OPTN/UNOS Pancreas Transplantation Committee
Report to the Board of Directors
November 17-18, 2008
St. Louis, MO

Summary

Action Items For Board Consideration

- The Board is asked to approve a recommendation to modify the LifeSource (MNOP) pancreas alternative allocation system to restore the national requirements for when pancreas islet candidates should receive priority for a donor pancreas. (Item 1, Page 3)

Other Significant Issues

- MAOB, DCTC, and the Florida OPOs (FLFH, FLMP, FLSW, FLUF, FLWC) submitted their intent to dissolve their existing pancreas alternative allocation systems. (Item 1, page 3)
- The Committee developed revisions to Policy 3.8.1.6 (Islet Allocation Protocol) to clarify policy language and to add criteria for active status on the pancreas islet waiting list and sent these revisions out for public comment. (Item 2, Page 5)
- The Committee drafted revisions to Policy 3.2.7 (Pancreas Waiting List Criteria) and Policy 3.2.9 (Combined Kidney/Pancreas Waiting List Criteria) to allow candidates who need the pancreas for technical reasons as part of a multiple organ transplant to be listed on the pancreas waiting list and sent these revisions out for public comment. (Item 3, Page 8)
- The Committee is planning an islet consensus conference for 2009. (Item 4, Page 10)
- The Committee is investigating changes to pancreas allocation in light of the proposed revisions to the kidney allocation system. (Item 5, Page 11)
- The Committee is working with the SRTR to develop a combined SPK/PAK/PTA outcomes review model for use by the MPSC in reviewing pancreas program outcomes. (Item 6, Page 14)
- The Committee is developing a definition of graft failure that could apply to both whole pancreas and islet transplants. (Item 8, Page 16)
- The Committee is working with the SRTR to create a pancreas donor risk index. (Item 9, Page 16)
- The Committee requested that HbA1c be added as an optional field in DonorNet®. (Item 10, Page 17)

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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 August 24, 2007, September 26, 2007, December 7, 2007, March 14, 2008, May 9, 2008, July 18, 2008, and September 12, 2008:

1. Alternative Allocation System (AAS) Review

In Spring 2008, the OPTN sent applications to all groups with existing alternative allocation systems asking them to apply to continue their AAS's. At the time, there were five pancreas AAS's. Three groups (MAOB, DCTC, Florida Statewide) chose not to apply to continue their pancreas AAS's. The Pancreas Committee is responsible for reviewing all pancreas AAS applications and making a recommendation about whether the AAS should be continued.

a. LifeSource (MNOP) (Exhibit A)

LifeSource (MNOP) Organ Procurement Organization's alternative allocation system (AAS) for pancreas allocation was originally implemented in 2000 and has been revised several times since 2000. The LifeSource AAS has two components. This recommendation is to maintain the first component of the LifeSource AAS regarding level of mismatch and to eliminate the second component regarding additional priority for pancreas islet candidates. The two components of the LifeSource AAS are:

- The national allocation only gives priority for candidates who have a zero antigen mismatch with the donor. LifeSource allows additional priority for its pancreas candidates who have a 1, 2, or 3 antigen mismatch with the donor over candidates who have a 4, 5, or 6 antigen mismatch with the donor. Kidney/pancreas (KP) candidates have priority over all non-zero mismatch pancreas alone (PA) candidates. Additionally, ABO identical candidates have priority over ABO compatible candidates for each local classification.
    1. 0 ABDR Mismatch High PRA OPO PA - ABO Identical
    2. 0 ABDR Mismatch High PRA OPO PA - ABO Compatible
    3. High PRA OPO PA with Negative Crossmatch
    4. 0 ABDR Mismatch High PRA Regional PA
    5. 0 ABDR Mismatch High PRA National PA
    6. 0 ABDR Mismatch OPO PA - ABO Identical
    7. 0 ABDR Mismatch OPO PA – ABO Compatible
    8. For certain donors, OPO PA Islets* (See below for details)
    9. OPO KP** (not programmed)
    10. 1 ABDR Mismatch OPO PA - ABO Identical
    11. 1 ABDR Mismatch OPO PA – ABO Compatible
    12. 2 ABDR Mismatch OPO PA - ABO Identical
    13. 2 ABDR Mismatch OPO PA - ABO Compatible
    14. 3 ABDR Mismatch OPO PA - ABO Identical
    15. 3 ABDR Mismatch OPO PA - ABO Compatible
    16. Other ABDR Mismatch OPO PA - ABO Identical
    17. Other ABDR Mismatch OPO PA - ABO Compatible
    18. Regional PA
    19. National PA

20. 0 ABDR Mismatch OPO PA Islets - ABO Identical
21. 0 ABDR Mismatch OPO PA Islets - ABO Compatible
22. 1 ABDR Mismatch OPO PA Islets - ABO Identical
23. 1 ABDR Mismatch OPO PA Islets - ABO Compatible
24. 2 ABDR Mismatch OPO PA Islets - ABO Identical
25. 2 ABDR Mismatch OPO PA Islets - ABO Compatible
26. 3 ABDR Mismatch OPO PA Islets - ABO Identical
27. 3 ABDR Mismatch OPO PA Islets - ABO Compatible
28. Other ABDR Mismatch OPO PA Islets - ABO Identical
29. Other ABDR Mismatch OPO PA Islets - ABO Compatible
30. Regional PA Islets
31. National PA Islets

- LifeSource allocates pancreata to its pancreas islet candidates based upon donor characteristics different from the national pancreas allocation. LifeSource's pancreas AAS uses different donor age and BMI cut offs. The national allocation gives islet candidates priority over local pancreas alone candidates for pancreata from donors who are greater than or equal to 50 years old or have a BMI greater than or equal to 30 kg/m^2. Currently, the LifeSource AAS allocates pancreata from donors greater than or equal to 15 years old and with a BMI greater than or equal to 28 kg/m^2 to pancreas islet candidates before allocating pancreata to non-highly sensitized, non-zero mismatch local kidney/pancreas and pancreas alone candidates, as follows:
    1. 0 ABDR Mismatch High PRA OPO PA - ABO Identical
    2. 0 ABDR Mismatch High PRA OPO PA - ABO Compatible
    3. High PRA OPO PA with Negative Crossmatch
    4. 0 ABDR Mismatch High PRA Regional PA
    5. 0 ABDR Mismatch High PRA National PA
    6. 0 ABDR Mismatch OPO PA Islets - ABO Identical
    7. 0 ABDR Mismatch OPO PA Islets - ABO Compatible
    8. 1 ABDR Mismatch OPO PA Islets - ABO Identical
    9. 1 ABDR Mismatch OPO PA Islets - ABO Compatible
    10. 2 ABDR Mismatch OPO PA Islets - ABO Identical
    11. 2 ABDR Mismatch OPO PA Islets - ABO Compatible
    12. 3 ABDR Mismatch OPO PA Islets - ABO Identical
    13. 3 ABDR Mismatch OPO PA Islets - ABO Compatible
    14. Other ABDR Mismatch OPO PA Islets - ABO Identical
    15. Other ABDR Mismatch OPO PA Islets - ABO Compatible
    16. 0 ABDR Mismatch OPO PA - ABO Identical
    17. 0 ABDR Mismatch OPO PA – ABO Compatible
    18. OPO KP** (not programmed)
    19. 1 ABDR Mismatch OPO PA - ABO Identical
    20. 1 ABDR Mismatch OPO PA - ABO Compatible
    21. 2 ABDR Mismatch OPO PA - ABO Identical
    22. 2 ABDR Mismatch OPO PA - ABO Compatible
    23. 3 ABDR Mismatch OPO PA - ABO Identical
    24. 3 ABDR Mismatch OPO PA - ABO Compatible
    25. Other ABDR Mismatch OPO PA - ABO Identical
    26. Other ABDR Mismatch OPO PA - ABO Compatible
    27. Regional PA Islets
    28. National PA Islets
    29. Regional PA
    30. National PA

**The implementation of the above modification did not include programming of kidney/pancreas potential recipients on LifeSource's pancreas match results list. The OPO requested that the kidney/pancreas prioritization not be programmed in UNet[sm]. The OPO manually switches from the pancreas to the kidney/pancreas match run and back at the designated step in the process (including for zero mismatch pancreas and kidney/pancreas candidates as defined in policy). Please note that OPTN/UNOS policy allows for an OPO to switch from a pancreas to a kidney/pancreas match run and vice versa at any time.

The Committee considered each component of the LifeSource AAS separately. The Committee voted to recommend that the component of the LifeSource AAS regarding level of mismatch be continued. (11-Support, 0-Oppose, 2-Abstain)

However, the Committee opposed the component of the LifeSource AAS regarding islet priority being continued. (1-Support, 3-Oppose, 9-Abstain) The Committee noted that it would be in favor of the AAS being continued if LifeSource prioritized local kidney/pancreas candidates above islet candidates for all types of donors. The Committee believes this change would increase utilization because kidney/pancreas combinations have a lower discard rate than islets. Therefore, prioritizing kidney/pancreas candidates would further the goal of getting more organs transplanted.

A resource assessment and impact summary is attached as **Exhibit B**. the Committee recommends the following resolution for consideration by the Board:

> **RESOLVED, that the modifications to the LifeSource alternative allocation system to restore the national requirements for when pancreas islet candidates should receive priority for a donor pancreas are hereby approved, effective pending notice and programming in UNet[sm].**

b. Tennessee Statewide (TNUK)

The state of Tennessee's AAS differs from standard pancreas allocation in the following ways:

- The KP and PA candidates from both OPOs in Tennessee are combined into a single statewide list.
- Within each statewide category, candidates are divided by ABO identical and ABO compatible status with priority for the ABO identical category

The Committee voted to recommend that the Tennessee Statewide AAS be continued. (11-Support, 0-Oppose, 0-Abstain)

2. Proposal to clarify islet allocation protocol: Policy 3.8.1.6 (Islet Allocation Protocol)

At its March 14, 2008, meeting, the Committee was concerned that the current islet allocation policy language is ambiguous because it does not define when a candidate is medically suitable for an islet transplant, and it allows a program to accept an unlimited number of pancreata for islet infusion for a candidate without that candidate ever receiving an islet infusion. UNOS Research staff discovered that one candidate had accepted twenty-three organs in 2005 and 2006, but the candidate did not receive a transplant from these pancreata **(Exhibit C)**. There was no apparent violation of policy. Seven of the organs accepted by this candidate eventually went to research. Eleven pancreata were not ever processed for islets. The Committee was concerned that so many clinical-grade pancreata were not processed for islets. The Committee discussed whether there should be a limit on the number of organs that a candidate can accept before waiting time is reduced. The Committee recognized that not every isolation will yield enough islets for transplant for that candidate. The Committee decided that it was premature to recommend a policy change based on one candidate. The Committee forwarded the issue to the

Membership and Professional Standards Committee (MPSC) and requested that the MPSC investigate this particular situation.

At its July 18, 2008, meeting, the Committee reviewed a memo from the MPSC regarding this issue. The MPSC did not find any policy or bylaw violation with a center accepting a large number of islet offers for a single candidate and suggested that the Committee clarify islet allocation policy with attention toward developing more specific listing criteria for islet recipients to receive a second or third islet infusion.

The Committee stated the need for all islet offers to be made through UNOS only to candidates who are on the waiting list. The Committee also discussed the possibility of not allowing islets to be sent out of the country or even re-allocated within the country. The Committee formed a subcommittee to draft language to clarify islet allocation policy. Dixon Kaufman, MD, PhD, Marlon Levy, MD, Horatio Rilo, MD, and Peter Stock, MD, PhD, volunteered to participate on this subcommittee.

At its September 2008 meeting, the Committee reviewed language developed by the Islet Allocation Subcommittee **(Exhibit D)**. The purpose of these revisions is to clarify islet allocation protocol. The revisions concentrate on several areas: islet product medical suitability, the process for re-allocating islets, and criteria for listing a candidate as active on the pancreas islet waiting list.

Islet Product Medical Suitability
The medical suitability of an islet product for a candidate is defined as meeting the islet center's product release criteria contained in the center's Investigational New Drug application (IND), as approved by the FDA.

The Process for Re-allocating Islets
Any re-allocation of islets must be to a medically suitable candidate covered by the same IND, based on waiting time, and must follow other OPTN/UNOS policies.

Criteria for Listing a Candidate as Active on the Pancreas Islet Waiting List
A candidate is **not** eligible for active status if the candidate**:**

- Is insulin independent **and**
- Has an HbA1c value of less than or equal to 6.5%.

If the candidate is eligible for active status, the transplant center will need to document in the candidate's record every six months:

- That the candidate is currently insulin dependent

OR

- That the candidate has had an HbA1c test in the past 6 months,
- That the most recent HbA1c test had a value of greater than 6.5%, and
- That the candidate is insulin independent.

In August 2008, the Islet Allocation Subcommittee sent the proposed revisions to the NIH-funded Clinical Islet Transplant Consortium (CIT) principal investigators, who supported the changes.

