancreas Transplantation Committee at its meetings held on May 18, 2007, and July 26, 2007:

1. **White Paper on Charges for Pancreata Recovered for Islet Transplantation**

During the June 2006 meeting of the Pancreas Transplantation Committee, Peter Stock MD, PhD. reviewed with the Committee background information regarding the reimbursement issues that are affecting islet cell transplantation. OPOs are currently being instructed to treat any pancreas procured for islet cell transplantation the same as other organs recovered. Since multiple pancreata may be required to achieve insulin independence, the cost has become challenging and even prohibitive for some centers.

Dixon Kaufman, MD, provided additional background to the Committee by describing the January 2005 consensus conference to improve pancreas allocation (held in Miami, Florida). One of the sessions during this conference addressed the financial barriers to the field. During this session, discussions were held among the pancreas and islet transplanters and CMS representatives. CMS expressed that its understanding for pancreas procurement is that the cost for procuring a whole organ is the same as for islet cells. Transplant centers are increasingly unable to pay this full charge. The whole concept is still very confusing and is exacerbated by a November 2004 memo from Riverbend, a Medicare intermediary, for cost accounting. There is continuing uncertainty with regard to the accounting for this procedure. The Committee determined that it would write a white paper to explain its understanding of the current situation, make recommendations, and seek remediation.

During the October 2006 meeting, the Committee continued its discussion about how to communicate with CMS regarding the effect that its reimbursement policies are having on patient access to islet cell transplantation. Dr. Kaufman discussed his work on a white paper to further explain the issues.
One of the purposes of the paper is to define pancreata which are transplantable as whole organs, those that are transplantable as islet cells, and those that are suitable for research purposes. By describing which organs may be suitable for each purpose, Dr. Kaufman explained that the Committee could more effectively make an argument for modifications to the acquisition fee. Dr. Stock also mentioned that the current fee structure is having an effect on centers with islet cell transplantation grants from the Juvenile Diabetes Research Foundation (JDRF) and other sources; some of these centers may have to reduce the number of islet cell transplants as a result. This result appears inconsistent with goals underlying this funding, i.e., studying the efficacy of pancreatic islet transplantation, as well as federal goals to increase organs procured and transplanted per donor. The opportunity to better align the various regulations and policies impacting these goals may be the appropriate focus for discussion with CMS and others.

Gregory Fant, PhD, of HRSA offered to the Committee that the regular meetings between HRSA and CMS may be an appropriate forum to initially raise this issue. Dr. Fant also advised the Committee that one of the reasons CMS may not have made adjustments to its reimbursement policies is due to its interpretation of regulations regarding reimbursement of islet cell transplantation. One member remarked that the Committee is not asking for a change in regulation, rather the Committee is asking that CMS

review its interpretation and clarify the language regarding the amount that OPOs must charge for acquisition of pancreata for islet cell transplantation.

One member remarked that this effort will require a consensus of stakeholders, primarily the Center for Islet Transplantation (CIT), JDRF, UNOS, the American Society for Transplantation (AST), and the American Society for Transplant Surgeons (ASTS). The Committee agreed and decided to generate the white paper as a mechanism for consensus building among these groups. This white paper, once completed, will be reviewed by either the Board or Executive Committee.

In May 2007, the Committee reviewed the latest draft of the white paper on charges for pancreata recovered for islet transplantation, which has been approved by the Juvenile Diabetes Research Foundation, American Society of Transplantation, and the American Society of Transplant Surgeons. The paper identifies two specific limitations related to organ acquisition charges for islets that, if rectified, could result in a substantial increase in utilization of pancreata from deceased donors and promote further scientific evaluation of islets as a biological cellular therapy for Type I diabetes. The first limitation is that current regulations do not adequately delineate the criteria by which donor pancreata recovered for islet transplantation can be considered unsuitable for transplantation and therefore billed at a discounted rate. Secondly, application of full standard acquisition charge (SAC) for pancreata which result in islets that are successfully transplanted may be inappropriate since multiple transplants may be required to achieve insulin independence. HRSA recommended that the paper include citations, distinction of which final rule is referenced, and delineation of which agency should address certain issues. Members also suggested that the magnitude of the issue (e.g., effect of reimbursement policies on access to islet cell transplantation) be mentioned in the paper. Dr. Kaufman agreed to make these changes. The Committee voted to send the white paper (pending final modifications) to the OPTN/UNOS Board of Directors or Executive Committee for approval and circulation to CMS (11-Approved, 0-Opposed, 0-Abstentions). In June and July, Committee members made final changes to the white paper (Exhibit A). The Committee still intends to garner support for publishing and sending these recommendations to CMS from other relevant organizations in the islet cell transplantation community.

