EXECUTIVE SUMMARY
OF THE MINUTES
OPTN/UNOS BOARD OF DIRECTORS MEETING

June 1-2, 2015
Atlanta, Georgia

Carl Berg, M.D., OPTN/UNOS President, called the meeting to order at 10:30 a.m. on June 1, 2014. A quorum was present, and 38 of the Board members were in attendance during the meeting.

During the first day of the meeting, the Board discussed several topics of significance to the transplant community including: OPTN operations and IT programming; ongoing liver allocation and redistribution efforts; and implementation of the revised kidney allocation system. No actions were taken on these issues following the discussions.

The Board approved several resolutions contained in the Consent Agenda in a single vote. Three items were removed from the consent agenda for further discussion during the meeting. The subject of the individual resolutions approved in the Consent Agenda follows here:

1. The Board approved the minutes of the November 12-13, 2014, meeting of the Board of Directors held in St. Louis, Missouri.
2. The Board approved the appointment of OPTN/UNOS Committee Chairs.
3. The Board approved the following actions for new members: Fully approve 2 new transplant hospitals; fully approve 1 new individual member; fully approve 2 new public organizations; and fully approve 2 new medical/scientific organizations. The Board also approved the following changes in membership status for existing members: Fully approved 8 transplant programs for members; conditionally approved 1 new transplant program for 24 months; conditionally approved 3 new living donor component for 12 months; and fully approved reactivation of 5 transplant programs and 1 living donor component.
4. The Board approved additions and changes to Policies 1.2 (Definitions), 2.9 (Required Deceased Donor Infectious Disease Testing), 5.3.B (Infectious Disease Screening Criteria), 5.4.C (Liver Offers), 5.5.B (Host OPO and Transplant Hospital Requirements for Positive Hepatitis B, Hepatitis C, or Cytomegalovirus (CMV) Infectious Disease Results), and 5.5.C (OPO Requirements for Positive HIV Results) that clarify what to do when serologies affecting match run appearance are updated.
5. The Board approved the white paper entitled “Ethical Principles to be Considered in the Allocation of Human Organs.”
6. The Board approved changes to OPTN Bylaws Appendix E.5 (Kidney Transplant Programs that Perform Living Donor Recovery) and Policies 13.5.C (HLA Typing Requirements for OPTN KPD Donors), 13.7.E (Prioritization Points), 13.7.F (OPTN KPD Waiting Time Reinstatement), 13.9.B (Logistical Requirements), 13.10 (Crossmatching Protocol), 13.11 (Transportation of Kidneys), and 13.12 (Communication between KPD Donors and Recipients) that convert Kidney Paired Donation (KPD) operational guidelines in to policy.

7. The Board approved changes to the Transplant Recipient Registration form in the Tiedi® application to collect ex vivo lung perfusion (EVLP) data for lung transplant recipients.
8. The Board approved changes to Policies 18.1 (Data Submission Requirements) and 18.6 (Reporting of Living Donor Adverse Events) that improve reporting of aborted procedures and non-transplanted organs.
9. The Board approved changes to approve changes to the Waitlist℠ application to collect Extracorporeal Membrane Oxygenation (ECMO) data upon waitlist removal for lung candidates.
10. The Board approved changes to Policies 18.1 (Data Submission Requirements) and 18.2 (Timely Collection of Data) that require members to report transplant and follow up data on VCA recipients.
11. The Board approved changes to Policy 3.6.D (Waiting Time Transfers) that clarify individual waiting time transfers.
12. The Board approved changes to Bylaws Article 11.1.A (The Public Comment Period) and 11.6 (Developing Organ Allocation Policies) that improve the policy development process.
13. The Board approved changes to Bylaws Appendix C (Membership Requirements for Histocompatibility Laboratories) and Policies 4.2 (Requirements for Laboratory Review of Reports) and 4.3 (Requirements for Waiting List Data Verification) as part of phase II of the histocompatibility rewrite.
14. The Board approved changes to Policy 16.4.D (Internal Labeling of Vessels) that modify the sterile internal vessels label.
15. The Board approved changes to Policy 1.2 (Definitions) and Policy 18.1 (Data Submission Requirements) that require the completion of the Deceased Donor Registration Form Completion for all donors.
16. The Board approved changes to Policies 9.1 (Status and Score Assignments), 9.1.B (Pediatric Status 1A Requirements), 9.1.C (Pediatric Status 1B); 9.3.A (Pediatric Status Exception for Candidates 18 Years or Older) Pediatric Classification for Liver Allocation that will result in the automatic transfer of Pediatric Classification for registered liver candidates turning 18 years of age.
17. The Board approved changes to Policies 1 (Administrative Rules and Definitions), 2.5 (Hemodilution Assessment), 2.7.B (Informing Personnel), 2.9 (Required Deceased Donor Infectious Testing), 2.11.A (Required Information for Deceased Kidney Donors), 2.14 (Deceased Donor Management), 3.6.B.i (Non-function of a Transplanted Kidney), 3.8.B (Removing Pancreas Islets Candidates from the Waiting List), 5.3.A (Reporting Unacceptable Antigens for Calculated Panel Reactive Antibody (CPRA)), 5.4.C (Liver Offers), 5.4.E (Backup Organ Offers), 8.2.B (Deceased Donor Kidneys with Discrepant Human Leukocyte Antigen (HLA) Typings), 8.3 (Points), 9.1.A (Adult Status 1A Requirements), 9.1.B (Pediatric Status 1A Requirements), 9.1.C (Pediatric Status 1B), 9.1.D (MELD Score), 9.1.F (Liver-Intestine Candidates), 9.3.D (Specific MELD/PELD Exceptions), 9.3.F (Candidates with Cholangiocarcinoma), 9.5 (Points), 9.5.A (Points for Waiting Time), 9.6.H (Allocation of Liver-Intestines), 9.7.C (Rights Conferred by the Allocation System), 11.2 (Points), 14.3 (Informed Consent Requirements), 14.3.A.ii (Living Kidney Donor Informed Consent Requirements), 14.7.B (Placement of Non-directed Living Donor Kidneys), 14.8 (Packaging, Labeling, and Transporting of Living Donor Organs, Vessels, and Tissue Typing Materials), 15.1 (Patient Safety Contact), 15.2 (Potential Candidate Screening Requirements), 15.4.B (Requirements for Living Donor Recovery Hospital and