The Committee voted to send the following language out for public comment (10-Support, 0-Oppose, 0-Abstain):

> **3.8.1.~~5~~6** Islet Allocation Protocol. Allocation of pancreata for islet transplantation shall be to the most medically suitable candidate based upon need and transplant candidate length of waiting time. After ~~If after~~ islet processing is completed, the transplant center will determine if the islet preparation is medically ~~un~~suitable for the candidate. Medical suitability is defined as meeting

the islet transplant center's islet product release criteria contained in the center's Investigational New Drug (IND) application, as approved by the FDA. The center must document whether the islets are medically suitable or medically unsuitable for the candidate for whom the center accepted the islets. If the islets are medically unsuitable for the candidate, the center must also document the reason the islets were medically unsuitable for the candidate. This documentation must be maintained and submitted upon request.

If the transplant center determines that the islets are medically unsuitable for the candidate for whom the center accepted the islets, the islets from that pancreas will be reallocated to a medically suitable candidate at a transplant center covered by the same IND, based upon waiting time. The transplant center that accepted the islets on behalf of the original candidate is responsible for documenting:

- to which candidate the center re-allocated the islets, and
- that the center re-allocated the islets to the medically suitable candidate covered by the same IND who had the most waiting time.

The transplant center must maintain this documentation and submit it upon request. ~~to the next most suitable candidate within the OPO that the Investigational New Drug (IND) application allows~~.

Islet allocation must abide by all applicable OPTN/UNOS policies, including but not limited to:

- Policy 3.2.1 (Mandatory Listing of Potential Recipients), which states that all candidates who are potential recipients of deceased donor organs must be on the Waiting List,
- Policy 3.2.1.4 (Prohibition for Organ Offers to Non-Members), which stipulates that organ offers cannot be made to non-member centers,
- Policy 3.2.4 (Match System Access), which requires that organs only be allocated to candidates who appear on a match run,
- Policy 6.4.1 (Exportation), which states that the exportation of organs from the United States or its territories is prohibited unless a well documented and verifiable effort, coordinated through the Organ Center, has failed to find a suitable recipient for that organ on the Waiting List.

~~The purpose of this policy is to allow for the application of medical judgment and to avoid islet wastage. The outcomes of this allocation policy will be reported to the Board by the Kidney & Pancreas Transplantation Committee within three years.~~

Waiting Time

A candidate is eligible to accrue waiting time:

- while listed in an active or inactive status; and
- until the candidate has received a maximum of three islet infusions.

Waiting time ~~shall~~will begin when a candidate is placed on Waiting List. Waiting time will end when the candidate is removed from the waiting list. Waiting time will accrue for a candidate until he/she has received a maximum of three islet infusions or the transplant center removes the candidate from the waiting list, whichever is the first to occur. If the candidate is still listed at this time or subsequently added back to the Waiting List, waiting time will start anew.

One point will be assigned to the candidate waiting for the longest period with fractions of points assigned proportionately to all other candidates, according to their relative waiting time. For example, if there are 75 candidates waiting for islets, the candidate waiting the longest would receive 1 point (75/75 x 1 = 1). A person with the 60th longest time of waiting would be assigned 0.2 points (75-60)/75 x 1 = 0.2). The calculation of points is conducted separately for each

geographic (local, regional and national) level of islet allocation. The local points calculation includes only candidates on the local Waiting List. The regional points calculation includes only candidates on the regional list, without the local candidates. The national points calculation includes all candidates on the national list excluding all candidates listed on the Host OPO's local or regional waiting list~~. Candidates shall continue to accrue waiting time while registered on the Waiting List as inactive.~~

Active and Inactive Status

A candidate is **not** eligible for active status if the candidate:

- Is insulin independent **and**
- Has an HbA1c value of less than or equal to 6.5%.

The transplant center is responsible for keeping the candidate's listing status current in UNet^{SM}.

If the candidate is listed as active and is insulin dependent, the transplant center must maintain documentation in the candidate's record of his/her current insulin status. To retain active status for an insulin dependent candidate, the transplant center must document in the candidate's record every six months that the candidate is currently insulin dependent.

If the candidate is listed as active and is insulin independent, the transplant center must maintain documentation in the candidate's record of his/her insulin status and HbA1c level with the date of the HbA1c test. To retain active status for an insulin independent candidate, the transplant center must document in the candidate's record every six months:

- That the candidate has had an HbA1c test within the past six months with a result of greater than 6.5%, **and**
- That the candidate is insulin independent.

The transplant center must use the most recent HbA1c value when determining whether the candidate is eligible for active status.

If a candidate's clinical condition changes, and the candidate is no longer eligible for active status, the transplant center must change the candidate's status in UNet^{SM} within 72 hours of the transplant center's knowledge of this candidate's clinical change. The transplant center must maintain documentation in the candidate's record of when the center learned of this clinical change. If a transplant center wishes to list an inactive candidate as active, the transplant center must have documentation that the candidate had the appropriate HbA1c level and insulin status in the past six months. The transplant center must present any documentation required by this policy to the OPTN upon request.

Removal from the Waiting List

The transplant center must remove the candidate from the waiting list within 24 hours of the candidate receiving his/her third islet infusion.

3. **Proposal to allow candidates who need a pancreas for technical reasons as part of a multiple organ transplant to be listed on the pancreas waiting list: Policy 3.2.7 (Pancreas Waiting List Criteria) and Policy 3.2.9 (Combined Kidney-Pancreas Waiting List Criteria)**

In September 2007, the Committee reviewed a memo from the UNOS Department of Evaluation and Quality requesting that Policy 3.2.7 be modified. This policy states that "each candidate registered on the Pancreas Waiting List must be diagnosed as a diabetic or have pancreatic deficiency." The proposed revision would allow candidates who require the procurement or transplantation of the pancreas for technical reasons as part of a multiple organ transplant to be placed on the pancreas waiting list.

Currently, candidates can only be placed on the pancreas waiting list if they have diabetes or pancreatic deficiency. However, sometimes a pancreas is allocated to a candidate without diabetes or pancreatic deficiency as part of a multi-visceral transplant. These candidates are not on the waiting list. This modification would allow candidates who need a pancreas for technical reasons to appear on the pancreas waiting list.

Committee members made a distinction between pancreas transplants that treat diabetes and pancreas transplants that only facilitate the transplantation of other organs. There was concern that listing multi-visceral candidates on the pancreas waiting list would increase the cost of the multi-organ transplants. Committee members noted that this particular policy change deals with a compliance issue. On the other hand, any policy change in this area has the potential to change the standard acquisition charge. Some members noted that the OPOs want to count the pancreas as a transplanted organ in such cases. The Committee decided not to move forward until it has received input on the financial implications of the policy change. The Committee contacted the Pediatric Transplantation, Liver and Intestinal Organ Transplantation, Organ Procurement Organization, Policy Oversight, and Transplant Administrators Committees for feedback.

In March 2008, the Committee reviewed the following feedback to the memo it sent to the Pediatric Transplantation, Liver and Intestinal Organ Transplantation, Organ Procurement Organization, Policy Oversight, and Transplant Administrators Committees:

Committee	Feedback
Pediatric Transplantation Committee	The Pediatric Transplantation Committee cannot support the proposed change until there is a policy addressing the scenario of an organ transplanted not to replace function, but rather to facilitate the transplant of other organs, and the language of the proposal is fully aligned with the Final Rule definition of a pancreas transplant candidate as "medically suited to benefit from an organ transplant."
Liver and Intestinal Organ Transplantation Committee	The Liver and Intestinal Organ Transplantation Committee commented that there should be a fee for a single organ and a fee for multiple organs, regardless of how many organs are required.
Policy Oversight Committee	The POC stated that the costs and accounting issues should be resolved between CMS and HRSA before the POC can offer its support.
Organ Procurement Organization Committee	The OPO Committee believes that patients receiving a pancreas for any reason need to be listed for a pancreas transplant. The center should be charged the SAC for the pancreas regardless of how the pancreas, or portion of the pancreas, is going to be used. The OPO should be able to record the pancreas as an organ transplanted as part of its performance metrics.
Transplant Administrators Committee	The Transplant Administrators Committee (TAC) recognizes that there is a financial impact with transplanting pancreata as transplant centers are being charged an additional Standard Acquisition Cost (SAC), as of 2007. The TAC agreed that there should be a separate fee for pancreata if it was transplanted for technical reasons.

The Committee agreed that they would not be able to solve or change the financial issue. However, the Committee may be able to draft language that would resolve the compliance issues. The policy should

allow the pancreas to be used in a multi-organ transplant for metabolic reasons or for technical reconstruction. UNOS Staff will draft policy language for the Committee to review at its July meeting.

At the July 2008 meeting, the Committee voted to send the following language out for public comment (15-Support, 0-Oppose, 0-Abstain):

> **3.2.7 Pancreas Waiting List Criteria.** Each candidate registered on the Pancreas Waiting List must be diagnosed as a diabetic, or have pancreatic deficiency, or require the procurement or transplantation of the pancreas for technical reasons as part of a multiple organ transplant.

The Committee also decided to write a memo to the Pediatric Transplantation Committee explaining why it was moving forward with the policy revision and addressing the Pediatric Transplantation Committee's concerns. The Committee noted that any financial issues relating to multi-visceral transplants were CMS issues, not OPTN issues.

In September 2008, the Committee considered additional revisions to Policy 3.2.7 (Pancreas Waiting List Criteria) and Policy 3.2.9 (Combined Kidney-Pancreas Waiting List Criteria). These revisions modify the policy language to make the terms more clinically accurate. The Committee changed the phrase "diagnosed as a diabetic" to "diagnosed with diabetes" and the phrase "have pancreatic deficiency" to "have pancreatic exocrine insufficiency."

The Committee reviewed supporting evidence for the revision to Policy 3.2.7 to add a third category of waiting list criteria for candidates who need the pancreas for technical reasons as part of a multiple organ transplant (**Exhibit E**). The Committee reviewed data on the number of multi-visceral transplants that include the pancreas, which shows that the trend in the number of multi-visceral transplants including the pancreas is increasing. The Committee requested data on the age distribution of these multi-visceral candidates. The Committee also examined data on the diabetes status of the recipients of multi-visceral transplants that included the pancreas. In 2007, 88.4% of the candidates who received a pancreas with a multi-visceral transplant did not have diabetes. This data indicates the need for another listing category for multi-visceral candidates.

The Committee voted to send the following language out for public comment (11-Support, 0-Oppose, 0-Abstain):

> **3.2.7 Pancreas Waiting List Criteria.** Each candidate registered on the Pancreas Waiting List must be diagnosed with diabetes ~~as a diabetic~~, or have pancreatic exocrine insufficiency ~~deficiency~~, or require the procurement or transplantation of the pancreas for technical reasons as part of a multiple organ transplant.
>
> **3.2.9 Combined Kidney-Pancreas Waiting List Criteria.** Each candidate registered on the Kidney-Pancreas Waiting List must be diagnosed with diabetes ~~as a diabetic~~ or have pancreatic exocrine insufficiency ~~deficiency~~ with renal insufficiency.

4. Islet Consensus Conference

In December 2007, the Committee discussed the possibility of having a consensus conference on islets. This conference would include all the groups that play a role in islet transplantation, such as the large islet centers, the Health Resources and Services Administration (HRSA), the Centers for Medicare and Medicaid Services (CMS), and the National Institutes of Health (NIH). This conference would not take place until at least 2009. The goals of this conference would be to determine the present state of the islet field, to move away from the idea that whole pancreas and islet transplants are competing treatments, and

to see what it would take to move islet transplantation from an experimental treatment to a treatment that can be reimbursed. The Committee considered whether this would be the right time to bring people together to discuss islet reimbursement. This consensus conference would be an opportunity to frame the issue, even if it is early for the technology.

In March 2008, the Committee continued discussing plans for an islet consensus conference in 2009. Possible topics for discussion are lowering acquisition costs and guidelines for payers to eventually pay for all or part of an islet transplant.

In July 2008, the Committee agreed that the preferred location for the islet consensus conference would be the Washington, DC area so that government officials might be able to attend. The Committee must find outside funding in order to be able to hold this consensus conference. The Committee formed a subcommittee to develop an agenda and budget for the conference and to apply for grant money for the conference from groups like the JDRF and NIH. Rainer Gruessner, MD, Dixon Kaufman, MD, PhD, Marlon Levy, MD, Horatio Rilo, MD, and Peter Stock, MD, PhD, agreed to serve on this subcommittee.