The Committee recommends the following resolution for consideration by the Board:

> ****RESOLVED, the OPTN/ UNOS Board of Directors hereby approves the white paper titled "White Paper on Charges for Pancreata Recovered for Islet Transplantation" as presented in Exhibit A, effective September 18, 2007.**

2. HHS Program Goal Progress Update

In May, UNOS staff provided an update on the efforts of the OPTN to achieve the HHS Program Goals. The goals presented aim to increase the number of donors, organs transplanted, and organs transplanted per donor (Exhibit B). The number of deceased donor organs transplanted (24,461) did not meet the 2006 HHS goal of 25,651, but the trend for this goal is upward. In 2006, the OPTN met the goal of increasing non-DCD donors each year. For the goal of increasing donation after cardiac death (DCD) donors each year, the OPTN is one year behind the program goal. The rate for organs transplanted per non-DCD donor in 2006 was 3.13, a rate lower than the 2006 program goal of 3.44. Expanded criteria donors (ECD) have a much lower rate of organs transplanted than standard criteria donors (SCD), which reduced the overall rate. The number of organs transplanted per donor for DCD donors did not reach the 2006 program goal; however, there was a sharp increase in this rate in 2006 compared to the previous several years. A member commented that separate goals for ECD and SCD donors should be considered by HHS. The Committee requested that pancreas-specific data for these program goals be reported at the next meeting.

3. Data Request: Report on Recovery of Deceased Donor Pancreata

At a previous meeting, the Committee reviewed a data analysis presented by UNOS staff on refusal reasons for pancreata from "good" deceased donors. A "good" donor is defined as a donor who is age 19-40, has a BMI less than 30, is not a DCD, and has a negative serology. The most common refusal reason was donor quality/age. The Committee requested further information on the 581 previously identified "good" donors, including:

- the number of donors in which the liver was not used,
- how often the liver was shipped out of the area and then discarded,
- whether HLA information was available at the time of the match, and
- the characteristics of the donors whose livers were transplanted.

During the May 2007 meeting, Jennifer Wainright, PhD, presented a data analysis in response to these requests (Exhibit C). Almost 90% of the livers from these donors were transplanted, with only 0.7% of the livers from "good" donors shared and discarded. HLA information was available at the time of the match 92% of the time. Donor characteristics were more variable. The most common cause of death for these donors was head trauma at 59.3%, followed by cerebrovascular accident and anoxia. Motor vehicle accidents accounted for 30.6% of the circumstances of death. Blunt injury, stroke, and gun shots were the most common mechanisms of death. Most donors did not have a history of cancer (98.4%), diabetes (98.8%), hypertension (87.7%), cigarette use (74.9%), cocaine use (79.3%), or heavy alcohol use (79.9%). Sixteen percent were classified as high risk donors, according to the Centers for Disease Control guidelines and 35.4% had tattoos. Members asked for a list of refusal reasons and commented that cold ischemic time may be an important factor in the decision. Members expressed concern that time is wasted by offering pancreata to centers that will not accept them. The Committee also mentioned procurement issues, including damage to the organ in procurement and long wait time to procure or to receive the pancreas. A member noted that risk adjustment needs to be addressed so that centers are not adversely affected for accepting pancreata from high risk donors.

During its January meeting, the Committee discussed the differences in waiting time for pancreata between Donor Service Areas (DSA). At that time, the Committee requested DSA specific information about pancreas allocation, reimbursement, and barriers to pancreas placement. To obtain this information, UNOS staff developed a draft of an online survey to be sent to Organ Procurement Organization (OPO) Executive Directors. Members commented that it may be difficult to get OPOs to respond to very specific questions, whereas broader questions may not result in useable data points. A member noted that there is a national demand for pancreata but not necessarily a local demand, so it is important to understand how to improve placement. Another member said that if the pancreas is a national resource, then perhaps the allocation system should have a more national focus. A member suggested that questions be included in the survey about placement time relative to procurement. The Committee discussed the need for teams that are skilled and proficient in pancreas recovery. Furthermore, availability of local procurement teams capable of procuring pancreata remains a concern. The Committee raised the issue of reimbursement and financial disincentives for the pancreas (i.e., lower reimbursement even though more work is involved in pancreas recovery than for other organs). Another member commented on the massive increase in the number of pancreas offers since DonorNet® was implemented and suggested that there may be a better way to screen these offers. The Committee formed a subcommittee to review the draft of the survey. Kim Patton, RN, CPTC, Dixon Kaufman, MD, PhD, Kenneth Brayman, MD, PhD, Paul Volek, MPH, and Stephen Rayhill, MD volunteered to serve on this subcommittee.

