EXECUTIVE SUMMARY
OF THE MINUTES
OPTN/UNOS BOARD OF DIRECTORS MEETING
December 13-14, 2006
Tucson, Arizona

Dr. McDiarmid called the meeting to order at 4:00 p.m. on December 13, 2006. A quorum was present, and 38 of the Board members were in attendance during the meeting.

The Board approved several resolutions contained in the Consent Agenda in a single vote. The subject of the various individual resolutions follows here:

1. The Board approved "Best Practice Guidelines" for histocompatibility testing practices, and these guidelines will be posted on the OPTN website as a professional resource.

2. The Board approved modifications to Policy 3.6.11 (Allocation of Livers for Segmental Transplantation), which will utilize specific criteria to identify split liver donors on every OPO match run while also identifying candidates who have indicated they would be willing to accept a segmental graft.

3. The Board approved modifications to Policy 3.6.4.1 (Adult Candidate Status) and Policy 3.6.4.2 (Pediatric Candidate Status), which will reduce the requirement for the AST level for primary non-function from 5000 to 3000 and allow RRB review for Status 1A and 1B cases that do not meet the criteria and clarify the language addressing hepatic artery thrombosis in adult candidates.

4. The Board approved modifications to Policy 3.6.2.2 (Liver Allocation to Candidates Willing to Accept an Incompatible Blood Type), which will modify the MELD/PELD score requirements for candidates who are willing to accept a liver from a donor of any blood type.

5. The Board approved modifications to Policy 2.2 (Evaluation of Potential Donors), which will clarify the responsibilities of the Host OPO in undertaking specified evaluations of potential donors and will require that when specified evaluations are undertaken and the information is not available, the Host OPO must explain those circumstances.

6. The Board approved revisions to the Bylaws, Appendix A and Appendix B "Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership" that will categorize potential violations into three categories of violations; further improve the timeliness of the Membership and Professional Standards Committee (MPSC) compliance monitoring; and codify the MPSC process for facilitating Member compliance with OPTN requirements.

7. The Board approved modifications to Policies 3.4.1 (Time Limit for Acceptance) and 7.6.1 (Entry and Validation of Offers) to require centers to access donor information electronically within one hour of the initial offer and to validate patient-specific refusal reasons online.

8. The Board approved modifications to Policy 3.8.2 (Waiting Time Adjustment) to provide a mechanism for candidates listed for pancreas or pancreatic islet transplant to transfer waiting time between the whole organ and pancreas islet cell lists.

9. The Board approved modifications to Policy 3.7.2 (Geographic Sequence of Thoracic Organ Allocation), which will create a new Zone E for thoracic organ allocation, defined as greater than 2500 miles from the donor hospital.

10. The Board approved the minutes of the September 20, 2006, Meeting of the Board of Directors in Richmond, Virginia.

11. The Board approved modifications to the Bylaws Article VII (Permanent Standing Committees) to remove the Communications Committee as a Permanent Standing Committee.

12. The Board approved the distribution of a white paper entitled "OPO Guidelines – Specimens for Histocompatibility Testing." The intent of this document is to provide information and guidelines for OPOs on the types of specimens that should be collected for histocompatibility testing; how to handle the specimens to maintain maximum quality; and the amount of material that is needed by the laboratory.

13. The Board approved modifications to the Bylaws, Appendix 3A – HLA A, B and DR Antigen Values and Split Equivalences Table, which is required to be updated annually pursuant to Policy 3.5.14 (Broad and Split Antigen Specificities) to reflect current histocompatibility practices.

14. The Board approved modifications to Policy 3.6.4.2 (Pediatric Candidate Status), which will change the recertification and lab requirements for pediatric Status 1B candidates with metabolic diseases and hepatoblastoma, and reduce the requirement for red blood cell replacement for combined liver-intestine candidates.

15. The Board approved membership changes including three new transplant centers; fifteen new programs in existing member centers; one new medical/scientific organization member; and recognition under the multi-visceral program criteria of a pediatric hospital.

16. The Board granted conditional approval to one existing program that experienced a change of status due to a change in key personnel.

17. The Board approved a thoracic organ transplant six-month follow-up form to confirm the status of patient and graft survival at six months post-transplant.

Following passage of the Consent Agenda, the Board granted final approval to the proposed alternative allocation system for Region 8, which will establish broader sharing of livers for candidates with MELD/PELD scores of >= 29.

The Board approved new Policy 3.11.4.2 (Combined Liver-Intestine Organs from Donors 0-10 Years of Age), which will allow combined liver-intestine grafts to be allocated to national candidates from the liver waiting list if there are no local Status 1A or 1B candidates or candidates with a PELD score of 20 or greater. The intent of this proposal is to increase the availability of smaller size organs for pediatric liver-intestine candidates.

The Board approved modifications to Policy 3.6.4.7 (Combined Liver-Intestine Candidates), which will provide an additional 23 MELD/PELD points for candidates aged 0-17 awaiting a combined liver-intestine transplant.

The Board approved modifications to Policy 3.8.1 (Pancreas Allocation), which will assign priority based upon candidate sensitization, using a more precise standard to define sensitization than panel reactive antibody (PRA) level as presently used in organ allocation, in addition to waiting time. A related proposal to apply these policy modifications to OPOs operating with an approved AAS for allocating pancreata was withdrawn. Finally, the Board directed that the approved modifications shall be applied to OPOs operating with an approved AAS, as well as the national system for allocating pancreata, unless an application is made to continue the AAS by February 1, 2007.

