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

## June 23-24, 2014 Richmond, Virginia

Kenneth Andreoni, M.D., OPTN/UNOS President called the meeting to order at 3:00 p.m. on June 23, 2014. A quorum was present, and 39 of the Board members were in attendance during the meeting.

The Board approved several resolutions contained in the Consent Agenda in a single vote. One item was 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 11-12, 2013, meeting of the Board of Directors held in Atlanta, Georgia.
- 2. The Board approved the appointment of OPTN/UNOS Committee Chairs.
- 3. The Board approved changes to Policy 13.7.E (Prioritization Points) that transfers the priority points language from the existing OPTN/UNOS Kidney Paired Donation Pilot Program (KPDPP) Operational Guidelines into OPTN Policy.
- 4. The Board approved the guidance document entitled "Guidance to Liver Transplant Programs and Regional Review Boards for MELD/PELD Exceptions Submitted for Neuroendocrine Tumors and Polycystic Liver Diseases."
- 5. The Board approved changes to Policy 3.4.C (Candidate Registrations) that require all candidates for living donor transplant to be added to the waiting list prior to transplant.
- 6. The Board approved the following member-specific actions:
  - Approve 5 new histocompatibility laboratory members, 1 individual member, 6 medical/scientific members, and 4 public organization members
  - Approve 2 new transplant programs in existing transplant hospitals
  - Approve a recommended change of status for 2 existing transplant programs
  - Grant 12-month conditional approval to 1 existing transplant program and 3 living donor components
  - Grant full approval to 3 existing transplant programs and 2 living donor components that were previously conditionally approved
- 7. The Board approved changes to OPTN Bylaws, Appendix D (Membership Requirements for Transplant Hospitals and Transplant Programs), sections D.9 and D.10; Appendix K (Transplant Program Inactivity, Withdrawal, and Termination), sections K.1 and K.3; and Appendix M (Definitions). These changes require transplant programs to notify all candidates and potential candidates of a program's functional inactivity.

Following passage of the Consent Agenda, the Board approved modifications to the Bylaws, Article VIII (Financial Considerations) to establish an OPTN reserve fund, and set criteria for the appropriate use of the reserve fund.

The Board approved the 2015 fiscal year OPTN budget andf associated decrease in the registration fee from \$810 to \$793.

The Board approved the 2013 OPTN audited financial statements for the year ended September 30, 2013.

The Board approved changes to Policies 10.1.E (LAS Values and Clinical Data Update Schedule for Candidates at Least 12 Years Old); 10.2.B (Lung Candidates with Exceptional Cases); and 10.2.B.i (LRB Review Process) to implement the adolescent classification exception that permits transplant programs to request an exception from the Lung Review Board (LRB) to classify lung candidates less than 12 years old as adolescents for the purposes of prioritization by lung allocation score (LAS).

The Board approved changes to Policies 3.4.H (*In Utero* Candidate Registrations); 5.3.C (Pediatric Heart Acceptance Criteria); 6.1 (Status Assignments); 6.1.D (Pediatric Heart Status 1A Requirements); 6.1.E (Pediatric Heart Status 1B Requirements); 6.1.F (Pediatric Heart Status 2 Requirements); 6.3 (Status Exceptions); 6.3.A (RRB and Committee Review of Status Exceptions); 6.4 (Waiting Time); 6.5.A (Allocation of Hearts by Blood Type); 6.5.B (Sorting Within Each Classification); 6.5.C (Allocation of Hearts from Donors at Least 18 Years Old); and 6.5.D (Allocation of Hearts from Donors Less Than 18 Years Old) and approved congenital heart disease diagnoses that will qualify a candidate for pediatric status 1A.

The Board approved the removal of the "pilot" label from the OPTN/UNOS Kidney Paired Donation Pilot Program, based on the progress of the program since its first match run in October 2010, effective pending approval from HRSA.