5. Impact of the ProposedNew Kidney Allocation System on Pancreas Allocation

In response to the Kidney Transplantation Committee's decision to have the kidney follow the pancreas in allocation, the Pancreas Transplantation Committee decided to look into the pancreas allocation system in September 2007. The Committee mentioned that, if the kidney follows the pancreas, there could be only one pancreas list and that kidney/pancreas (KP) candidates would be interspersed with pancreas alone (PA) candidates. A possible goal of the new pancreas allocation system could be to increase utilization of the pancreas, and the Committee could investigate the possibility of using net benefit as well. Another consideration would be the effect of the system on living donation if it were easy to get a kidney/pancreas transplant. The Committee asked how they should move this change forward in a way that would be congruent with the work of the Kidney Transplantation Committee. The Committee decided to begin its investigation by requesting data to support having the kidney follow the pancreas. The Committee would like to determine if the kidney follows the pancreas currently in high performing OPOs. Then the Committee could begin looking into alternatives for a new system using some of the same principles as the kidney allocation score (KAS). Outcomes of the various types of pancreas transplants should be investigated. Eventually, the Committee would like to uncouple pancreas allocation from the KAS process. The Committee formed a subcommittee to begin discussions on this topic. Rainer Gruessner MD, Dixon Kaufman, MD, PhD, Chris Kuhr, MD, Chris Marsh, MD, Peter Stock, MD, PhD, Jim Markmann, MD, PhD, and Marlon Levy, MD, volunteered to serve on this subcommittee. (In August 2007, the Committee formed a subcommittee assist UNOS staff in evaluating whether the five pancreas alternative allocation systems meet certain requirements. Sandip Kapur, MD, Christian Kuhr, MD, and James F. Markmann, MD, PhD volunteered to participate on this subcommittee. This subcommittee has been merged with the subcommittee charged with evaluating pancreas allocation.)

In December 2007, the Committee continued its discussion of the Kidney Transplantation Committee's decision to have the kidney follow the pancreas in the new kidney allocation system. The Kidney Transplantation Committee's goal with this decision is to decrease organ wastage. The Pancreas Transplantation Committee agreed that there is a rationale for minimizing pancreas wastage by having the kidney follow the pancreas. As due diligence, the Committee discussed methods of allocating pancreata to candidates who will benefit the most while still retaining kidneys for the kidney allocation system. The Committee discussed limiting kidney/pancreas transplants to candidates with Type 1 diabetes. Other members noted that some centers successfully do kidney/pancreas transplants in candidates with Type 2 diabetes. The Committee decided that this issue needed further discussion at the next in-person Committee meeting. The Committee requested data on the number of candidates with Type 2 diabetes over the age of 45 who had received kidney/pancreas transplants. Jennifer Wainright, PhD, presented this

data in March 2008 **(Exhibit F)**. In 2006, there were 38 SPK transplants in candidates with Type 2 diabetes older than 45 years. An additional 56 transplants occurred in older candidates with diabetes of unknown type. The majority of SPK transplants in candidates with Type 2 diabetes older than 45 years old occurred in recipients who had a BMI between 18.5 and 30. Eleven of these transplants occurred in recipients with a BMI over 30. The Committee also offered to send a letter to all pancreas programs about how to appropriately list candidates for a kidney/pancreas transplant once the new kidney allocation system is in place.

The Pancreas Review Subcommittee met in between Committee meetings to continue discussion and to begin compiling initial data. Minutes from the Pancreas Review Subcommittee meetings are attached as **Exhibit G**.

During its February 5, 2008, meeting, the Pancreas Review Subcommittee discussed the merits and disadvantages of separate and combined KP and PA lists. The subcommittee requested data on the number of candidates who moved from the PA to the KP list and on the number of KP transplants for candidates with creatinine clearance greater than 20. Dr. Wainright presented this data to the Committee **(Exhibit H)** in March 2008. 51 candidates who were listed for PA on or before December 31, 2006 were later listed for KP in 2006. 40 candidates who were listed for PA on or before December 31, 2007 were later listed for KP in 2007. In 2006, there were 265 KP transplants of candidates who had a creatinine clearance greater than 20. In 2007, there were 233 KP transplants of candidates who had a creatinine clearance greater than 20. In March 2008, the Committee requested data on the number of KP recipients who had a creatinine clearance greater than 20 who were also on dialysis and the number who were zero antigen mismatch recipients **(Exhibit I)**. The Committee discovered that only 15% of KP transplants in 2006 and 2007 were for candidates with a creatinine clearance greater than 20 who were not yet on dialysis. The subcommittee did not consider this to be an excessive number. 1.2% of KP candidates with a creatinine clearance greater than 20 in 2006 through 2007 received a zero mismatch transplant. The Committee agreed this issue should be considered in any national allocation policy. In July 2008, the Committee requested data on the number of kidney alone recipients who had a creatinine clearance greater than 20 and are not yet on dialysis for comparison.

At its March 14, 2008, meeting, the Committee reviewed current allocation policies for kidney/pancreas candidates and discussed the impact of the Share 35 policy and multi-organ transplants on KP candidates. The Committee also discussed the possibility of transplant centers listing patients on the KP list when the candidate did not need a pancreas transplant in order for the candidate to receive a kidney more quickly in the future. The Committee discussed trying to have a policy change for the kidney to follow the pancreas before KAS is implemented. If KAS is delayed, this idea could still go through. Data from the Kidney Transplantation Committee has shown that kidney/pancreas transplants have a greater net benefit than many other kidney transplants. The Committee will consider developing criteria for when a candidate should receive a kidney with a pancreas to alleviate concerns about gaming of the system in the future. One possibility would be to limit priority to candidates with no circulating c-peptide, who are on dialysis, and who are younger than 45 years old. The Committee also discussed combining the PA and KP lists.

In March, the Committee requested data on the number of times that a kidney alone transplant was performed when both the pancreas and kidney were sent to the same transplant center. The Committee wanted to know the reason for not transplanting the pancreas and the fate of the pancreas if a kidney alone was transplanted and the pancreas was not. The Committee requested this data to help them develop a national system for allocating pancreata and kidney/pancreas combinations and to determine what, if any, listing criteria might be appropriate for KPs. Dr. Wainright presented this data at the July 2008 meeting **(Exhibit I)**. 16 kidney/pancreas candidates who were listed in 2006 received a kidney-only transplant in 2006. In 2006, there were 924 kidney/pancreas transplants. This situation occurred at one transplant

center three times and at another transplant center two times during this period. The 11 other cases were single cases at 11 different transplant centers. Therefore, the Committee does not believe that transplant centers are listing candidates for a kidney/pancreas transplant in order to receive a kidney more quickly.

In March, the Committee also requested data on the number of multi-organ transplants as a percentage of all kidney transplants **(Exhibit I)**. From 2005 to 2007, kidney-alone transplants accounted for 88.1% of all kidney transplants, followed by kidney/pancreas transplants at 7.9% and kidney/liver transplants at 3.5%.

Additionally at the March 2008 meeting, the Committee requested data on median waiting time for pediatric kidney candidates who are not sensitized and are on dialysis **(Exhibit I)**. For pediatric registrations from September 29, 2005 to June 30, 2007, the median waiting time for pediatric kidney recipients was 281 days. Children 0-5 years old had the longest median waiting time at 355 days. At the July 2008 meeting, the Committee requested that these pediatric median waiting times be compared to the KP median waiting times.

The Pancreas Review Subcommittee met via conference call on April 29, 2008 to discuss possible models for kidney allocation for kidney/pancreas candidates. This subcommittee is collaborating with the Pediatric Transplantation Committee to develop modifications to the way KPs are allocated that are acceptable to both Committees. In April 2008, the subcommittee requested that the SRTR model several different allocation options for the kidney following the pancreas locally with different priorities between KP and PA candidates and between KP and pediatric kidney candidates. This modeling will be ready for the subcommittee's review in fall 2008. The subcommittee has also been investigating whether there should be any restrictions on when the kidney follows the pancreas, such as limiting KP transplants to candidates who had a creatinine clearance less than 20 or were on dialysis.

The subcommittee requested data on how often both kidneys are allocated to adult KI transplants or to adult multiple organ transplants (i.e., neither kidney is allocated to a pediatric candidate) for deceased kidney donors under 35 years old **(Exhibit J)**. For both the pre-Share 35 and post-Share 35 policy change time frames, both kidneys from a donor were allocated to multi-organ recipients only 2.0% and 2.3% of the time, respectively. The percentage of donors where both kidneys went to a pediatric candidate increased from 0.7% for the pre-Share 35 period to 2.4% for the post Share 35 period. The percentage of donors where one kidney was allocated to a pediatric candidate increased from 9.8% in the pre-Share 35 period to 14.2% in the post-Share 35 period. This data shows that both kidneys from a donor seldom both go to a multi-organ recipient, which could indicate that an increase in the number of KP transplants would not adversely affect pediatric kidney candidates. At the July 2008 meeting, the Committee wanted to know how many kidneys from donors over 35 went to pediatric recipients. The Committee also requested more specificity on the types on multi-organ transplants in this analysis.

At its May 9, 2008 conference call, the Committee continued its discussion of possible changes to pancreas allocation policy, including the possibility of using net benefit and setting age limits and waiting time requirements for when the kidney will follow the pancreas. The Committee requested data on the number of pancreas transplants by donor age, by type of transplant (SPK, PAK, or PTA), and by SCD/ECD/DCD status and the number of PA and SPK candidates by age group **(Exhibit K)** to determine if there was a difference in the quality of pancreas accepted for different types of pancreas candidates. The Committee found no substantial variation in donors for PAK, PTA, and SPK.

At its May 2008 meeting, the Committee requested data on the waitlist death rates and net benefit for Pancreas Recipients to help in the development of potential listing criteria. Kathryn Meyer, MS, SRTR Liaison, presented this data at the July 2008 Meeting **(Exhibit L)**. Both diabetic KP and diabetic KI candidates had shorter waitlist lifespan than non-diabetic KI candidates for all age groups. Diabetic KP

and diabetic KI candidates had similar waitlist lifespan for all age groups. However, diabetic KP recipients have a longer lifespan post-transplant than diabetic KI recipients. The SRTR also provided the Committee with a chapter from the SRTR Annual Report, "Calculating Life Years From Transplant (LYFT): Methods for Kidney and Kidney-Pancreas Candidates." **(Exhibit M)**

At its July 2008 meeting, the Committee discussed net benefit for kidney/pancreas candidates and potential concerns from the kidney transplant community that the number of KP transplants in older patients will increase if the kidney follows the pancreas in allocation. The Committee requested data on outcomes for KP recipients over the age of 50 in comparison to KP recipients under 50. The Committee also wondered how many dialysis patients over 50 would be interested in getting a kidney/pancreas transplant. The Committee noted that many DSAs already have the kidney follow the pancreas. The Committee requested data on the average age of the donor in DSAs where the kidney follow the pancreas compared to DSAs where the kidney does not follow the pancreas. Committee members also commented on the need to keep pancreas utilization in mind when deciding when the kidney should follow the pancreas. The Committee agreed that there should be minimum listing criteria for KP transplants.

6. Pancreas Outcomes Review Model

In August 2007, Randall Sung, MD, of the Scientific Registry of Transplant Recipients (SRTR) presented some background information on outcomes review models. The SRTR publishes center-specific reports for a variety of organs transplants, and graft survival and patient survival are a part of these models. Transplant centers often use these reports to compare their outcomes to a national average and to what outcome would be expected for that center. The SRTR was asked to develop survival models for solitary pancreas transplantation. There is a simultaneous kidney-pancreas model, which also needs to be reviewed. The models take the national experience and find determinants of national experience, then apply them to transplant centers. The expected outcome is a prediction of what the outcome would be if the donor, recipient, and transplant characteristics of that center were applied nationally. Part of the difficulty of developing such a model for pancreas transplantation is that the volume is small. It is harder to tell whether the difference between expected and actual outcomes is significant. Similarly, the small volume makes it difficult to determine what should be in the model. Models for one-year and three-year outcomes can have different characteristics. The models are applied to three cohorts to establish validity. To develop the pancreas outcomes models, the SRTR will start with a comprehensive modeling process. The subcommittee will advise the SRTR on what should be in the model or not in the model based on clinical experience. Peter Abt MD, David Axelrod MD, MBA, Dixon B. Kaufman MD, PhD, Venkatesh Krishnamurthi MD, Christopher Marsh MD, and Alexander Wiseman MD volunteered to participate on this subcommittee.

In December 2007, Chris Marsh, MD, updated the Committee on the work of the Pancreas Outcomes Review Model Subcommittee. The subcommittee is working to develop outcomes review models for pancreas alone transplants with the SRTR. The problem is that the numbers are too small to evaluate centers and have statistical significance. The subcommittee has recommended trying to roll the pancreas after kidney (PAK) and pancreas transplant alone (PTA) transplants (both types of pancreas-alone transplants) into the KP model. The SRTR will use an indicator variable to see if there is a difference between SPKs and pancreas-alone transplants. They will also determine how many centers are still considered small centers when all pancreas transplants are added together.

The Committee discussed whether it is appropriate to measure outcomes for pancreas alone transplantation. It might deter centers from continuing to perform pancreas alone transplants. Once all the evidence is analyzed, the Committee may recommend to the MPSC that an outcomes model not be used for pancreas alone transplants.

