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

November 12-13, 2014 St. Louis, Missouri

Carl Berg, M.D., OPTN/UNOS President called the meeting to order at 3:00 p.m. on November 12, 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: balance of transplant volumes versus outcomes; OPTN Strategic Planning; ongoing liver allocation and redistribution efforts, and implementation of the revised kidney allocation system. No actions were taken on these issues following the discussions.

On the second day of the meeting, the Board approved the slate of nominees as recommended by the Nominating Committee, for the election of members of the Board of Directors for terms beginning on July 1, 2015.

The Board affirmatively waived the requirement that not more than 50 percent of Board members who are transplants candidates, transplant recipients, organ donors and family members may be employees of OPOs, transplant centers, voluntary health organizations, transplant coordinators, histocompatibility experts, or other non-physician transplant professionals. This waiver will remain in effect until the Board affirmatively declines to waive this requirement for the affected Board members.

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 June 23-24, 2014, meeting of the Board of Directors held in Richmond, Virginia.
- 2. The Board approved the following new members: 4 medical/scientific, public organizations, individual, and business members for two year terms; and 2 new transplant hospitals.
- 3. The Board approved the guidance document "Guidance for VCA Deceased Donor Authorization."
- 4. The Board approved changes to Policies 9.3.G (Candidates with Hepatocellular Carcinoma (HCC)) to cap the HCC Exception Score at 34.
- 5. The Board approved the white paper entitled "Ethical Considerations in Organ Allocation to Pediatric Candidates."

- 6. The Board approved the guidance document entitled "Guidance to Organ Procurement Organizations for Allocation of Heart-Lung Blocks."
- 7. The Board approved additions and changes to Policies 2.6.B (Deceased Donor Blood Subtype Determination), 5.3. C (Liver Acceptance Criteria), 9.5.B (Points Assigned by Blood Type), 13.7.A (Blood Type), 13.7.B (A2 and A2B Matching), 14.4.A.i (Living Donor Blood Subtype Determination), and 8.5. E (Allocation of Kidneys by Blood Type).
- 8. The Board approved the guidance document entitled "Recognizing Seasonal and Geographically Endemic Infections in Organ Donors: Considerations during Living Donor Evaluation."
- 9. The Board approved changes to Policy 18.1 (Data Submission Requirements) to clarify member data submission and documentation requirements.
- 10. The Board approved a change in the effective date for changes to Policy 7.1.6 (Eligible Death Definition) and Policy 7.1.7 (Imminent Neurological Death) from January 1, 2015 to January 1, 2016.
- 11. The Board approved additions to the OPTN Bylaws Article X (Amendment of Charter) and Article XI (Adoption of Policies) that permit clerical changes to the OPTN Policies and Bylaws.
- 12. The Board Approved additions and changes to Policies 10.1.C (Priority and Clinical Data Update Schedule for Candidates less than 12 Years Old), 10.1.E (LAS Values and Clinical Data Update Schedule for Candidates at Least 12 Years Old), 10.1.F (The LAS Calculation), 10.1.F.i (Lung Disease Diagnosis Groups), 10.1.F.ii (PCO2 in the LAS), 10.1.F.iii (Bilirubin in the LAS), 10.1.F.iv (Creatinine in the LAS), 10.2.B.iv (LAS Values and Diagnoses Approved by the LRB), 10.3 (Waiting Time), and 10.5 (Probability Data Used in the LAS Calculation) to ensure that the LAS calculation is accurate and the implementation of the LAS modifications are not delayed.
- 13. The Board is asked to approved changes to Policy 10.1.G (Reporting Additional Data for Candidates with an LAS of 50 or Higher) to clarify the data reporting requirements for lung candidates with an LAS of 50 or higher.
- 14. The Board approved additions or changes to Policies 18.5.C (Submission of Living Donor Death and Organ Failure), 18.5.D (Reporting of Non-Transplanted Living Donor Organs), 18.5.E (Reporting of Living Donor Organs Not Transplanted in the Intended Recipient), and 18.6 (Reporting of Living Donor Adverse Events) to require the reporting of aborted living donor recovery procedures.

Following passage of the consent agenda, the Board discussed several additional proposals from the Committees.

The Board approved changes to Policy 2.11.E (Required Information for Deceased Pancreas Donors) to make collection of serum lipase a requirement.