Host OPOs), 16.2 (Organs Recovered by Living Donor Recovery Hospitals), 16.4.A (Internal Packaging), 18.1 (Data Submission Requirements), 18.2 (Timely Collection of Data), 19.9 (Access to Recipient Outcomes Data), 20.2.A (Booking Travel), 20.4.B (Transportation To and From the Airport), 20.4.C (Rental Cars), 20.8.A (Expense Reimbursement Form), 20.8.B (Receipts) to complete identified "quick fixes" from the policy rewrite parking lot.

18. The Board approved changes to Policy 1.2 (Definitions) that define and clarify the definition of a transplant.
19. The Board approved changes to Policies 2.12.F (Multiple Organ Procurement), 3.4.C (Candidate Registrations), 3.4.F (Multi-Organ Candidate Registrations), 5.4.D (Multiple Organ Procurement and Offers), 5.8 (Allocation of Multi-Organ Combinations), and 6.4.A (Waiting Time for Multi-organ Candidates) that clarify the multi-organ Policies.

Following passage of the consent agenda, the Board discussed several additional proposals from the Committees beginning with the three proposals that were removed from the Consent Agenda.

The Board approved changes to Bylaws Appendix B and Appendix D that require members to develop, implement, and maintain a quality assessment and performance improvement (QAPI) plan.

The Board approved the guidance document entitled "Guidance for Developing and Implementing Procedures to Mark Kidney Laterality."

The Board approved the guidance document entitled "Guidance to Liver Transplant Programs and Regional Review Boards for MELD/PELD Exceptions Submitted for Neuroendocrine Tumors (NET), Polycystic Liver Disease (PLD), Primary Sclerosing Cholangitis (PSC) and Portopulmonary Hypertension (POPH)."

The Board approved the 2015-2018 OPTN Strategic Plan with the following high level strategic goals: Increase the number of transplants; Provide equity in access to transplants; Improve waitlisted patient, living donor, and transplant recipient outcomes; Promote living donor and transplant recipient safety; and Promote the efficient management of the OPTN.

The Board approved changes to the Bylaws, Article VIII (Financial Considerations) that will establish an OPTN Reserve Fund and procedures for Board approval of withdrawals from this fund.

The Board approved the 2016 OPTN Operating Budget and related modifications to Policy 3.4A (Registration Fee) to reflect an increase in the OPTN patient registration fee from $793 to $812.

The Board approved changes to Policies 1.2 (Definitions), 2.6 (Deceased Donor Blood Type Determination and Reporting), 2.6.A (Deceased Donor Blood Type Determination), 2.6.B (Deceased Donor Blood Subtype Determination), 2.6.C (Primary Reporting of Deceased Donor Blood Type and Subtype), 2.6.D. (Secondary Reporting of Deceased Donor Blood Type and Subtype), 2.15.B (New: Pre-Recovery Verification), 3.3 (Candidate Blood Type Determination and Reporting before Waiting List Registration), 3.3.A (Blood Type Determination before Registration on the Waiting List), 3.3.B (Secondary Reporting of Candidate Blood Type), 5.4.B (Order of Allocation), 5.5.A Receiving and Reviewing Organ Offers), 5.6 (Blood Type Verification Upon Receipt), 5.7 (New: Pre-Transplant Verification), 5.7.A (New: Pre-Transplant Verification Prior to Organ Receipt), 5.7.B (New: Pre-Transplant Verification Upon Organ