In March 2008, Dr. Sung presented the SRTR's work on pancreas outcomes review model. The MPSC will use these models to evaluate centers if the center has performed more than ten transplants in a 2.5 year period. The number of graft failures and patient deaths are very small for pancreas (PAK and PTA) transplants, which can make models less predictive. Almost 70% of centers could not be evaluated using a pancreas model because they do not perform enough transplants. Only 50% can be evaluated by the existing kidney/pancreas model. Therefore, the subcommittee is investigating combining the PAKs and PTAs into the KP model. A combined model would allow the evaluation of 65% of centers. A combined model would have more events (graft failure and patient death), which could make the model more predictive. The survival curves for PAK and SPK are similar, but the slope of the curve for PTA is different. Therefore, any combined model should be stratified based on PTA to allow the PTA recipients to have a different hazard. The index of concordance for a combined model (stratified with additional covariates) is 0.63, compared to 0.61 for the current SPK model and 0.59 for a PTA/PAK model. There were several fields the subcommittee could not include in a model because data are not available or not reliable, such as HbA1c, coronary artery disease, and pancreas preservation time. Additionally, it is difficult to have a concrete definition of graft failure for the pancreas. The Pancreas Outcomes Review Model Subcommittee will continue to review covariates to determine what should be included in a final model.

In July 2008, Dr. Marsh updated the Committee again on the work of the Pancreas Outcomes Review Model Subcommittee. The subcommittee has completed work on a model for 1-year graft survival that accounts for SPK, PAK, and PTA transplants. The subcommittee is now working on a combined SPK/PAK/PTA model for 1-year patient survival. The next step is to develop 3-year graft failure and patient survival models.

Minutes from the Pancreas Outcomes Review Model Subcommittee meetings can be found in **Exhibit N**.

7. Request from the MPSC on the SRTR Outcome Analysis Model for Kidney/Pancreas Programs

In December 2007, the Committee considered a memo from the Membership and Professional Standards Committee (MPSC) requesting feedback on using the currently published SRTR kidney/pancreas model to review outcomes for kidney/pancreas programs. The MPSC reviews transplant program performance through an analysis of expected compared to observed one-year graft and patient survival rates. The SRTR develops models to analyze and compare these rates. Programs that have observed one-year survival rates below expected rates are identified for further inquiry by the MPSC. Currently, the MPSC monitors one-year post transplant graft and patient survival rates for kidney, liver, heart, and lung transplant programs. In October 2006, the MPSC requested that the Pancreas Transplantation Committee in cooperation with the SRTR develop a model to analyze pancreas program outcomes, including programs that perform pancreas alone, combined kidney/pancreas, and pancreas after kidney transplants. The Pancreas Outcomes Review Model Subcommittee is currently working on fulfilling this charge. During its November 13-14, 2007, meeting, the MPSC discussed using the currently published SRTR model for combined kidney/pancreas program outcomes as a starting point to review pancreas program performance until the Pancreas Transplantation Committee and SRTR finalized an outcome analysis model. The MPSC requested that the Pancreas Transplantation Committee consider use of the current model for evaluating one-year survival rates for programs that perform combined kidney/pancreas transplants. The MPSC provided the following resources:

- The most recent report from the SRTR showing the data for kidney/pancreas programs identified to have experienced lower than expected patient and/or graft outcomes for transplants performed between January 1, 2004 and June 30, 2006 (4 programs),
- The Bylaw that references the MPSC's review of transplant program survival rates, and
- The SRTR Risk Adjustment Model

The Pancreas Transplantation Committee discussed the possibility of using this kidney/pancreas model before the subcommittee finished its review. The Committee believed that several important elements are not included in the SPK model, such as BMI and recipient age. The SRTR has included elements that are statistically significant, but others can be added for face validity. The Committee wanted more time to evaluate the model before it is used. The Committee voted to oppose on the MPSC's request (1-Support, 4-Oppose, 0-Abstain).

8. Definition of Pancreas Graft Failure and Graft Function

In July 2008, the Committee discussed revising the definition of pancreas graft failure. Currently, the SRTR considers graft failure to be any time the center reports graft failure, death, retransplant, or removal of the organ. However, centers do not consistently use the same endpoints for reporting graft failure that does not result in death, retransplant, or removal of the organ. The Committee discussed several possible definitions. One definition was that pancreas graft failure was the loss of insulin independence. A second definition uses the achievement of euglyclemia as an indicator of graft function:

A. Insulin independent euglycemia (using current ADA standards for glycemia control)- i.e. fasting BG <126 mg/dl and HgbA1c that is within the normal range.
B. Euglycemia (using current ADA standards for glycemia control)- requiring less that 30% of the individual's pre-transplant insulin requirement (again based on a unit/day/kg body weight measure).
C. Euglycemia (using current ADA standards for glycemia control)- requiring more than 70% of the individual's pre-transplant insulin requirement (again based on a unit/day/kg body weight measure).
D. Complete graft failure.

The Committee also considered combining sections B and C of the second definition so that there would only be one level of insulin-dependent euglycemia. The Committee preferred the second definition. The Committee was concerned that if any use of insulin constituted graft failure, centers might be reluctant to put recipients on low doses of insulin. An additional advantage to this definition is that it can be applied to both whole pancreas and islet cell transplantation. Committee members will make minor revisions to the second definition and circulate the definition to the Pancreas Outcomes Review Model Subcommittee and to the full Committee. Once the Committee agrees on a definition, the Committee will advise the community on what should be reported as pancreas graft failure.

9. Pancreas DRI/DPI Subcommittee Update

David Axelrod, MD, MBA, updated the Committee on the work of the Pancreas DRI/DPI Subcommittee. This subcommittee is working with the SRTR to develop a pancreas donor risk index (DRI). DRI is a measure of organ quality that is computed using a weighted function of several relevant donor and transplant characteristics. Donor Percentile Index (DPI) is developed by using the DRI to rank organs from highest to lowest quality and then assigning each organ a percentile based on where they rank according to other organs in the sample. This is how the kidney DRI is incorporated into the kidney allocation score (KAS). The DRI can be used to inform clinical decisions, to assess pancreas utilization, and in allocation. The SRTR has created a 1-year pancreas graft failure model with an index of concordance of 0.62. The model includes donor age, donor gender, donor race, donor BMI, donor height, donor cause of death being CVA or stroke, DCD status, and pancreas preservation time as covariates. The model controls for the recipient characteristics of age, race, albumin, duct management, peripheral vascular disease, PRA, private primary payment, and previous pancreas transplant. The model shows that there is a difference in graft failure outcomes for recipients who receive pancreata from donors that have a low versus a high DRI. The subcommittee's next steps are to evaluate whether long-term pancreas graft

failure would be a more appropriate outcome, to assess DRI trends in patient and graft survival, to assess trends in pancreas utilization, and to investigate the use of DPI in allocation.

Minutes from the Pancreas Outcomes Review Model Subcommittee meetings can be found in **Exhibit O**.

10. Donor Management

In September 2007, a member called in to the meeting to suggest some additional evaluation criteria for donors. The surgeon asked that an HbA1c exam be used in the donor evaluation process. The Committee discussed adding an HbA1c field to DonorNet® and whether this field should be optional or required. Committee members agreed that HbA1c levels are helpful for certain donors, but it may be problematic to screen the entire population. The Committee decided that it did not want to make any fields mandatory without first asking the OPO Committee for feedback. The Committee voted to encourage OPOs to include HbA1c levels on donors being considered for pancreas donation when possible and to endorse HbA1c as an enhancement in DonorNet as an optional field (13-Support, 0-Oppose, 0-Abstain).

The member also suggested that transplant programs use intravenous antibiotics on donors with trauma. The Committee decided not to make any recommendations on this topic. The member proposed that as much of the superior mesenteric artery (SMA) and right gastroepiploic artery should be preserved as possible during the pancreas recovery. The Committee will include these recommendations in the pancreas recovery standards previously presented to the Committee.

At its September 2008 meeting, the Committee discussed the scope of the request to add HbA1c as an optional field in DonorNet®. After discussion, the Committee confirmed that it wanted HbA1c to be an optional field. However, the Committee decided to investigate the possibility of making HbA1c a mandatory field in DonorNet, which would mean that the value would be required for an OPO to run a pancreas match. The Committee decided to ask the OPO Committee how realistic it would be for OPOs to obtain the donor's HbA1c value before the match is run. The Committee will also consult the Histocompatibility Committee on the feasibility of performing the HbA1c lab at the same time as the tissue typing.

The Committee clarified some details about the HbA1c field. The unit of measurement for HbA1c is percent. The minimum allowable value should be 2 and the maximum 15. The field should allow up to one decimal place. An HbA1c test is a stand-alone lab; it is not part of a lab panel.

11. White Paper on Charges for Pancreata Recovered for Islet Transplantation

A white paper on charges for pancreata recovered for islet transplantation was approved in concept by the Board on September 18, 2007. The Board did not have the final language at this meeting because revisions from the Association of Organ Procurement Organizations (AOPO) and from Board members were being added at the time of the meeting. In December 2007, the Executive Committee approved the white paper on charges for pancreata recovered for islet transplantation. This white paper was sent to Secretary Leavitt of the Department of Health of Human Services (HHS) on May 5, 2008 **(Exhibit P)**.

12. Discussion of Committee Priorities

In August 2007, Rainer Gruessner, MD, introduced the discussion of Pancreas Transplantation Committee priorities. Committee members suggested issues the Committee should address prior to the meeting. These suggestions were divided into groups for discussion. The Committee deferred the discussion of one set of items until the September 2007 meeting in Chicago. Items postponed until later meetings include:

- DonorNet® issues
- Modification to waiting time adjustment policy
- Data issues
- Facilitated pancreas allocation
- Quality assessment forms
- Discharge instructions

The topics addressed during the conference call were financial issues, allocation issues, the utilization of pancreata, and kidney-related issues. Dr. Gruessner asked the Committee to consider what product should result from each priority. Possible outputs would be a policy proposal, a white paper, and a resource manual, among others.

Financial Issues

The financial issues include the impact of the Centers for Medicare and Medicaid Services (CMS) ruling on intent to transplant and reimbursement for islet cell transplantation. The white paper on charges for pancreata recovered for islet transplantation will address this issue. During the discussion of intent to transplant, the Committee noted that the white paper addresses the issue of intent to transplant islet cells but not whole pancreata. The Committee also considered that the organ procurement organization (OPO) does incur a fee by having a surgeon come in to look at the pancreas, whether it is used or not. Under the CMS ruling, the standard acquisition charge (SAC) applies once a surgeon intends to procure the organ, as opposed to intending to transplant the organ. Therefore, OPOs may be less likely to send organs out on anatomical waivers because they will have already incurred the costs. Also, CMS does not want kidney procurement to take on extra costs from other organs. The Committee would like to write a separate letter to CMS suggesting that the fee be different for a pancreas that is not transplanted. Additionally, the Committee would like to reach out to the other organ-specific committees, particularly the Thoracic Organ Transplantation Committee, to determine if other organs are affected by the ruling.

Another way to address the topic of reimbursement for islet cell recovery is to have a meeting with the Health Resources and Services Administration (HRSA), CMS, and private payers to discuss the current issues in islet transplantation and how changes in financing of islet cell recovery could stimulate growth in the field.

Allocation Issues

The Committee discussed that whole pancreas and pancreatic islet transplants are not competing procedures. They are options that are available to patients with different health statuses. In order to promote the transplants as complementary, the Committee should work on an algorithm to determine which transplant would benefit which patients. Very simply, patients who are low surgical risk are good candidates for whole pancreas transplant, and patients who are high surgical risk may be better suited to islet cell transplantation. The Committee will work towards eventual publication of this concept.

Utilization of Pancreata

The Committee also discussed the publication of data previously presented to the Committee on the poor utilization rates for pancreata and noted that the broader transplant community was generally unaware of this data. The purpose of this communication would be to educate the community on the availability of additional generally acceptable pancreata and to encourage more transplantation. The Committee would like to identify best practices in the OPOs. Additionally, this effort would be complementary to the work of the Breakthrough Collaborative.

The Committee has been developing pancreas recovery standards, which were presented in May 2007. The Committee would like to expand on this effort and make a resource manual on pancreas transplants.

This manual would include the finalized pancreas recovery standards and information on how to recover a pancreas for islet transplantation, among other items.

Kidney-Related Issues
The Committee has identified addressing the renal debt payback system as a priority as well. The Kidney Transplantation Committee voted to send out for public comment a proposal that would eliminate zero antigen mismatch sharing except for patients with a PRA or CPRA of over 20% and pediatric patients. Existing payback debts would remain in place, and new debts could be accrued for those kidneys which continue to be shared. In the meantime, debts will remain a problem where they already exist. Part of the problem is that many pancreata offered for paybacks are not accepted. Data presented to the Kidney Transplantation Committee showed that only 6% of kidneys offered for payback were accepted. The Pancreas Transplantation Committee would like to look into a way to encourage OPOs to reduce their debts levels. Any actual policy change or something that would be monitored would have to go through the policy development process, including public comment.

