

EXECUTIVE SUMMARY
OF THE MINUTES
OPTN/UNOS
BOARD OF DIRECTORS MEETING
June 29-30, 2006
Atlanta, Georgia

Dr. Delmonico called the meeting to order at 9:00 a.m. on June 29, 2006. A quorum was present, and 33 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 modifications to the Bylaws Appendix 3A (HLA Antigen Values and Split Equivalences) to update the table to reflect current practices in laboratory practice.
2. The Board approved modifications to Policy 3.5.11.3 (Panel Reactive Antibody) to clarify modifications approved by the Board in June 2005 to require that the specification of unacceptable antigens must be able to support a PRA level of 80% or higher.
3. The Board approved membership changes including two new transplant centers; one new program in an existing member center; fifteen live donor liver programs; and one new independent histocompatibility laboratory.
4. The Board approved applications to renew the membership of non-institutional members who desire to continue their membership for additional two-year terms.
5. The Board approved modifications to the Heart Status 1A Justification Form to include collection of type of RVAD, LVAD, or Total Artificial Heart including device infection information. The form will also collect the type of BNP test used and "paced rhythm," if applicable for exceptions.
6. The Board discontinued the Region 9 – New York State Alternative Organ Allocation/ Distribution System (AAD System) for Lungs.
7. The Board discontinued the State of Florida AAD System for Lungs.

Following passage of the Consent Agenda, the Board established a working group under the auspices of the OPO Committee to develop the essential elements that must be addressed in protocols for Donation after Cardiac Death (DCD) donor organ recovery.

The Board approved extensive modifications to the Bylaws Appendix B, Criteria for Institutional Membership that would bring greater consistency to the requirements among the different organs; update the requirements to reflect current practices; clarify the language to make the requirements easier to understand; and codify committee interpretations of certain requirements.

The Board approved for distribution for public comment, modifications to Bylaws Appendix A, Application and Hearing Procedures for Members and Designated Transplant Programs, that provide for classifying potential policy violations and expedited review of such potential violations by the Executive Committee based on the seriousness of the alleged violation and the potential threat to patient health or public safety.

The Board approved for distribution for public comment, modifications to Bylaws Appendix B, Attachment I, Section XII(CC)(11) (Patient Notification), that will require transplant programs to notify candidates of a confidential line of communication to report issues or concerns directly to UNOS.

The Board approved for distribution for public comment, modifications to Appendix B, Attachment I, Section VI of the OPTN Bylaws and Section XII(C) of the UNOS Bylaws that will define the term “on site” with relation to program coverage by surgeons and physicians and include a requirement for submission of a Program Coverage Plan to ensure the availability of transplant surgeons and physicians.

The Board approved for distribution for public comment, modifications to Appendix A, Section 1.03A (Procedures Upon Application for Membership), that will require applicants to submit a Plan for Continuing Policy Compliance that reports results from an assessment by the named primary transplant physician or surgeon regarding the involvement of any of the program’s physicians or surgeons in any prior transgression of OPTN requirements.

The Board approved for distribution for public comment, modifications to Bylaws Appendix B, Section II (Transplant Hospitals – Investigations of Personnel); and Appendix B, Attachment I, Sections IV (Investigations of Personnel) and VII (Transplant Surgeon and Physician), that will require the Transplant Hospital, at the request of the MPSC, to conduct a peer review inquiry of personnel identified by the MPSC who are associated with one or more designated transplant programs, to examine the individual’s role in a matter under review by the MPSC.

The Board approved for distribution for public comment, modifications to Appendix B, Attachment I, Section XII(C) of the UNOS Bylaws that add as an additional criterion for membership that an individual seeking approval through fellowship training or acquired clinical experience must submit a letter of recommendation from the primary transplant surgeon or primary transplant physician who supervised the fellowship training program.

The Board approved the corrective action plan submitted by St. Vincent Medical Center and requested clarification from the center regarding ongoing physician relationships, program coverage, and candidate notifications.

The Board approved the 2007 OPTN Operating Budget and proposed Registration Fee based upon the current level of operational activities.