Receipt), 13.6.A (Requirements for Match Run Eligibility for Candidates), 13.6.B (Requirements for Match Run Eligibility for Potential KPD Donors), 14.4 (Medical Evaluation Requirements for Living Donors), 14.4.A (Living Donor Blood Type Determination), 14.4.Ai (Living Donor Blood Subtype Determination), 14.4.B (Living Donor Medical Evaluation Requirements) 14.5 (Registration and Blood Type Verification of Living Donors before Donation), 14.5.A (New: Living Donor Blood Type Determination), 14.5.B (New: Living Donor Blood Subtype Determination) 14.5.C (New: Reporting of Living Donor Blood Type and Subtype), 14.7 (New: Living Donor Pre-Recovery Verification), 14.9 (New: Living Donor Organ Check-In), 14.10 (New: Living Donor Pre-Transplant Verification), 16.1 (Organs Not Requiring Transport), and 16.4.C (Internal Labeling of Blood and Tissue Typing Materials) to modify ABO determination, reporting, and verification requirements and align with CMS regulation where possible.

The Board approved changes to Bylaws Appendix F (Membership and Personnel Requirements for Liver Transplant Programs) to add criteria for intestine surgeons and physicians.

The Board approved changes to OPTN Bylaws Appendix J (Membership Requirements for Vascularized Composite Allograft (VCA) Transplant Programs) that establish membership requirements for VCA transplant programs.

The Board considered proposed extensive changes to the Bylaws that would establish pediatric training and experience requirements. A majority of the directors present voted in favor of this proposal, however the Bylaws require that a majority of the entire Board must vote to approve changes to the bylaws. Therefore, these proposed modifications to the Bylaws were not approved. The Board reconsidered the original proposal later in the meeting, but no action was taken. The Board then directed that the interested parties including the Pediatric Transplantation Committee and representatives of the professional societies including ASTS collaborate to develop an acceptable proposal that could be distributed for public comment in the fall 2015 cycle.

The Board approved changes to Policies 3.6.C (Waiting Time Transfers) and 3.8 (New: Collective patient Transfers), and Bylaws K.3.B (Notice to the Patients of Long-term Inactive Status), K.4.B (Notice to the Patients), and K.6 (Transferred Candidates Waiting Time) that authorize collective patient and waiting time transfers.

The Board approved changes to Policies 1.2 (Definitions), 2.2.12 (OPO Responsibilities), 2.15.C (Authorization Requirement), 5.2 (Maximum Mismatched Antigens), 5.4.B (Order of Allocation), 5.5.A (Receiving and Reviewing Organ Offers), 5.5.B (Time Limit for Acceptance), 12 (Allocation of Vascularized Composite Allografts) 14.5 (Registration and Blood Type Verification of Living Donors Before Donation), 18.1 (Data Submission Requirements), 18.2 (Time Data Collection), and 18.3 (Recording and Reporting Outcomes of Organ Offers); and OPTN Bylaws, Appendices D.2 (Program Requirements), D.4 (Transplant Program Director), D.5 (Transplant Program Key Personnel), D.6 (Changes in Key Transplant Program Personnel), D.9.A (Functional Inactivity), D.10.A (Transplant Program Performance), D.10.B (Notification Requirements for Waiting List Inactivation), D.10.G (Relocation or Transfer of Designated Program), K.1 (Transplant Program Inactivity), K.2 (Short-term Transplant Program Inactive Status), K.3 (Long-term Transplant Program Inactive Status), and M (Definitions) that implement VCA programs.

In the first order of business on the second day of the meeting, Dr. Berg gave the President's address, and recognized members of the Board and Committee Chairs whose terms were expiring.

The Board approved additions and modifications to Policies 2.7.A (Exceptions to HIV Screening Requirement), 5.3.C (Liver Acceptance Criteria), 5.4.B (Order of Allocation), 5.4.F (Allocation to Candidates Not on the Match Run), 13.6.B (Requirements for Match Run Eligibility for Potential KPD Donors), 14.4.E (Living Donor Exclusion Criteria), 15.3 (Informed Consent of Transmissible Disease Risk), 15.4.A (Transplant Program Requirements), 15.6 (Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors), 16.7.B (Vessel Recovery, Transplant, and Storage), 16.7.C (Blood Type Verification Prior to Transplant of Deceased Donor Vessels), and 16.7.E (Blood Type Verification Prior to Transplant of Living Donor Vessels) to align the OPTN Policies with the HIV Organ Policy Equity (HOPE) Act.

The Board declined to consider a proposal to approve a guidance document regarding informed consent for living donors in high risk populations.

The Board approved the document entitled "Guidance Document for VCAs from Living Donors" with a minor technical amendment.

The Board approved changes to Policies: 13.3 (Informed Consent for Candidates); 13.4 (Informed Consent for KPD Donors); 13.6.A (Requirements for Match Run Eligibility for Candidates); and 13.6.B (Requirements for Match Run Eligibility for Potential KPD Donors) that create requirements for informed consent of all paired candidates and donors for all KPD programs, with minor amendments.

The Board approved changes to Policies 1.2 (Definitions) and 3.6 (Waiting Time) to clarify the definition of pancreas graft failure.