The Committee is also concerned about maintaining a voice in the development of the new kidney allocation system. The Kidney Transplantation Committee had decided to remove pancreata from the kidney algorithm and have the kidney follow the pancreas in the simulation modeling, based partially on the fact that kidney-pancreas patients have good net benefit. There was some concern within the Kidney Transplantation Committee that there would be some gaming of the system by putting patients on the KP list who really only need a kidney so that they can receive a kidney faster. Also, a candidate may wait for a perfect pancreas, passing up acceptable ones in the meantime. This practice would result in inefficient utilization of organs.

13. Committee Orientation

During the September 2007 meeting, Elizabeth Sleeman, MHA, UNOS liaison to the Pancreas Transplantation Committee, gave an orientation presentation to the Committee to introduce them to the policy development process. Topics included:

- The OPTN regulatory framework
- Membership of the OPTN
- Pancreas Transplantation Committee charge
- Pancreas Transplantation Committee roster
- UNOS and SRTR support staff for the Pancreas Transplantation Committee
- The five phases of the policy development process: origination, research, development, implementation, and evaluation
- Policy development tools, such as The Final Rule, the Statement of Principles and Objectives of Equitable Organ Allocation, the HRSA Program Goals, and a Checklist for Analytic Modeling.
- The annual goals for 2007-2008:
    - To continue to work with the ASTS, AST, and JDRF to develop a consensus statement regarding CMS reimbursement for pancreas islet transplantation
    - To continue to develop guidelines for pancreas procurement to further limit the number of viable pancreata that are discarded, thereby possibly increasing the number of pancreas transplants
    - To develop new ways to expedite placement of solitary pancreata (e.g. through tiered acceptance protocols)
    - To recommend risk-adjustment factors to be used in center-specific reports that will promote the fair evaluation of pancreas transplant centers
    - To provide proposals for increasing the number of pancreas donors and transplants (for whole pancreas or pancreatic islets)

- To identify the impediments to these proposals
- To evaluate the KARS policy development for the effect on simultaneous pancreas-kidney transplantation

During the December 2007 meeting, Ms. Sleeman presented the six goals in the OPTN/ UNOS Strategic Plan. These goals address alleviating the donor shortage, changing allocation principles, reducing variation in access to transplantation, ensuring living donor safety, maintaining oversight of the OPTN, and improving OPTN data systems. The Committee's annual goals have been mapped to these strategic challenges. The Committee should keep the strategic plan in mind when setting priorities and initiating new Committee projects.

Ms. Sleeman gave the Committee some additional orientation information on the role of the regional representatives and UNOS Communications Department contact information. The regional representatives are responsible for reporting on committee activity during regional meetings, presenting committee proposals out for public comment, gathering input from the regions, and reporting the view of the region at committee meetings. The regional representatives should make sure that members in their region know the process for voicing their concerns to the Committee.

The Health Resources and Services Administration (HRSA) and UNOS have requested that Committee members let UNOS staff know if they are contacted by the media. UNOS staff can provide talking points for Committee members as well. The UNOS media line is available at (804) 782-4730 and has a pager option for non-business hours.

In July 2008, UNOS and SRTR staff presented the Committee with orientation information covering the following topics:

- Committee Roles and Responsibilities by Elizabeth Sleeman, MHA
- OPTN Regulatory and Contractual Framework by Elizabeth Sleeman
- OPTN/UNOS Policy Development Framework and Process: Strengthening Evidence-Based Health Policy Capabilities to Improve Transplantation by Karl McCleary, MPH, PhD
- Policy Implementation: Technology Considerations by Paula Bryant, MBA, and Aaron Powell, PMP
- Research Support for OPTN Committees by Jennifer Wainright, PhD
- Progress Toward Reaching the HHS Donor-Related Program Goals by Jennifer Wainright
- Overview of the Scientific Registry of Transplant Recipients by Randall Sung, MD
- Committee Charge by Elizabeth Sleeman
- OPTN Long-range Strategic Goals and Priorities by Elizabeth Sleeman
- 2008-2009 Pancreas Committee Annual Goals by Elizabeth Sleeman

During the discussion of policy implementation, the Committee was concerned about the delayed implementation of the Kidney Transplantation Committee's proposal to limit mandatory sharing of zero mismatch organs that was approved by the Board of Directors in June 2008. The Committee voted to send a letter to the president and senior leadership of UNOS explaining its concerns and proposing a clinical decision making structure for policy implementation priority decisions. (16-Support, 0-Oppose, 0-Abstain) The Committee formed a subcommittee to gather data on the impact of the delayed implementation on kidney/pancreas recipients, particularly on death rates on the waiting list with increased waiting time, and to draft a letter on behalf of the Committee. Dixon Kaufman, MD, PhD, Marlon Levy, MD, and Peter Stock, MD, PhD, agreed to serve on this subcommittee.

UNOS Staff also updated the Committee on past projects of the Committee. The White Paper on Charges for Pancreata Recovered for Islet Transplantation, which was approved by the Executive Committee in December 2007, was sent to the Secretary of Health and Human Services and other CMS and HRSA

officials on May 30, 2008. The Board approved the Committee's proposed modifications to Policy 3.8.8 (Waiting Time Reinstatement for Pancreas Recipients) to allow an additional method of waiting time reinstatement in June 2008. (27-Support, 1-Oppose, 0-Abstain) These modifications went into effect on July 18, 2008.

14. Pancreas Program Goals Data

At the May 2007 meeting, the Committee reviewed progress on the Program Goals for 2006 for all organs combined and requested an update on these rates for only pancreas transplants. At the September 2007 meeting, Dr. Wainright gave a presentation on the recovery of deceased donor pancreata as requested by the Committee **(Exhibit Q)**. In 2006, there were 924 kidney/pancreas transplants and 423 pancreas-alone transplants. These numbers are slight increases from previous years. The vast majority of these organs come from non-DCD (donation after cardiac death) donors for both kidney/pancreas and pancreas-alone transplants. In 2006, the pancreas was recovered from 25% of all donors and was transplanted from 18% of all donors. Of the pancreata that were recovered, 71% were transplanted. The Committee suggested that data on the number of pancreata recovered from the past six months may be lower because of the Center for Medicare and Medicaid Services (CMS) ruling on intent to transplant. Additionally, the Committee requested that this data be broken down by donation service area (DSA). The Committee considered that utilization may be higher in DSAs where there are multiple pancreas transplant programs because of increased competition. The Committee also requested data on utilization based on waiting time in each DSA and based on how pancreas-alone versus kidney/pancreas candidates are prioritized. The Committee asked if there are data on what happened to the pancreata that were recovered but not transplanted. Dr. Wainright presented this data to the Committee at the March 2008 meeting **(Exhibit R)**. There is a wide variation in number of pancreas transplants by DSA. The number of DCD pancreas transplants is low in every DSA. The discard rate for pancreata increased from 22% to 29% between 2003 and 2007.

15. Utilization Data for "Ideal" Pancreas Donors

At the October 2006 meeting, the Committee reviewed data from 2005 on refusal reasons for pancreata that were offered from "good" donors, referred to here as "ideal" donors. The most frequently cited refusal reason for these donors was donor quality/age. At the May 2007 meeting, the Committee examined data on the disposition of the livers of the 582 ideal donors, as well as whether HLA information was available at the time of the match. Characteristics of the 513 ideal donors whose livers were transplanted were reviewed. The Committee requested tabulation of the number of ideal donors whose livers were transplanted and had none of the risk factors discussed in previous meetings. Dr. Wainright presented this data at the September 2007 meeting **(Exhibit Q)**. Of the ideal donors, 11.9% of livers were not transplanted, and 88.1% were transplanted. Of the 69 non-transplanted livers, 4 were shared and discarded, 13 were recovered for transplant and discarded locally, and 15 were recovered for transplant and submitted for research. Very few ideal donors had a history of cancer (1.4%) or diabetes (0.8%). 11.6% had hypertension. 24% had a history of cigarette use, 19.1% of cocaine use, and 18.9% of heavy alcohol use. 16% were classified as Center for Disease Control (CDC) high risk, and 34.5% had a tattoo. The majority of these donors (59.3%) died of head trauma. Cerebrovascular accidents (CVAs) accounted for 21.8% of deaths and anoxia for 16.4%. 30.8% of ideal donors did not have any of the risk factors stated above. Of the ideal donors with no risk factors, the majority died of head trauma (59.5%), followed by CVA (22.1%) and anoxia (17.2%). The Committee discussed the possibility of publishing this data. A Committee member will work on a draft of this paper. One purpose of this paper is to test the hypothesis of whether the Breakthrough Collaborative's goal for the number of organs transplanted per donor is possible. In order to supplement the existing data, the Committee requested the following data:

- Turndown reasons for 513 ideal donors (% anatomic)

- Risk factors in ideal donors turned down for reasons other than anatomic/injury
- Turndown numbers of the 513 ideal donors by DSA to see if there are "hotspots" (with the number of pancreas transplants per DSA as denominator)
- Characteristics of the 513 ideal donors versus the 1466 donors of pancreata transplanted in 2005
- Turndown numbers for the 513 ideal donors, stratified by "pancreas surgeon/program recovery" versus "no pancreas surgeon/program recovery"
- Stratification of the 513 ideal donors by "not recovered" versus "recovered but not transplanted"
- Acceptance, transplant, and death rates by DSA for the 513 ideal donors
- Baseline characteristics of the 513 ideal donors, with the addition of terminal blood glucose, amylase, and insulin use/amount
- Turndown reasons for the 163 ideal donors who did not have any presently identified risk factors
- Consent rates for the pancreas versus the liver in the 513 ideal donors.

The Committee commented that utilization may be low because of the lack or surgeons trained to procure the pancreas in some areas of the country. Committee members noted there is not enough financial incentive for the liver surgeons to procure the pancreas as well, especially because pancreas recovery is technically difficult. The survey being developed by a subcommittee may be able to provide data to support this hypothesis. The Committee also noted that livers drive procurement times and the crossmatch for the pancreas may not be available in time. Some OPOs have developed solutions for this problem and best practices might be identified. However, it is also possible that these practices cannot be adopted in all localities. The Committee offered that the current fee schedule may disadvantage the pancreas. The Committee recognized that the renal payback debt system also affects pancreas utilization. The Kidney Transplantation Committee has voted to limit mandatory shares to candidates with a PRA over 20% and children. Until the proposal goes through public comment and is sent to the Board, the only thing to Committee can do is to develop a resource document asking Organ Procurement Organizations (OPOs) and transplant centers to try to reduce their kidney debts. Committee members noted that this problem would be hard to solve locally and that transplant programs, surgeons, and OPOs are unlikely to comply unless they must. Transplant surgeons will act in the best interest of their patients, which is to accept a kidney. The Committee asked whether all of these offers could go through OPOs without a policy change. Currently 35% of offers go to surgeons, 35% to OPOs, and the remainder to transplant coordinators. The OPTN does not mandate who receives these calls. UNOS Staff offered to send the public comment document to volunteers from the Pancreas Transplantation Committee for review prior to the actual public comment period. Rainer Gruessner, MD, Chris Kuhr, MD, and Christopher Marsh, MD, will review this document.

Dr. Wainright presented the data requested in September 2007 to the Committee at the March 2008 meeting **(Exhibit R)**. 163 of the 513 ideal donors whose livers were transplanted had no risk factors. Reasons for non-transplant for the 513 ideal donors include poor organ function, recovered for transplant and discarded locally, ruled out after evaluation in the OR, recovered for research, and no recipient located. Donor Quality/Age was the most frequently used turndown code for the pancreas from these donors, followed by patient ill, unavailable, refused, and number of HLA mismatches unacceptable. When stratified by the presence of a pancreas program in the donor's DSA, poor organ function was a more common refusal reason for pancreata recovered from a DSA without a pancreas program, and recovered for research, recovered for islet transplant, no recipient located, and ruled out after evaluation in OR were more common refusal reasons for pancreata recovered in a DSA with a pancreas program. Donor social history and number of HLA mismatches unacceptable were more common turndown codes for pancreata recovered from a DSA without a pancreas program, whereas organ anatomical damage/defect was a more common turndown code for pancreata recovered from a DSA with a pancreas program. Comparing the 1466 donors whose pancreata were transplanted in 2005 and the 513 ideal donors whose pancreata were not transplanted, the donors whose pancreata were not transplanted were

more likely to have the risk factors of hypertension, smoking, cocaine, heavy alcohol, CDC high risk, and tattoos. There was less difference in risk factors between the pancreata that were recovered and not-recovered, although the trend is similar. 58.7% of donors had been given insulin. The most common refusal reasons for the pancreas from the 163 ideal donors with no risk factors were recovered for transplant and discarded locally, poor organ function, and ruled out after evaluation in the OR. The most common turndown codes for these 163 donors were donor age or quality, patient ill, unavailable, refused, and number of HLA mismatches unacceptable. For the 513 ideal donors who were liver donors, the consent rates for the liver and the pancreas were both 100%.