4. **Pancreas Recovery Standards**

In May, Khalid Khwaja, MD, presented pancreas recovery standards (Exhibit D and Exhibit E). The intent of the presentation was to bring the Committee to a consensus on the step-by-step procedure for pancreas recovery that could be endorsed as a best practice guideline. If adopted nationally by recovery teams, these standards may make surgeons more confident in accepting a pancreas procured by another team. The Committee made suggestions to the procedure to make it acceptable to as many stakeholders as possible. Dr. Khwaja will make changes and submit the standards to the Committee for final approval. A member suggested that a video of this procedure be made. The Committee would like to circulate these guidelines to pancreas program directors and OPOs. UNOS staff will recommend a path forward for disseminating this procedure as a best practice guideline.

5. **Pancreas Tiered Acceptance**

UNOS staff presented information on the DSA Task Force Work Group Tiered Acceptance Project (Exhibit F). The purpose of this project is to develop a system to streamline the organ placement process by using standard acceptable donor profiles rather than screening the individual donors. If a donor does not meet the criteria for a particular profile, then candidates who are assigned to that profile will not be placed in the match run. Thus, the system is designed to eliminate candidates who would not consider an organ from a particular donor from the match run. Each transplant program could specify the acceptable ranges for criteria in its profiles and assign each candidate to a profile. The system allows for different ranges within each profile based on distance and for individual candidate criteria, such as hepatitis C virus (HCV), hepatitis B core antibody (HBV), and, and HTLV+ for pancreas candidates. The DSA Task Force asked the Committee to review the Tiered Acceptance concept and the elements in the two profiles, to discuss the need for a third profile, and to send its recommendations to the Operations Committee. The Pancreas Transplantation Committee decided that only two profiles are necessary for the pancreas. The Committee set up a subcommittee to review the characteristics for pancreas and pancreas-kidney donors. Rainer Gruessner, MD, Juan Sanabria, MD, Alexander Wiseman, MD, Stephen Rayhill, MD, and Kim Patton RN, CPTC volunteered for this subcommittee.

The Committee discussed the large number of offers being made for organs that would never be accepted because of distance. The Operations Committee recommended to use the distance field on DonorNet® to screen candidates and take them off the match run. Tiered acceptance would supersede this screening measure once it is implemented. The Committee voted to utilize geography as a screen for whole pancreas matches in DonorNet® (8-Yes, 0-No, 0-Abstentions).

6. **Referral from Membership and Professional Standards Committee (MPSC) Regarding Program Inactivity**

The Committee reviewed a letter from a pancreas transplant program under review by the MPSC for inactivity (Exhibit G). Reasons for this inactivity included payback debt levels due to acceptance of zero-antigen mismatched kidneys. The Committee debated what data would be necessary to bolster a recommendation for a change in policy. The SRTR remarked that modeling would not be appropriate for this review. The Committee decided to write a letter to MPSC Chair, Tim Pruett, MD, to request that payback debts be disassociated from Simultaneous Pancreas-Kidney (SPK) transplant unless the payback is an SPK (9-Yes, 0-No, 0-Abstentions). The Committee Chair will draft this letter and submit it to the Committee for approval. The Committee also considered writing a letter to pancreas transplant program directors regarding this issue asking them for their support and determining what data would be available for developing a policy proposal to address this issue. In July 2007, the Committee sent a memo to the current MPSC chair, Robert S. D. Higgins, MD, MSHA, stating that it is reasonable to consider the effect of the renal payback system on pancreas transplant programs when evaluating these programs (Exhibit H).