The Board approved a comprehensive rewrite of the Polices that govern histocompatibility testing, including the following changes: that Policies 4.1 through 4.15 are stricken in their entirety and replaced with new Policies 4.1 (HLA Typing), 4.2 (Resolving Discrepant Donor and Recipient HLA Typing Results), 4.3 (Antibody Screening and Reporting), 4.4 (Crossmatching), 4.5 (Blood Type Determination), 4.6 (Preservation of Excess Specimens), and 4.7 (HLA Antigen Values and Split Antigen Equivalences); changes to Policies 2.8.C (Required Information for Deceased Heart Donors), 2.8.D (Required Information for Deceased Lung Donors), and 4.16 (Reference Tables of HLA Antigen Values and Split Equivalences).

The Board approved changes to Policies 2.3 (Evaluating and Screening Potential Deceased Donors), 2.4 (Deceased Donor Medical and Behavioral History), 2.5 (Hemodilution Assessment), 2.7 (HIV Screening of Potential Deceased Donors), 2.7.A (Exceptions to HIV Screening Requirement), 2.8 (Required Deceased Donor Information), 2.9 (Requested Deceased Donor Information) and its subsections, 2.10 (Post Recovery Follow Up and Reporting) and its subsections, 2.11 (Deceased Donor Management), 2.12 (Organ Procurement) and its subsections, 2.13 (Requirements for Controlled Donation after Circulatory

Death (DCD) Protocols) and its subsections, Table 14-2: Requirements for Living Kidney Donor Medical Evaluations, 14.5.A (Living Kidney Donor Psychosocial Evaluation Requirements), and 16.4.D (Internal Labeling of Vessels). These changes allow OPOs some latitude in selecting appropriate tests for donors without adversely impacting patient safety and while taking into consideration changes required due to the release of the 2013 PHS Guideline.

The Board approved changes to Policy 9.1.D (MELD Score) that would add serum sodium to the calculation of the Model for End-Stage Liver Disease (MELD) score, and approved amendments to clarify that this calculation would be performed for candidates with an initial MELD score greater than 11.

The Board approved changes to the Bylaws, Appendix D (Membership Requirements for Transplant Hospitals and Transplant Programs), section D.10.A and Appendix M (Definitions). The changes will better identify those transplant programs that may be underperforming in the area of patient and graft survival.

The Board approved changes to the Bylaws, Appendix L, Sections L.14 (Routine Reviews), L.15 (OPTN Determinations and Actions), L.17 (Interviews), and L.18 (Hearings) that will restore the notification requirements for members receiving the adverse action of Probation.

The Board approved the following changes to Policies 14.1.B (Required Protocols for Liver Recovery Hospitals), 18.1 (Data Submission Requirements), 18.2 (Timely Collection of Data), 18.5 (Living Donor), 18.5.A (Reporting Requirements after Donation), 18.5.B (Reporting Requirements after Living Liver Donation), 18.5.B (Submission of Living Donor Death and Organ Failure), 18.5.C (Reporting of Non-transplanted Living Donor Organs), and 18.5.D (Reporting Donor Organs Not Transplanted in the Intended Recipient). These changes would require transplant programs to report required fields on the Living Donor Follow-Up (LDF) form at required post-operative reporting periods of 6, 12, and 24 months.

The Board approved additions and changes to Policies 1.2 (Definitions), 2.2 (OPO Responsibilities), 2.12.C (Authorization Requirement), 5.2 (Maximum Mismatched Antigens), 5.4.A (Nondiscrimination in Organ Allocation), 5.4.B (Order of Allocation), 5.5.A (Receiving and Reviewing Organ Offers), 5.5.B (Time Limit for Acceptance), 12.1 (Waiting Time), 12.2 (VCA Allocation), 14.6 (Registration and Blood Type Verification of Living Donors before Donation), 18.1 (Data Submission Requirements), 18.2 (Timely Collection of Data), 18.3 (Recording and Reporting the Outcomes of Organ Offers, and Bylaws Appendices D (Membership Requirements for Transplant Hospitals and Transplant Programs), D.2 (Designated Transplant Program Requirement), J (Membership Requirements for Vascularized Composite (VCA) Transplant Programs, K (Transplant Program Inactivity, Withdrawal, and Termination), and M (Definitions). The changes and additions represent the first phase in developing bylaw and policy language to guide VCA transplantation.

The Board approved the deletion of Policy 5.9 (Allocation of Other Organs) to address concerns that this outdated policy would create confusion when the new VCA (Vascular Composite Allograft) policies are implemented.