Kathryn Meyer, MS, SRTR liaison to the Pancreas Transplantation Committee, presented data on the transplant and waitlist mortality rates by the 513 ideal donors by DSA **(Exhibit S)**. There is no national trend for transplant rates by number of ideal donors in the DSA for PAK/PTA transplants or for KP transplants. The transplant rate is calculated by dividing person years on the pancreas transplant list by the number of transplants in 2005. Similarly, there is no trend in waitlist mortality by number of ideal donors in the DSA for PAK/PTA transplants or for KP transplants.

The Committee still plans to publish this data to show that there is a possibility to expand pancreas utilization.

16. Pancreas Transplantation Committee Survey of OPOs and Transplant Centers

In September 2007, Dr. Wainright updated the Committee on the work of the Pancreas Survey Subcommittee. During the subcommittee's September 5, 2007 meeting, the subcommittee decided to expand the survey to include more groups in addition to OPO Executive Directors, such as transplant administrators, transplant coordinators, and pancreas transplant surgeons.

In December 2007, Dr. Wainright gave the Committee an update on the survey that the Committee sent to OPOs and transplant centers in November 2007. The Pancreas Survey Subcommittee has sent two reminder e-mails. There had been 151 responses, 60 for the OPO survey and 91 for the transplant center survey. The response rate was approximately 30%. The subcommittee will likely send out at least one more reminder. The Committee requested data on the percent of pancreas transplant activity that is represented by the respondents.

In March 2008, Dr. Wainright presented results of the survey sent by the Pancreas Transplantation Committee to OPOs and transplant centers to determine barriers to pancreas placement **(Exhibit R)**. The OPO survey had a 56% overall response rate. 84.5% of the OPOs responded (at least one employee from the OPO completed the survey). 79.2% of 2006 pancreas transplant (PA and KP) activity is represented by the OPOs that responded. The transplant center survey had a 26.9% overall response rate. 62.3% of the pancreas transplant centers responded (at least one employee from the transplant center completed the survey). 62.9% of 2006 pancreas transplant (PA and KP) activity is represented by the transplant centers that responded. Further results can be found in **Exhibit R**. This exhibits contain all the raw results to each question. Most questions are broken down by organization (one answer per organization); however, opinion questions are broken down by job group. Additionally, the results are broken down by region and by high-performing, middle-performing, and low-performing OPOs (based on recovery rates). The goal of the breaking down the survey in this way was to determine if there are any characteristics that set the high-performing OPOs apart from the low-performing OPO.

The Committee noted that there were not many differences in practice between high and low-performing OPOs. The vast majority (87.5%) of high recovery rate OPOs said they have a formal policy for local allocation of the pancreas, compared to smaller percentages of low and middle recovery rate OPOs (60% and 50%, respectively). The Committee asked the Pancreas Survey Subcommittee to investigate the

formal policies of the high and low recovery rate OPOs further. Also, the vast majority of middle and high recovery rate OPOs (76.9% and 83.3%, respectively) issue waivers when exporting whole pancreata. Only 33.3% of low recovery rate OPOs do so. The Committee noted that there are likely financial reasons for OPOs not offering waivers because they must pay surgeon recovery fees and allocate costs according to the CMS ruling on intent to transplant regardless of whether the organ is accepted.

The Committee also discussed the possibility of publishing the data. The Pancreas Survey Subcommittee will pursue this idea further.

The Committee requested the following information on the survey data:

- Survey results on how centers who responded "yes" to whether they had an active islet program had responded to the two questions regarding revisions to CMS policy. Previous analyses had combined centers who responded "yes" and "other" to the question about having an active islet program into one category.
- Clarify answers about formal pancreas allocation policies for those OPOs who answered 'other' when asked whether they have a formal policy.
- Provide text fields for description of pancreas allocation policy to Pancreas Survey Subcommittee members.
- Explore why OPOs do not issue waivers for exported pancreata.

At its July 2008 meeting, the Committee reviewed the additional survey data it requested in March 2008 **(Exhibit I)**. 100% *(n=10*) of respondents who said that their program has an islet transplant program responded "yes" to both CMS policy questions. UNOS staff also provided the Committee with the text field responses from the survey where centers described their pancreas allocation policies.

Minutes from the Pancreas Survey Subcommittee meetings can be found in **Exhibit T**.

17. Pancreas Transplant Registries

In September 2007, a Committee member informed the Committee that the International Pancreas Transplant Registry (IPTR) was no longer collecting data. There was no continuation of funding from NIH for the project. A Committee member asked that the Committee try to find a way to support the registry because the data is used by so many pancreas transplant surgeons. Dr. Gruessner excused himself from the discussion because his wife was involved with the IPTR. The Committee stated that the IPTR is helpful when comparing whole pancreas and islet cell transplants. The Committee noted that the SRTR or the JDRF might be able to help to continue the IPTR. UNOS staff mentioned that it was not in the OPTN's purview to be involved with the contracts of these other organizations. The Committee asked whether UNOS might be able to assist in light of the fact that the organization does support other registries. The Committee voted to ask the Board to support finding a way to keep the registry functioning. (12-Support, 0- Oppose, 1-Abstain) Dr. Gruessner abstained from the vote.

A Committee member asked if UNOS or the SRTR is collecting data on islet transplants. UNOS and SRTR staff informed the Committee that neither organization is collecting such data, although UNOS has discussed developing forms to collect data on islet transplants. The Committee noted that other islet registries may not be complete because reporting by centers is voluntary. The Committee believes that for the islet field to be successful, it must be transparent. Therefore, complete data on islet transplants are essential. Some Committee members recalled that there had been a subcommittee call to discuss fields for an islet transplant form in 2006 and requested that the Committee be reminded of these discussions. The Committee stated that it would like to work with all the other organizations that collect islet transplantation data and that UNOS should take a leading role with this data. UNOS staff agreed to investigate the status of the collection of islet transplant data within the organization. The Committee set

this issue as a priority and will decide how to move forward once UNOS staff provides a progress update. The Committee requested that UNOS look into how to ensure the protection of data collected by IPTR and Collaborative Islet Transplant Registry (CITR) because this data is of interest to the OPTN. The Committee also requested that concurrent reporting to multiple databases be considered. A goal of this data collection would be the ability to compare whole pancreas and islet transplants.

In December 2007, the Committee asked for an update on whether UNOS could assist with continuing the International Pancreas Transplant Registry (IPTR). UNOS staff stated that they could supply data to the registry. The other registries that UNOS supports have an outside funding source. The SRTR liaisons stated they also had infrastructure but would need funding to work on any registry. The Committee considered sending a letter to the Board expressing its concerns about the data that would be lost without the IPTR. Committee members decided that they should pursue helping the IPTR find funding as individuals outside of the OPTN structure. The Committee also inquired about the lack of islet data, particularly on the UNOS website. UNOS staff informed the Committee that they are working to find data for the Committee to use.

In March 2008, UNOS Staff informed the Committee that UNOS is working with CITR to be able to share CITR data with the Committee. The Committee will need to compile a list of data elements that the Committee wants CITR to send.

18. Waiting Time Modification Requests

In December 2007, the Pancreas Transplantation Committee considered a waiting time modification request. In this case, a candidate was informed she was listed on the kidney/pancreas list with a listing date of 6/15/2007. However, the candidate was actually only placed on the kidney list. The candidate was removed from the kidney list because of a living donor transplant. At the time of the request, the candidate was on the pancreas list with a listing date of 10/16/2007. The request is to change the listing date on the pancreas list to 6/15/2007 because it was the date the center intended to list the candidate for a kidney/pancreas transplant. The Committee voted to approve this waiting time modification request. (9-Support, 0- Oppose, 0-Abstain)

In April 2008, the Committee considered a waiting time reinstatement case via e-mail. In this case, a candidate requested that her waiting time be transferred from the pancreas islet to the whole pancreas list at the same center because the center's islet program had inactivated. The Committee approved the request. (13-Support, 0-Oppose, 0-Abstain)

Policy 3.8.8 (Waiting Time Reinstatement for Pancreas Recipients) states that "immediate and permanent non-function shall be defined as pancreas graft failure requiring the removal of the organ within the first two weeks of transplant." The Organ Center requested that the Committee clarify whether a partial pancreatectomy is considered a "removal of the organ" for the purposes of Policy 3.8.8. In July 2008, the Committee stated that a partial pancreatectomy in the first two weeks of transplant should be treated as a "removal of the organ" for the purposes of Policy 3.8.8. (14-Support, 0-Oppose, 0-Abstain)

The Committee decided to form a subcommittee to review all future waiting time reinstatement and transfer requests. David Axelrod, MD, MBA, Venkatesh Krishnamurthi, MD, and Chris Kuhr, MD, volunteered to serve on this subcommittee.

19. Pancreas Tiered Acceptance Subcommittee

In August 2007, Dr. Wainright presented information on the DSA Task Force Work Group Tiered Acceptance Project. 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. Under the current system, transplant centers enter individual screening criteria for each candidate. 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. The system needs to be detailed enough to effectively screen out candidates, but simple enough that centers will use it not only for new candidates but also for candidates already on the list. 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 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 at its May 18, 2007 meeting. The Committee delegated the remaining considerations to a subcommittee. Christian Kuhr MD, Marlon Levy MD, Kim Patton RN, CPTC, and Ron Taubman served on this subcommittee.

In December 2007, Ms. Sleeman informed the Committee about the work of the Tiered Acceptance Subcommittee **(Exhibit U)**. The subcommittee met in November to validate the template for pancreas tiered acceptance profiles. The subcommittee decided to add whether the candidate will accept CDC high-risk donors as an individual screening criterion in the final template. Also, the subcommittee decided to use local, regional, and national distance categories instead of local, non-local up to 1000 miles, and non-local greater than 1000 miles. The Operations Committee is now in charge of Tiered Acceptance and will determine what the next steps are.

20. Updates from the Kidney Transplantation Committee

In September 2007, Peter Stock, MD, PhD, informed the Committee of the recent activities of the Kidney Transplantation Committee. In May 2007, the Kidney Transplantation Committee decided to have the kidney follow the pancreas in the simulation modeling for the new kidney allocation system. Currently, there is variation across the country as to whether the kidney follows the pancreas or the pancreas follows the kidney in the allocation sequence. The Kidney Transplantation Committee found that candidates with Type 1 diabetes have the best net benefit of all the groups of kidney candidates. The Pancreas Transplantation Committee could look into how the pancreas would be allocated if the kidney follows the pancreas as currently recommended. The Kidney Transplantation Committee is concerned that there could be gaming of the system in the new allocation scheme. For example, centers might list a candidate who only needs a kidney transplant for a kidney-pancreas transplant in order to get an offer faster. Also, kidney-pancreas candidates might turn down acceptable pancreata in order to wait for a "perfect" pancreas, which would reduce utilization.

In March 2008, UNOS Staff informed the Committee that the kidney allocation system proposal had not been released for public comment yet. The Pancreas Transplantation Committee will meet to discuss this proposal when it is available.

21. Regional Pancreatic Recovery Teams

In September 2007, the Committee discussed how to move forward with the idea of regional pancreatic recovery teams. One possibility is to write a letter to OPOs that do not have active pancreas centers asking them what their plan is for the procurement of the pancreas. The Committee noted that the responsibility for recovering the pancreas is on the transplant center that will transplant the pancreas. However, many programs cannot fly their surgeons to procure organs. The Committee requested a list of

which DSAs do and do not have pancreas transplants centers and a comparison of utilization of the pancreas in these DSAs. Committee members noted that facilitating the procurement of the pancreas is consistent with the HRSA program goals and the Committee's annual goals. The Committee decided to partner with the OPO and Membership and Professional Standards Committees to explore this idea further. The Committee noted that there is no guarantee that a transplant surgeon will accept a pancreas procured by other teams, but anatomical waivers may help to mitigate this concern. The Committee stated that it is often helpful to know the credentials of the surgeon who is procuring the pancreas and that the OPOs should provide this information to the accepting transplant surgeon.

22. Pancreas Recovery Standards

Khalid Khwaja, MD, presented pancreas recovery standards at the May 2007 Pancreas Transplantation Committee meeting. In September 2007, the Committee discussed how to disseminate these standards. A video of this procedure may be put on the American Society of Transplant Surgeons website. The Committee agreed to expand these standards for publication. The Committee suggested that pitfalls in the procurement process be included in the article. The Committee discussed the possibility of publishing these standards as a mini-review in the American Journal of Transplantation (AJT). Other alternatives include publishing a resource document or submitting the standards to the National Guidelines Clearinghouse. Both of these options would require Board approval. A Committee member will see if there is interest in these standards from the AJT. These standards have been presented to the Organ Availability Committee in addition to the Pancreas Transplantation Committee.

23. Facilitated Pancreas Allocation

In September 2007, Ms. Sleeman explained the facilitated pancreas policy (Policy 3.8.1.4). This policy allows the Organ Center, under certain circumstances, to offer the pancreas to centers that sign up to be on the facilitated pancreas list. Under this method, some of the screening criteria are not used. The Committee considered whether there could be a facilitated pancreas field in Waitlist[SM]. In the current policy language, a center must send a letter to the Organ Center to be offered pancreata under this policy. The Committee suggested that a letter be sent to transplant centers to educate them about facilitated pancreas allocation while UNOS Staff investigates the feasibility of adding a field to Waitlist.