7. Facilitated Pancreas Allocation

UNOS staff explained the policy for facilitated pancreas allocation and suggested that education may be helpful to make it more well-known (Exhibit I). The Committee recommended writing a letter to program directors to inform them of the facilitated pancreas allocation option. UNOS staff will share which centers have elected to participate in facilitated pancreas allocation once it is available.

8. Research Design for Alternative Allocation Systems

The Committee formed a subcommittee to review the five alternative pancreas allocation systems (Exhibit J). In order to comply with the OPTN Final Rule and OPTN/UNOS Policies, alternative allocation systems must demonstrate that they meet certain requirements at pre-determined time intervals. This subcommittee will assist UNOS Staff in this on-going assessment.

9. Recognition of Outgoing Members, Terms Ending June 30, 2007

The Committee Chair recognized and thanked the following Committee members for their service to the Pancreas Transplantation Committee:

Khalid Khwaja MD	Region 1 Representative
Michael J. Hanaway MD	Region 3 Representative
Richard J. Knight MD	Region 4 Representative
Christopher L. Marsh MD	Region 5 Representative
Stephen C. Rayhill MD	Region 6 Representative
Dixon B. Kaufman MD, PhD	Region 7 Representative
Juan R. Sanabria MD	Region 10 Representative
Issac Bayon	At Large
Muralikrishna S. Golconda MD	At Large
Robert A. Goldstein MD	At Large
Mary S. Leffell PhD	At Large
James F. Markmann MD, PhD	At Large
Helen Nelson RN, BSN, CCTC, CPTC	At Large
Kim J. Patton RN,CPTC	At Large
Tammie S. Peterson RN, BSN	At Large
Paul J. Volek MPH	At Large

10. Update on Computer Programming/Implementation Issues

UNOS Staff provided the Committee with an update on implementing calculated panel reactive antibody (CPRA) into UNet[sm]. This project will be implemented in the following phases:

- **Phase 1**, CPRA will appear on UNet[sm] reports, but it will not influence the match run. (anticipated implementation: Fall 2007)
- **Phase 2,** the UNet[sm] will use CPRA to award sensitization points, but PRA data will still be available on reports. (anticipated implementation: early 2008)
- **Phase 3,** PRA data will no longer be available on UNet[sm] reports. (anticipated implementation: to be determined)

11. Request from MPSC: Development of a Pancreas Outcome Review Model

The Membership and Professional Standards Committee submitted a request to the Committee to assist the SRTR in the development of a pancreas outcome review model (Exhibit K). The SRTR gave the Committee background information on its outcomes models. The SRTR publishes center-specific reports which compare actual and expected outcomes instead of comparing actual outcomes to a national average. These models are updated every six months to include characteristics that have a significant effect on outcomes. Historically significant characteristics are generally kept in the model. There is also the opportunity for inclusion of elements that are deemed to be important even if they are not significant. The SRTR would like to create an outcomes model for pancreas-after-kidney and pancreas-alone transplants. Members volunteered for a subcommittee to identify the initial co-variants that should be in

the model. Peter Stock, MD, PhD, Rainer Gruessner, MD, Stephen Rayhill, MD, Juan Sanabria, MD, and Muralikrishna Golconda, MD will serve on this subcommittee.

12. Review of Proposals Distributed for Public Comment on June 15, 2007 and July 13, 2007

On July 26, 2007, the Pancreas Transplantation Committee met jointly with the Kidney Transplantation Committee via conference call and Microsoft Live Meeting to discuss the public comment proposals that were distributed on June 15, 2007 and July 13, 2007.

1. **Request for Incorporating CPRA into an Existing Alternative System for Kidneys (Histocompatibility Committee)**

   During its May 2007 meeting, the Kidney Committee recommended that the request to maintain this alternative system should be circulated for public comment. At that time, the Committee stated that the design of this system, which would grant two priority points to moderately sensitized candidates, may provide the Committee with the data necessary to implement a "sliding scale" for sensitization in the new kidney allocation system. During its July 2007 conference call, Kidney Committee did not formally vote on this proposal, but reiterated its support that this alternative system be continued when the CPRA policy modifications are implemented.

   The Pancreas Committee voted to approve this proposal as written: 6 approved, 0 opposed, 1 abstention.