The Board approved an additional \$10 increase in the Registration Fee to provide funding for new membership and compliance activities above the current level of operational activities.

The Board approved the 2005 Audited Financial Statements for OPTN Operations and the related OMB Circular A-133 compliance audit for the year ended September 30, 2005.

Secretary's Note: The Board of Directors, in closed session serving as the UNOS Board of Directors, approved several resolutions to provide funding that will be used to develop a new OPTN Data System costing approximately \$8,137,000 including an increase in the UNOS Computer Registration Fee, withdrawal from corporate reserve funds, establishing a line of credit with Wachovia Bank, potential federal funding, and continued corporate fund raising.

The Board directed that OPTN data collection should be reviewed and approved by the Policy Oversight Committee (POC) annually and submitted to the Board for its approval.

The Board directed that the OPTN will, on rare occasions, collect limited but necessary data regarding patient safety in areas in which the OPTN has a unique perspective or responsibility for monitoring patient safety, which may include requirements articulated in the OPTN contract or the OPTN Final Rule.

The Board approved modifications to Policy 7.1.3 that would remove the requirement for following transplant candidates after graft failure.

The Board directed that certain data elements recommended for deletion by the POC shall no longer be required for validation of the Transplant Candidate Registration (TCR), Transplant Recipient Registration (TRR), Transplant Recipient Follow-up (TRF) forms.

The Board directed that collection of OPTN immunosuppression data should be collected in its current format, but will be collected on the TRR form at the time of discharge and at twelve months follow-up only.

The Board directed that collection of post-transplant malignancy data shall be limited to tumor types, site, and cancer diagnosis date. Collection of these data will be reevaluated by the Policy Oversight Committee and Board in two years.

The Board directed that the OPTN will address within six months what limited elements other than patient and graft survival will be required for follow up after five years.

The Board approved modifications to Policies 3.1.7 (Alternative Allocation/Distribution System) and 3.6 (Allocation of Livers) to effect the November 2005 Board Resolution that there shall no longer be paybacks required or permitted in liver allocation and transplantation.

The Board resolved that the OPTN and UNOS are strongly opposed to practices in which patients in need of transplantation travel abroad to purchase organs in exploitive situations.

The Board adopted the terms “kidney paired donations” and “kidney list donations,” for use in OPTN/UNOS matters. Existing Bylaw and Policy references shall be amended to conform to these terms. “Kidney list donations” and “list paired donations” are synonymous terms and may be used interchangeably. The Board also requested the Department of Health and Human Services to assist the OPTN in federal legislative efforts to amend NOTA to specifically endorse kidney paired donation and kidney list donation, and also to seek supportive language in the Report of Conferees to accompany the 2007 HHS Appropriation, and other legislative vehicles, as appropriate.

The Board approved the recommendation to waive all registration fees generated by the transfer of a transplant candidate from Kaiser Permanente-San Francisco Medical Center (CAKP) to another OPTN member, due to the inactivation of CAKP’s kidney transplant program.

The Board ratified the Executive Committee’s action declining to approve the request that the Ohio heart AAD System be allowed to continue, and reaffirms that the new heart allocation policy shall be implemented as scheduled.

The Board approved modifications to Policy 3.7.2 (Geographic Sequence of Thoracic Organ Allocation) such that Zone D will be defined as greater than 1500 miles from the donor hospital to no greater than 2500 miles from the donor hospital, and the creation of Zone E, which will be defined as greater than 2500 miles from the donor hospitals.

The Board resolved that the following amendments to the Bylaws shall be approved for distribution for public comment:

Donation after Cardiac Death (DCD) Protocols. OPOs/Transplant Hospitals must develop by January 1, 2007 [and once developed must comply with*], protocols to facilitate the recovery of organs from DCD donors.

*The suggested language is proposed to strengthen the Bylaws to include express provisions regarding compliance with DCD protocols and recovery of DCD organs.

The Board approved a modification to the Bylaws that will include language stating, “In order to recover organs from a DCD donor, an OPO must follow an established protocol.”