The Board approved changes to Policies 9.3.G.vi (Extensions of HCC Exceptions) to delay HCC exception score assignment.

The Board approved the addition of section A.3.F. (Geographically Isolated Transplant Program Applicants) to the Bylaws to permit approval of transplant programs that cannot satisfy the current key personnel requirements due to its geographical isolation.

The Board approved additions and changes to Policies 2.2 (OPO Responsibilities), 2.4 (Deceased Donor Medical and Behavioral History), 2.7.B (Informing Personnel), Policy 2.9 (Required Deceased Donor Infectious Disease Testing), Table 14-2 (Requirements for Living Kidney Donor Medical Evaluations) with the exception of NAT-related requirements, 15.3 (Informed Consent of Transmissible Disease Risk), 15.3.A (Deceased Donors with Additional Risk Identified Pre-transplant), 15.3.B (Deceased Donor at Increased Risk for Transmission of Blood-borne Pathogens), and 16.7.B (Vessel Storage) to align the Policies with the 2013 PHS Guideline.

The Board approved changes to the Bylaws Appendix J (Membership and Personnel Requirements for VCA Programs) that clarify that a transplant hospital requesting to perform VCA transplants must specify the specific type of VCA transplant it intends to perform.

After extended discussion, the Board *tabled* a proposal to modify Policies 1.2 (Definitions), 2.6 (Deceased Donor Blood Type Determination and Reporting), 2.15.B (Organ Procurement Procedures), 3.3 (Candidate Blood Type Determination and Reporting before Waiting List Registration), 5.4.B (Order of Allocation), 5.5.A (Receiving and Reviewing Organ Offers), 5.6 (Blood Type Verification Upon Receipt), 5.7 (Released Organs), 13.6.A (Requirements for Match Run Eligibility for Candidates), 13.6.B (Requirements for Match Run Eligibility for Potential KPD Donors), 14.4.A (Medical Evaluations for Living Donors), 14.6 (Registration and Blood Type Verification of Living Donors before Donation), 16.1 (Organs Not Requiring Transport), and 16.4.C (Internal Labeling of Blood and Tissue Typing Materials). The Operations and Safety Committee will continue to refine the proposal and will present a comprehensive revised version to the Board at a later date.

The Board approved additions and changes to Policies 14.2.A (ILDA Requirements for Kidney Recovery Hospitals), 14.2.B (Protocols for Kidney Recovery Hospitals), 14.3 (Informed Consent Requirements).

The Board approved additions and changes, with certain amendments for clarity, to Policies 14.1 (Required Protocols for Recovery Hospitals), 14.5 (Psychosocial Evaluations Requirements for Living Donors), 14.4 (Medical Evaluation Requirements for Living Donors), 14.6 (Registration and Blood Type Verification of Living Donors Before Donation), 14.7.A (Prospective Crossmatching Prior to Kidney Placement, 14.7.B (Placement of Non-directed Living Donor Kidneys, 14.7.C (Transplant Hospital Acceptance or Living Donor Organs), 14.8 (Packaging, Labeling, and Transporting of Living Donor Organs, Vessels, and Tissue Typing Materials) to establish psychosocial and medical evaluation requirements.

The Board approved additions and changes to Policies 2.11.A (Required information for Deceased Kidney Donors); 2.11.B (Required information for Deceased Liver Donors); 2.11.C (Required Information for Deceased Heart Donors); 2.11.D (Required Information for Deceased Lung Donors); 2.11.E (Required Information for Deceased Pancreas Donors); 3.4.D (Candidate Human Leukocyte Antigen (HLA Information); and 4.2 (Requirements for Performing and Reporting HLA Typing) to provide greater consistency in HLA typing requirements across organ types.

The Board approved additions and changes to Policies 13 (Kidney Paired Donation (KPD)), 13.5 (Histocompatibility Testing), 13.6 (Matching within the OPTN KPD Program), 13.7 (KPD Screening Criteria, and 13.10 (Crossmatching Protocol) to implement KPD histocompatibility testing.

The Board also received reports from several committees regarding progress toward OPTN Strategic Goals including increasing the number of transplants; increasing access to transplants; promoting transplant patient safety; promoting living donor safety; and promoting the efficient management of the OPTN.