2. **Proposed Modifications to OPTN/UNOS Policy 4.0 (Acquired Immune Deficiency Syndrome (AIDS), Human Pituitary Derived Growth (HPDGH), and Reporting of Potential Recipient Diseases or Medical Conditions, including Malignancies, of Donor Origin) (Operations Committee)**

   The Kidney and Pancreas Committees met jointly via conference call in July 2007 to discuss this proposal. Overall, the Committees agreed with the intent of the proposal to improve patient safety. The Committees offer the following observations to the Operations Committee for consideration. Some Committee members remarked that the origin of disease is not always apparent which may make reporting of donor derived disease transmission nearly impossible. Additionally, the Committees discussed how the requirement for reporting "suspected or confirmed donor-derived transmissions" would be difficult to monitor and enforce.

   The Committees provide the following specific recommendations to the Operations Committee for consideration:

   1. Clarify the time limit of 24 hours mentioned in proposed policy 4.7.2.3 to be a business 24 hours. The Committee understands that the reporting tool is available through the UNOS and OPTN websites and that weekend transplant center personnel will likely have access to the internet; however, clarification of business 24 hours could improve compliance with this time limit.

   2. Clarify the language in policy 4.6.2.1. Currently, the language suggests that organs from donors with certain central nervous system (CNS) malignancies should not be used. The Committee does not believe that this is an appropriate or correct statement for policy language.

   3. Note in the policy that there are certain situations that require immediate notification (e.g., if a tumor is discovered on a kidney that is about to be transplanted).

   Pancreas Committee Vote: 4 approved, 1 opposed, 1 abstention
   Kidney Committee Vote: 14 approved, 1 opposed, 0 abstentions

3. **Proposed Modifications to OPTN/UNOS Policy 7.4 Submission of Organ-Specific Transplant Recipient Follow-up Forms. (Operations Committee)**
The Kidney and Pancreas Committees met jointly via conference call in July 2007 to review this proposal. The Committees voted to approve the proposal without further recommendations.

Kidney Committee Vote: 16 approve, 0 opposed, 0 abstentions
Pancreas Committee Vote: 5 approved, 0 opposed, 1 abstention

4. **Proposed Modifications to OPTN/UNOS Policy 3.5.9 (Minimum Information/Tissue for Kidney Offer) (Organ Availability Committee)**
The Kidney and Pancreas Committees met jointly via conference call in July 2007 to discuss this proposal. Both Committees expressed concerns about this proposal as described below. The Committees did not believe that enough evidence has been generated about pulsatile perfusion to support this policy recommendation. To date, no randomized controlled trials with sufficient statistical power have been conducted to examine the effects of pulsatile perfusion. All of the studies reviewed in the development of this proposal were of a retrospective observational design. Additionally, one Committee member stated that the chosen outcome of delayed graft function is fairly low in DCD kidneys and so the inclusion of this organ category may be inappropriate in this policy proposal.

The Committees also expressed concern that this proposal encourages a practice pattern. One member suggested that this practice should be vetted through other channels (e.g., society meetings, congresses, the peer reviewed literature) rather than through OPTN policy. The Committees understand that the sponsoring Committee's charge is to increase utilization of organs; however, the Committees disagree with the approach of dictating practice through policy.

Additionally, one member expressed that the requirement in proposed policy 3.5.9.2.3, which would encourage machine perfusion for sclerotic kidneys, is arbitrarily set at >10% glomerulosclerosis. This recommendation does not appear to be based on available evidence, and the Committees were hesitant to approve of this portion of the policy without adequate evidence to support it.

Finally, the Committees expressed concern over the policy development process employed for this proposal. Primarily, the Kidney Transplantation Committee expressed that it is inappropriate for one Committee to write and submit an organ specific policy without sending it to the organ specific Committee for review and comment.

Following this discussion, the Committees provided the following vote:
Kidney Committee Vote: 1 approved, 13 opposed, 0 abstentions
Pancreas Committee Vote: 1 approved, 4 opposed, 1 abstention

5. **Proposed Modifications to OPTN/UNOS Bylaws, Appendix B, Attachment I, Section XIII, C (2) Kidney Transplant Programs that Perform Living Donor Kidney Transplantation (Membership and Professional Standards and Living Donor Committees)**
The Kidney and Pancreas Committees met jointly via conference call in July 2007 to discuss this proposal. Both Committees expressed that the scope of this proposal is too large for an expedited public comment cycle of only 30 days. This timeframe has not allowed for adequate discussion or consideration during in-person Committee meetings. While the Committees believe that there needs to be coverage of living donation in the bylaws and policy, they are unable to approve this proposal at this time due to the concerns described below.