The Board approved new Attachment III to Appendix B of the Bylaws to set forth broad categories of model elements required to be addressed in OPO and Transplant Hospital DCD Recovery Protocols.

The Board granted final approval to modifications to Bylaws Appendix B (Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership) to require that OPOs and Transplant Hospitals must develop by January 1, 2007, and once developed must comply with, protocols to facilitate the recovery of organs from DCD donors. Effective March 30, 2007, these DCD protocols must address the model elements set forth in the newly approved Attachment III to Appendix B of the Bylaws.

The Board approved the Slate of Nominees for the election of the members of the Board of Directors for the term beginning at the conclusion of the last regular meeting of the Board of Directors prior to July 1, 2007.

The Board approved revisions to the UNOS Bylaws, Appendix B, Attachment I, Section XII, (C), (11) “Patient Notification” and to the OPTN Bylaws, Appendix B, Section II “Transplant Hospitals,” “Patient Notification” that will require notice to patients regarding how they can report to the OPTN their concerns or grievances with a transplant program or their experience with organ transplantation in general, and amended the proposed bylaw modification to allow for the potential to require additional notifications to patients as may be directed by the Executive Committee.

The Board approved modifications to Policy 3.5.11.3 (Panel Reactive Antibody), which will replace PRA with a Calculated PRA (CPRA), defined as the percentage of incompatible donors (i.e., donors expected to have one or more of the unacceptable antigens indicated on the Waiting List for the candidate).

The Board approved an additional proposal directing that these modifications to Policy 3.5.11.3 (Panel Reactive Antibody) shall apply to all OPOs operating with approved alternative systems for assigning priority in sensitized kidney patients as well as the national kidney allocation system, unless an affected OPO applies to incorporate CPRA into its existing alternative system.

The Board approved modifications to Policies 3.5.11.1 (Time of Waiting), which will require a dialysis date to be recorded for pediatric kidney candidates on dialysis, even though this date does not currently affect allocation priority for pediatric candidates under national policy.

The Board directed that the OPTN/UNOS evaluate the implications of retaining weight as a required data field on the pancreas and kidney/pancreas Transplant Recipient Follow up (TRF) form in the context of the Policy Oversight Committee's (POC) data reduction proposals.

The Board approved a revised statement of purpose for the Minority Affairs Committee directing that the Committee seek to develop policies that will directly address challenges faced by minorities in need of transplantation, candidates, recipients, and donors in the United States, as well as living donor issues pertaining to minorities. Through periodic review of data including rates of referral for transplant evaluation, listing, and transplantation, waiting list morbidity and mortality, graft and patient survival, and indicators of morbidity and quality of life for different ethnic groups, the Minority Affairs Committee will assess the impact of policies on minority transplant candidates and recipients.

The Board approved the following principles for data collection:

Institutional members must provide sufficient data to OPTN to allow it to:

a) Develop transplant, donation, and allocation policies;
b) Determine if Institutional Members are complying with policies;
c) Determine Member-specific performance;
d) Ensure patient safety when no alternative sources of data exist; and
e) Fulfill the requirements of the OPTN Final Rule.

The Board approved the following operational statements for data collection:

1. The OPTN will only collect data that is contracted by HRSA.

2. Data collected and submitted by Institutional Members to the OPTN may differ in nature and character for specific populations, forming exceptions to Guiding Principles above (e.g. Pediatrics, Living Donors). For these exceptions to the foregoing principles, alternative sources of information must be explored and supported, duplication of existing efforts (e.g. registries) avoided, and sample data collection considered. The need and purpose of any such exceptions must be clearly articulated and subject to Policy Oversight Committee and Board approval, and public comment.

3. All future data requests by OPTN committees must be justified in the context of the above guiding principles, and new data collection will require approval by the Policy Oversight Committee and the Board of Directors of the OPTN, and be subject to public comment.

The Board approved modifications to Policy 3.6.4.4 (Liver Transplant Candidates with

Hepatocellular Carcinoma), which will clarify the language regarding tumor candidates who have undergone ablation therapy.

The Board approved modifications to Policy 7.0 (Data Submission Requirements) to require OPOs to submit patient level data for all imminent and eligible deaths in its DSA.

The Board approved modifications to Policy 7.7 (Submission of Death Notification Information) to require OPOs to submit patient level imminent neurological death notification data within 30 days of the date of the death notification.

The Board approved modifications to the Bylaws, Appendix B, Section II (Transplant Hospitals), which will require that transplant hospitals must fully inform the OPTN Contractor within 5 days of actual or threatened actions by any state or federal agency that would impose a significant limitation upon a transplant program's ability to serve transplant candidates or recipients.

The Board approved modifications to the Bylaws, Appendix B, Sections I (Organ Procurement Organizations) and III (Histocompatibility Laboratories), which will require that OPOs and Histompatibility Laboratories must fully inform the OPTN Contractor within 5 days of actual or threatened actions by any state or federal agency that would impose a significant limitation upon the institution's ability to procure organs or perform histocompatibility testing for the benefit of transplant candidates and recipients., respectively.