24. DonorNet® Update

In September 2007, Jason Chicirda, UNOS IT Liaison to the Pancreas Transplantation Committee, gave an update on the additional screening criteria that were implemented on September 12, 2007 and the ones that are proposed. The September 12, 2007 update divided the minimum and maximum age fields into local and import, added a field on the acceptance of HCV positive donors, and added donor minimum and maximum weight fields. The proposed fields include BMI, history of diabetes, history of hypertension, CDC high risk status, peak serum amylase, peak serum lipase, and HTLV I/II positive status.

25. Allocation Algorithm

In September 2007, Dr. Gruessner discussed the development of an algorithm for when a whole pancreas transplant versus an islet cell transplant is appropriate for transplant candidates. The purpose of a publication of this algorithm would be to show that whole pancreas and islet transplants are complementary not competing procedures. An article by Dr. Stock on this topic was given to the Committee at the meeting to be used as a starting point.

26. Letter Regarding CMV Status

In September 2007, the Committee reviewed a letter from a CMV- negative patient who had received a CMV-positive pancreas. She later contracted CMV and lost her graft. She wanted to inform the Committee of this occurrence in hopes of finding a way to prevent the same thing from happening to other patients. The Committee decided to forward the letter to the Operations Committee as a potential patient safety issue and to write to the patient to inform her of the Committee's action.

27. Memo sent to the MPSC Regarding the Impact of the Renal Debt Payback System on Pancreas Program Inactivity

In September 2007, Ms. Sleeman updated the Committee on a memo that had been sent to the Membership and Professional Standards Committee (MPSC) in response to a request for feedback from the MPSC. The memo states that the Pancreas Transplantation Committee believes it is reasonable to consider the effect of the renal payback debt system on pancreas transplant programs when monitoring these programs for inactivity. This memo was sent to the MPSC in July 2007.

28. Letter Regarding Kidney Payback Debt

In December 2007, the Committee reviewed a letter about the renal debt system from an OPO. The letter was written to the Kidney Transplantation Committee and the Pancreas Transplantation Committee was copied. The OPO requested a review of its long-term AB debt. The OPO has owed three AB kidneys since 1999, but it has no other long-term debt. The OPO has requested that these three kidneys be removed from its long-term debt tally so it can operate within short term debt parameters. Additionally, the OPO asked the Kidney Transplantation Committee to abolish the kidney debt system. On December 3, 2007, the Kidney Transplantation Committee voted to table the discussion until they could clarify issues about long-term debt vs. short-term debt. The Kidney Transplantation Committee proposed to discontinue paybacks in the new kidney allocation system.

29. Letter Regarding Multi-Organ Transplants

In December 2007, the Committee reviewed a letter from an OPO that had to rescind a KP offer in order to send out a zero mismatch kidney. As a result of the requirement to send out a zero mismatch kidney, the pancreas was discarded from a 26-year-old donor, the OPO yield was three instead of four, and a patient who had waited three years for a kidney/pancreas transplant was bypassed. The OPO is concerned that policy is vague in how it encourages multi-organ transplants. Also, OPOs are held responsible for yield of transplanted organs per donor. In this case, the policy resulted in the loss of a transplanted organ, which negatively affected the OPO's yield. The OPO requested that the policy regarding how kidneys are placed be reviewed and a clear priority drawn. The OPO suggested that priority be given to placing the maximum number of organs possible (except in life-saving instances). The Committee commented that UNOS also has a policy that the offer cannot be withdrawn, thus creating more conflict among policies. Also, the OPO was responsible for the cost of procuring that organ. The Committee noted that this situation would not have occurred if kidney/pancreas transplants had priority over zero antigen mismatches. The Committee decided to forward the letter to the Liver-Kidney Joint Subcommittee, which is working on multi-organ issues, and express its support about clarifying policy on this matter. The Committee will also inform the OPO of its support.

30. Memo from the OPO Committee: Issues Affecting OPOs in Pancreas Transplants

In March 2008, the Committee reviewed a memo sent by the OPO Committee to the Pancreas Transplantation Committee, Kidney Transplantation Committee, Liver and Intestinal Organ

Transplantation Committee, and the UNOS Department of Evaluation and Quality regarding priority for multi-organ transplants. The OPO Committee noted that there has been a long standing message that multi-organ transplants are encouraged and take some precedence over individual organ transplants. However, there is no policy language that supports that message and practice, and this broadly held concept needs to be clarified. The OPO Committee believes there needs to be a determination of when the multi-organ transplant takes precedence over the placement of individual organs.

The Committee commented that whereas there are few impediments for a kidney to follow a liver, the situation is not the same for the pancreas. There is some confusion about what list to use. The Committee wants to develop a list of where the kidney/pancreas should come in priority. The Committee has no problem with KPs coming after heart/kidneys and liver/kidneys, but the Committee wants to define situations where a KP might be prioritized over zero mismatch offers and pediatric candidates. The Committee noted that they could set rules for who could receive a KP and could combine the PA and KP list, which would reduce the number of kidneys that follow the pancreas. The Liver and Kidney Transplantation Committees are already working together to set criteria for liver/kidney transplants. The same could be done for kidney/pancreas and heart/kidney transplants. Having priority for KPs in DCD or ECD organs might be another way to facilitate more transplants. The Committee thought that KPs should certainly have priority over paybacks.

The Committee requested data on the average waiting time for unsensitized pediatric kidney recipients on dialysis since the Share 35 policy went into effect. The Committee also wanted to know the number of kidneys from good donors going to liver/kidney recipients and heart/kidney recipients.

The Committee agreed that multi-organ transplants should be encouraged. The current situation disadvantages kidney/pancreas transplants, and there should be a reconsideration of the situation that recognizes that there are some conditions under which a kidney/pancreas transplant should take priority over a pediatric, payback, or zero mismatch transplants. The Committee formed a subcommittee to continue this discussion and respond to the OPO Committee. David Axelrod, MD, Rainer Gruessner, MD, Dixon Kaufman, MD, PhD, Khalid Khwaja, MD, Chris Kuhr, MD, and Jim Markmann, MD, PhD, volunteered to serve on this subcommittee.

31. Letter Regarding Multi-visceral Transplants

In July 2008, the Committee discussed a letter from a member regarding multi-visceral transplants. The member noted that candidates should not be included in pancreas waiting list mortality rates and suggested that recipients of pancreata transplanted for technical reasons should not be subject to the same follow-up requirements as recipients of pancreata not transplanted as part of a multi-visceral transplant. The SRTR stated that multi-visceral recipients were already excluded from outcomes statistics. The Committee requested data on the percentage of multi-visceral transplant recipients that are diabetic at the time of transplant. The SRTR also updated the Committee on its decision to exclude multi-visceral candidates from pancreas waiting list mortality statistics as well. If a candidate is listed for the pancreas and the intestines, that candidate is not included in pancreas waiting list mortality rates.

32. Letter Regarding Crossmatch Policy and Acceptance and Refusal Reasons

In July 2008, the Committee reviewed a letter requesting that the Committee make a policy to require that a donor blood sample to be sent to the recipient center as soon as the center learns that its recipient is first or second on the match run or back up to another high PRA recipient. The Committee agreed that this practice is helpful. However, it cannot be a mandated policy because it would not be possible to ship the donor blood sample in advance in all circumstances. The Committee voted to send a letter to the member

explaining that the Committee supported the idea but could not base a policy on this recommendation. (11-Support, 0-Oppose, 1-Abstain)

33. Policy 3.8.1.7.1- Organ Offer Limit

In December 2007, the Committee reviewed a policy proposal that the Operations Committee plans to send out for public comment in February 2008. In May 2007, the Executive Committee resolved to allow OPOs to make offers for zero mismatch organs. Previously, only the Organ Center could make offers for zero mismatch organs. When the Organ Center was making all zero antigen mismatch offers, the time limits outlined in policy were calculated consistently. However, time was not calculated consistently across OPOs, so there was potential for candidates to be treated unequally. Additionally, because of DonorNet® advances, time was no longer a practical way to measure organ offer limits, and there was a monitoring challenge for UNOS staff. Using number of offers rather than number of hours solved all these problems. The Electronic Organ Placement Working Group (EOPWG) recommended using ten organ offers in place of four hours because the Organ Center can make roughly ten organ offers in four hours (and five offers in two hours). In September 2007, the Board approved changes to Policy 3.5.3.5 (Organ Time Limit). The modification changed how OPOs must offer zero antigen mismatch kidneys. The original policy required OPOs to offer kidneys for a certain number of *hours*; the modified policy required OPOs to make a certain number of *offers*. However, the policy for offering zero antigen mismatch pancreata and kidney/pancreas combinations was not changed at the same time. The current approved policy would require an OPO to:

- offer a zero mismatch pancreas for a specified number of *hours*;
- make a specified *number* of zero mismatch kidney offers; and
- offer a zero mismatch kidney/pancreas for a specified number of *hours*.

UNOS staff has drafted policy language to measure zero mismatch organ offer limits by number of offers. The Operations Committee is sponsoring this change, but before the proposed modifications go out for public comment, the Kidney Transplantation Committee, Pancreas Transplantation Committee, OPO Committee, and Transplant Coordinator Committee will have the opportunity to provide feedback on the proposed changes.

The OPO Committee recommended that the OPO have two business days to report the zero mismatch share to the Organ Center with the time period beginning at cross-clamp of the aorta. The Pancreas Transplantation Committee did not have a problem with these recommendations. The Pancreas Transplantation Committee also agreed that the OPO is not entitled to a payback if the OPO continues to make zero mismatch offers beyond what is required in policy. The requirement for organs to be offered as zero antigen mismatches within eight hours of procurement for standard criteria donors and within four hours of procurement for expanded criteria donors was eliminated in the language approved by the Board in September. The OPO Committee requested that this requirement be put back into policy, and the Pancreas Transplantation Committee supported this request.

The Committee was concerned that ten might not be an appropriate stopping point for zero mismatch offers. The Committee requested data on how many zero mismatch organ offers are made before the organ is accepted. The Pancreas Transplantation Committee voted to support these proposed modifications to change the measurement of zero mismatch organ offers from number of hours to number of offers. (5-Support, 0-Oppose, 0-Abstain) The Committee will reconsider the actual number of offers that should be made in March 2008.

34. Public Comment Proposals

a. Proposed Modification to the OPTN Bylaws, Appendix B, *Transplant Hospitals;* Section B. *Survival Rates;* and Section C *"Inactive Membership Status"; a*nd Attachment I, Section II, "*Inactive Program Status*"; and to the UNOS Bylaws, Attachment I, Section II "*Inactive Program Status*" and Attachment II, Section XIII, C, (10) "*Survival Rates.*" (Membership and Professional Standards Committee)

In December 2007, the Committee discussed the proposed bylaw modification. The modification documents the MPSC's current practice of holding informal discussions with Members during its review of survival rates and activity in transplant programs. The Committee agreed that the practice of holding informal discussions with members is a good practice. The Committee voted to support the proposed changes (7- Support, 0- Oppose, 0- Abstain.)

b. OPTN/UNOS Proposed Resource Document for the Medical Evaluation of Living Kidney Donors (Living Donor Committee)

In December 2007, he Committee considered whether it should weigh in on the Resource Document for the Medical Evaluation of Living Kidney Donors because it does not relate to the pancreas. The Committee noted that many parts of this document would be used as a template for any future resource documents, which could affect the pancreas. Therefore, the Committee should note any concerns about the document at this time. The Committee requested additional time to review the document. After further discussion after the meeting, the Committee responded to the proposal as follows:

The Pancreas Transplantation Committee discussed the proposed Resource Document for the Medical Evaluation of Living Kidney Donors as a template for resource documents for the medical evaluation of living donors for other organs. The Pancreas Transplantation Committee's concerns would apply to any such document. The Committee thinks that the blood pressure evaluation in Section 2b and metabolic focused evaluation in Section 2f are excessive. In Section 1.l, the Committee has concerns about the statement "and has disability and health insurance." The implication is that disability insurance is needed. This provision should be either eliminated or changed to reflect that the donor has considered the problems with going ahead without disability insurance. Further, it is unnecessary to determine if every potential donor has disability insurance. It is more than sufficient that potential donors are apprised of the possibility that they may have lost wages during their recovery and that they may want to look into disability insurance coverage.

c. Proposal to Change the OPTN/UNOS Bylaws to Require Written Notification (or Disclosures) to Living Donors from the Recipient Transplant Programs- Living Donor Committee

The Pancreas Transplantation Committee considered this proposal in March 2008. This proposal would require that recipient transplant centers must provide written notification to living organ donors within ten business days following their donation date to include the following:

- The telephone number that is available for living donors to report concerns or grievances through the OPTN;
- Disclosure that the recipient transplant center is required to submit Living Donor Follow-up (LDF) forms to the OPTN for a minimum of two years; and
- The plan for obtaining living donor data for completion of follow-up forms.