The Committees were primarily concerned with the methods used to develop these bylaw recommendations. Sixteen large transplant programs were surveyed and requirements were gleaned from their practices. The Committee expressed concern that smaller transplant programs may be unable to abide by the recommended bylaws due to staffing or other resource limitations. Larger centers will have larger staffs and more flexibility for staffing an independent donor advocate team.

The Committees did not formally vote on this proposal and instead decided to continue the discussion at the upcoming in person meetings in August and September 2007.

6. **Guidelines for the Medical Evaluation of Living Kidney Donors (Living Donor Committee)**
The Kidney and Pancreas Committees met jointly via conference call in July 2007 to discuss this proposal. Both Committees understood that these guidelines would not carry the weight of policy in terms of OPTN enforcement and monitoring, but expressed concern that the general public may perceive the guidelines to imply a standard of care. The Committees expressed that the guidelines should be less prescriptive and more general due to the changing nature of transplantation. Specifically, the Committees stated that the age contraindication, which suggests that individuals under the age of 18 should not be considered for donation, was too prescriptive and did not allow for extenuating circumstances when younger donors may be appropriate. The Committees also expressed that organizations such as the National Kidney Foundation and the American Society of Transplantation should be engaged in the development of guidelines. Finally, the Kidney Transplantation Committee expressed that it needs to be involved in the creation of policy or guidelines that specifically affect kidney transplantation. Neither Committee formally voted on this proposal.

7. **Guidelines for the Consent of Living Donors (Living Donor Committee)**
The Kidney and Pancreas Committees met jointly via conference call in July 2007 to discuss this proposal. Both Committees understood that these guidelines would not carry the weight of policy in terms of OPTN enforcement and monitoring, but expressed concern that guidelines to the general public imply a standard of care. Additionally, the Kidney Transplantation Committee expressed that it needs to be involved in the creation of policy or guidelines that specifically affect kidney transplantation. Neither Committee formally voted on this proposal.

13. **E-mail Discussion of Committee Priorities**
During July 2007, members of the Committee submitted suggestions to the full Committee via e-mail for what issues the Committee should consider in the next two years. These suggestions related both to whole pancreas transplantation and islet cell transplantation. The Committee members raised the following issues as possible priorities for the Pancreas Transplantation Committee:
    - CMS ruling on intent to transplant
    - Impact of the renal debt payback system
    - Development of an algorithm for when whole pancreas transplantation versus pancreatic islet transplantation should take place based on recipient health status
    - Financial reimbursement for islet cell recovery, including finalizing the Committee-approved white paper on reimbursement to be sent to CMS and proposing a conference to discuss islet reimbursement including representatives from HRSA, CMS, and private payers
    - Strong representation in KARS
    - Utilization of pancreata, specifically how to lower the discard rate and how to expedite shipping to other OPOs and transplant centers
    - Investigation of regional pancreatic recovery teams and other methods of designating who should procure a pancreas

- Development of or collaboration with existing standardized islet and pancreas transplant databases that would allow comparative analyses
- Development of a resource manual for standard recoveries, both for whole pancreas and islets
- Evaluation of donor management and assessment for whole pancreas and islets, including the use of insulin, the use of A1c for evaluation, and insulin intolerance in donors
- Assessment of policy dealing with prioritization of whole pancreas versus pancreatic islets and simultaneous kidney-pancreas transplants
- Discussion of the use of DCD pancreata
- Recommendations for additional screen-out criteria in DonorNet
- Analysis of the impact of DonorNet on the number of pancreas transplants
- Analysis of the efficacy of CPRA, once it is implemented
- Investigation of referral patterns for pancreas transplants
- Exploration of the continued need for facilitated pancreas allocation
- Discussion of the controversy of the efficacy of different preservation fluids and of whether these fluids could extend preservation time for islets
- Development of a standard quality control form for pancreas recovery to be used by islet centers
- Recommendations for additions to discharge instructions for pancreas transplant patients

The Committee will continue to discuss and to prioritize these items during its August 24, 2007 conference call and September 26, 2007 meeting.

PANCREAS COMMITTEE		JANUARY 1, 2007 - JUNE 30, 2007					
	MONTH	JANUARY	FEBRUARY	MARCH	APRIL	MAY	JUNE
	DAY					18	
	FORMAT					In Person	
NAME	POSITION						
Peter Stock MD, PhD	Chair					X	
Rainer W. Gruessner MD	Vice Chair					X	
Khalid Khwaja MD	Regional Rep.					X	
Michael Hanaway MD	Regional Rep.					X	
Richard Knight MD	Regional Rep.						
Christopher Marsh MD	Regional Rep.					X	
Stephen Rayhill MD	Regional Rep.					X	
Dixon Kaufman MD, PhD	Regional Rep.					X	
Alexander Wiseman MD	Regional Rep.					X	
Brian Flanagan PhD	Regional Rep.						
Juan Sanabria MD	Regional Rep.					X	
Kenneth Brayman MD, PhD	Regional Rep.					X	
Issac Bayon	At Large						
Muralikrishna Golconda MD	At Large					X	
Mary Leffell PhD	At Large						
James Markmann MD, PhD	At Large						
Helen Nelson RN, BSN, CCTC, CPTC	At Large						
Kim Patton RN,CPTC	At Large					X	
Tammie Peterson RN, BSN	At Large					X	
Paul Volek MPH	At Large					X	
James Burdick MD	Ex Officio, HRSA						
Gregory Fant PhD	Ex Officio, HRSA					X	
Ginny McBride RN,MPH,CPTC	Ex Officio, HRSA						
Laura Christensen MS	SRTR Liaison						
Jim Galloway PhD	SRTR Liaison						
Katherine Pearson	SRTR Liaison						
Randall Sung MD	SRTR Liaison					X	
Ciara Gould MSPH	Committee Liaison					X	
Maureen McBride PhD	Support Staff						
Dielita McKnight	Support Staff					X	
Sam Perry	Support Staff						
Jennifer Wainright PhD	Support Staff					X	
Kristal Wood	Support Staff						
Number of Committee Members Attending						19	
Total Number of Committee Members		33	33	33	33	33	33
Percentage of Committee Attending						57.58%	
Meeting Format						In Person	

PANCREAS COMMITTEE		JULY 1, 2007 - DECEMBER 31, 2007					
	MONTH	JUL	AUG	SEPT	OCT	NOV	DEC
	DAY	26					
	FORMAT	Live Meeting/ Teleconference					
NAME	POSITION						
Rainer W. Gruessner MD	Chair	X					
Dixon Kaufman MD, PhD	Vice Chair	X					
David Axelrod MD	Regional Rep.	X					
Peter Abt MD	Regional Rep.						
George Burke III, MD, FACS	Regional Rep.						
Marlon Levy MD	Regional Rep.	X					
Ron Taubman	Regional Rep.	X					
Christian Kuhr MD	Regional Rep.						
Joseph Leventhal MD, PhD	Regional Rep.						
Alexander Wiseman MD	Regional Rep.						
Sandip Kapur MD	Regional Rep.						
Venkatesh Krishnamurthi MD	Regional Rep.						
Kenneth Brayman MD, PhD	Regional Rep.						
Albert Hwa PhD	At Large	X					
David Harlan MD	At Large						
Khalid Khwaja MD	At Large						
James Markmann MD, PhD	At Large	X					
Christopher Marsh MD	At Large						
Helen Nelson RN, BSN, CCTC, CPTC	At Large						
Kim Patton RN, CPTC	At Large						
Paul Volek MPH	At Large						
Peter Stock MD, PhD	Ex. Officio	X					
James Burdick MD	Ex Officio						
Gregory Fant PhD	Ex Officio						
Christopher McLaughlin	Ex Officio						
Elizabeth Ortiz-Rios MD, MPH	Ex Officio	X					
Alan Leichtman PhD	SRTR Liaison	X					
Jim Galloway PhD	SRTR Liaison						
Keith McCullough MS	SRTR Liaison	X					
Randall Sung MD	SRTR Liaison						
Elizabeth Sleeman MHA	Committee Liaison	X					
Maureen McBride PhD	Support Staff						
Dielita McKnight	Support Staff						
Jennifer Wainright PhD	Support Staff	X					
Ciara J. Gould MSPH	Support Staff	X					
Number of Committee Members Attending		14					
Total Number of Committee Members		35	35	35	35	35	35
Percentage of Committee Attending		40%					
Meeting Format		Live Meeting/ Teleconference					