The Pancreas Transplantation Committee voted to support this proposal. (14-Support, 0-Oppose, 0-Abstain)

d. Proposal to the OPTN and UNOS Bylaws: Restoration of Membership Privileges Following an Adverse Action- MPSC

The Pancreas Transplantation Committee considered this proposal in March 2008. This proposal establishes the circumstances under which the MPSC can consider restoring a member's full privileges, including the timeframe. A member must wait twelve months before it can request the MPSC to consider a lesser action. The Committee voted to support this proposal. (14-Support, 0-Oppose, 0-Abstain)

e. Proposal to Require Transplant Centers to Inform Potential Recipients about Known High Risk Donor Behavior- Executive Committee

The Pancreas Transplantation Committee considered this proposal in March 2008. This proposal clarifies the criteria for high risk behavior and requires transplant professionals to obtain informed consent prior to implantation when the donor is classified as high risk according to these criteria. The Pancreas Transplantation Committee is concerned that the CDC guidelines upon which these criteria are based are out-of-date. Furthermore, the Committee thought that this process should be recommended by UNOS rather than mandated. The Committee recommends that NAT testing should take place, which should help alleviate concerns about high risk donors. The Committee voted to oppose the proposal until revisions are made to the criteria for high risk behavior. (3-Support, 8-Oppose, 1-Abstain)

f. Proposal to Change Organ Time Limits to Organ Offer Limits for Zero Antigen Mismatched Kidneys, Pancreata, and Kidney/Pancreas Combinations- Operations Committee

The Pancreas Transplantation Committee considered this proposal in March 2008. This proposal would change the rule that zero mismatch kidneys, KPs, and pancreata must be offered for four hours. Instead, ten zero mismatch offers must be made before the OPO can allocate from the local list. In December 2007, the Pancreas Transplantation Committee requested information on how many zero antigen mismatch pancreata and kidney/pancreas combinations are placed after the tenth offer. On the PA list, there were 22 zero antigen mismatch pancreas offers in 2007. Five of those offers were accepted, and the highest sequence number was six. On the KP list, there were 29 zero antigen mismatch offers and thirteen acceptances in 2007, one for PA alone and twelve for KP. The PA alone acceptance was at sequence ten, but three candidates were bypassed, so only seven offers were made. All of the accepted KPs were at sequence one. The Committee voted to support this proposal. (14-Support, 0-Oppose, 0-Abstain)

g. Proposal to Limit Mandatory Sharing of Zero Antigen Mismatch Kidneys to Children and Sensitized Adult Candidates- Kidney Transplantation Committee

The Pancreas Transplantation Committee considered this proposal in March 2008. This proposal would limit mandatory sharing of zero mismatch kidneys to pediatric and sensitized (PRA ≥20%) candidates. The intent of this modification is to reduce the number of mandatory shares of zero antigen mismatched kidneys for unsensitized kidney transplant candidates, resulting in fewer payback debts, shorter cold ischemic times for kidneys, and improved efficiency of the OPTN kidney allocation system. The Pancreas Transplantation Committee discussed this proposal at length. High payback debt in the local OPO does inhibit a center's ability to perform kidney/pancreas transplants. Limiting sharing has worked in some OPOs to reduce payback debt. In OPOs where kidney/pancreas transplants cannot occur, pancreata are being wasted. Additionally, zero mismatch offers are not equitable because some candidates happen to get an offer whereas others do not. However, there is generally longer graft survival for zero mismatch organs. Some Committee members believe that the problem is only with paybacks but not with zero mismatch sharing and are concerned that this proposal ignored biology. The Committee would like to know how much advantage there is for a zero antigen mismatch kidney. The Committee also believes that this proposal is only an interim step and that there should be more priority for kidney/pancreas candidates. The Committee voted to support the proposal. (9-Support, 3-Oppose, 0-Abstain)

h. Proposal to add the factor "change in bilirubin" to the lung allocation score (LAS)-Thoracic Organ Transplantation Committee

The Committee did not discuss this proposal because it has no effect on pancreas allocation.

i. Proposal to verify that foreign agencies importing organs to the United States, or receiving organs exported from the United States, are legitimate and test organs for transplant safety-Ad Hoc International Relations Committee

This proposal clarifies and strengthens existing policy language on importing and exporting deceased donor organs to and from the US. Specifically, this proposal addresses the following:

- Clinical (laboratory) safety of imported organs;
- Application of ethical practices in recovering deceased donor organs imported for transplant;
- Application of ethical practices in distributing organs exported from the US; and,
- Legitimacy of the foreign organization engaged in importing an organ to an OPTN member or receiving an organ exported from an OPTN member.

The intent of these modifications is to promote the safety of the organ for transplant purposes and to insert measures into policy to verify the credibility of the foreign agency importing an organ to or receiving an organ exported from the US.

The Committee agreed with the intent of this proposal. However, the Committee recommended that islets should not be exported out of the country because the field of islet transplantation is not yet developed enough. The Committee voted to approve the proposal with islets excluded. (13-Support, 0- Oppose, 0-Abstain)

j. Proposal to improve the safety of living donation by restricting the acceptance and transplant of living donor organs to OPTN member institutions- Living Donor Committee

This proposal requires OPTN member transplant programs that perform living donor transplants to only transplant organs recovered at an OPTN member institution. The Committee agrees with this proposal. Additionally, the Committee believes there should be a fast track process for donor hospitals to become OPTN member institutions. This process should not place undue administrative burden on the centers applying for membership to recover living donor organs. The Committee voted to approve this proposal. (17-Support, 0-Oppose, 0-Abstain)

k. Proposal to modify the bylaws pertaining to c*onditional approval status for liver transplant programs that perform living donor transplants*- Membership and Professional Standards Committee

The Committee did not discuss this proposal because it has no effect on pancreas allocation.

l. Proposal to change the OPTN/UNOS Bylaws to better define functional inactivity, voluntary inactive membership transplant program status, relinquishment of designated transplant program status, and termination of designated transplant program status- Membership and Professional Standards Committee

This bylaw proposal clarifies the current definition of functional inactivity by including information about waiting list inactivation in UNet^{sm}. The proposal defines short-term voluntary inactivation as inactivation of a program waiting list in UNet^{sm} for 14 days or fewer; and long-term voluntary inactivation as inactivation of membership status based on the expectation the program will remain inactive for greater than 14 days. These modifications also specify exactly what a member must do in terms of notifying candidates when a program voluntarily inactivates or relinquishes its designated program status (long-term inactivation).

The Committee was concerned that centers may not be able to transfer candidates within 60 days of relinquishment of designated program status because the transfer is dependent on another center's ability to accept and work up these candidates. Additionally, the Committee thought that these requirements would be difficult for islet programs to meet, particularly if the program is in between clinical protocols. The Committee supported this proposal with an amendment that it does not apply to islet transplantation programs because of the experimental nature of the islet transplantation field. (14-Support, 0-Oppose, 1-Abstain)

35. Update on Policy 7.1.3- Follow Up After Graft Failure

In March 2008, UNOS Staff updated the Committee on Policy 7.1.3 (Follow Up After Graft Failure). In June 2006, Policy 7.1.3 was modified to eliminate the requirement to follow patients after graft failure. The intent of the change was to discontinue follow-up after graft failure for kidney, pancreas, and kidney/pancreas recipients because death information can be ascertained from other sources. However, the approved policy language would require that centers follow all patients until death. The POC proposed to change the language to require that "each organ must be followed until graft failure." This change was approved by the Board in February 2008. Once it is implemented, transplant centers will no longer need to fill out follow-up forms for kidney, pancreas, and kidney/pancreas recipients after they have lost their graft.

36. Thank you to Outgoing Members, Terms Ending June 30, 2008

In March 2008, the Committee Chair recognized and thanked the following Committee members for their service to the Pancreas Transplantation Committee:

Alexander Wiseman, MD - Region 8 Representative
Kenneth L. Brayman, MD, PhD – Region 11 Representative
James F. Markmann, MD, PhD – At Large Representative
Helen Nelson, RN, BSN, CCTC – At Large Representative
Kim J. Patton, RN, CPTC – At Large Representative
Paul J. Volek, MPH – At Large Representative

PANCREAS COMMITTEE		JULY 1 - DECEMBER 31, 2007			JANUARY 1 - JUNE 30, 2008	
	MONTH	AUGUST	SEPTEMBER	DECEMBER	MARCH	MAY
	DAY	24	26	7	14	9
	FORMAT (select)	Live Meeting/ Teleconference	In Person	Live Meeting/ Teleconference	In Person	Live Meeting/ Teleconference
NAME	POSITION					
Rainer W. Gruessner MD	Chair	X	X	X	X	
Dixon Kaufman MD, PhD	Vice Chair	X	X	X	X	X
David Axelrod MD	Regional Rep.		X		X	
Peter Abt MD	Regional Rep.	X	X (by phone)	X	X	X
George Burke III, MD, FACS	Regional Rep.					
Marlon Levy MD	Regional Rep.		X			
Ron Taubman	Regional Rep.	X	X			X
Christian Kuhr MD	Regional Rep.	X	X	X	X	
Joseph Leventhal MD, PhD	Regional Rep.		X (by phone)			
Alexander Wiseman MD	Regional Rep.	X	X	X	X	X
Sandip Kapur MD	Regional Rep.		X (by phone)		X	
Venkatesh Krishnamurthi MD	Regional Rep.	X	X		X	X
Kenneth Brayman MD, PhD	Regional Rep.					
Albert Hwa, PhD	At Large	X	X	X	X	X
David Harlan MD	At Large			X		
Khalid Khwaja MD	At Large		X (by phone)		X	
James Markmann MD, PhD	At Large		X	X	X	X
Christopher Marsh MD	At Large	X	X	X	X	
Helen Nelson RN, BSN, CCTC, CPTC	At Large	X	X	X	X	
Kim Patton RN,CPTC	At Large	X	X	X	X	X
Paul Volek MPH	At Large	X		X	X	
Peter Stock MD, PhD	Ex Officio	X	X	X	X	X
Gregory Fant PhD	Ex Officio					
Elizabeth Ortiz-Rios MD, MPH	Ex Officio	X	X	X	X	X
Jim Galloway PhD	SRTR Liaison	X	X			
Randall Sung MD	SRTR Liaison	X	X	X	X	
Kathryn Meyer MS	SRTR Liaison	X	X	X	X	X
Sangeetha Krishnan	SRTR Liaison			X		
Elizabeth Sleeman MHA	Committee Liaison	X	X	X	X	X
Jason Chicirda	Support Staff		X	X	X	X
Dielita McKnight	Support Staff	X	X	X		
Jennifer Wainright PhD	Support Staff	X	X	X	X	X
Ciara J. Gould MSPH	Support Staff	X	X			
Karl McCleary PhD	Support Staff		X			

PANCREAS COMMITTEE		JULY 1, 2008 - DECEMBER 31, 2008	
	MONTH	JULY	SEPTEMBER
	DAY	18	12
	FORMAT (select)	In Person	Live Meeting/ Teleconference
NAME	COMMITTEE POSITION		
Rainer W. Gruessner MD	Chair	X	X
Dixon Kaufman MD, PhD	Vice Chair	X	X
David Axelrod MD, MBA	Regional Rep.	X	
Peter Abt MD	Regional Rep.	X	
George Burke III, MD, FACS	Regional Rep.		
Marlon Levy MD	Regional Rep.	X	X
Ron Taubman	Regional Rep.	X	X
Christian Kuhr MD	Regional Rep.	X	X
Joseph Leventhal MD, PhD	Regional Rep.		
Ahmad Abdulkarim MD, PhD	Regional Rep.		
Sandip Kapur MD	Regional Rep.		X
Venkatesh Krishnamurthi MD	Regional Rep.	X	X
Dinesh Ranjan MD	Regional Rep.	X	X
Mary Beth Drangstveit RN	At Large	X	
David Harlan MD	At Large	X (by phone)	
Albert Hwa PhD	At Large	X	X
Khalid Khwaja MD	At Large	X	
Christopher Marsh MD	At Large	X	X
Patricia Niles RN, BS, CPTC	At Large		X
Horatio Rilo MD	At Large	X	X
Meg Rogers	At Large	X	
Paul Volek MPH	At Large	X	
Peter Stock MD, PhD	Ex. Officio	X	
Gregory Fant PhD	Ex Officio		
Elizabeth Ortiz-Rios MD, MPH	Ex Officio	X	X
Kathryn Meyer MS	SRTR Liaison	X	X
Randall Sung MD	SRTR Liaison	X	
Elizabeth Sleeman MHA	Committee Liaison	X	X
Jason Chicirda	Support Staff	X (by phone)	X
Jennifer Wainright PhD	Support Staff	X	X
Karl McCleary, MPH, PhD	Support Staff	X	
Paula Bryant, MBA	Support Staff	X	
Aaron Powell, PMP	Support Staff	X	
Mary Ellison, PhD	Support Staff	X	
Alex Miller, MPP	Support Staff		X