## EXECUTIVE SUMMARY OF THE OPTN/UNOS BOARD OF DIRECTORS MEETING June 6 – 7, 2016 Richmond, Virginia

Betsy Walsh, JD, OPTN/UNOS President, called the meeting to order at 11:00 a.m. on June 6, 2016. A quorum was present, and 32 of the Board members were in attendance in person or by electronic means of communications.

During the first day of the meeting, the Board approved several resolutions contained in the Consent Agenda in a single vote. The subject of the individual resolutions approved in the Consent Agenda follows here:

- 1. The Board approved the minutes of the December 1-2, 2015, meeting of the Board of Directors held in Richmond, VA.
- 2. The Board approved the appointment of OPTN/UNOS Committee Chairs.
- 3. The Board approved several routine actions for new members and changes in membership status for existing members.
- 4. The Board approved changes to Policies 5.3.C (Informed Consent for Kidneys Based on KDPI Greater than 85%), 8.2.B (Deceased Donor Kidneys with Discrepant Human Leukocyte Antigen (HLA) Typings), 8.3 (Kidney Allocation Points), 8.5.C (Informed Consent for Kidneys Based on KDPI Greater than 85%), 8.5.E (Allocation of Kidneys by Blood Type), 8.5.G (Highly Sensitized Candidates), 8.6 (Double Kidney Allocation), 8.7.B (Choice of Right versus Left Donor Kidney), 8.5.H (Allocation of Kidneys from Deceased Donors with KDPI Scores less than or equal to 20%), 8.7.A (Mandatory Sharing), 8.7.C (National Kidney Offers), and 8.7.D (Kidney-Non-renal Organs Allocated and Not Transplanted) that add clarification to kidney allocation policy and increase equitable access to very highly sensitized candidates..
- 5. The Board approved changes to Policies 1.2 (Definitions), 2.2 (OPO Responsibilities), 16.1 (Organs Recovered by Living Donor Recovery Hospitals), 16.2 (Packaging and Labeling Responsibilities), 16.3 (Packaging and Labeling), 16.3.B (Internal Labeling of Organs), 16.3.C (Internal Labeling of Blood and Tissue Typing Materials), 16.3.D (Internal Labeling of Vessels), 16.3.E.ii (Mechanical Preservation Machine), 16.3.F (External Labeling), 16.4.A (Organ Packaging Documentation Requirements), and 16.5 (Verification and Recording of Information before Shipping) that require OPOs to use TransNet<sup>sm</sup> for deceased donor organ labeling and packaging and to transmit case data to the OPTN Contractor to allow for web-based tracking of organs in transit.
- 6. The Board approved changes to Policy 15.6 (Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors) to require that members participating in a HOPE Act research study variance provide periodic reports to the OPTN from their data safety monitoring boards.

- 7. The Board approved changes to Policy 4.10 (Reference Tables of HLA Antigen Values and Split Equivalences) that add an HLA DQA1 equivalency table to policy that identifies the relationship between parent antigens and corresponding allelic subtypes.
- 8. The Board approved changes to OPTN Bylaws Appendices D (Membership Requirements for Transplant Hospital and Transplant Programs), J (Membership Requirements for Vascularized Composite Allograft Transplant Programs), J.3 (Primary VCA Transplant Surgeon Requirements), M (Definitions), and OPTN Policy 1.2 (Definitions) that identify and list covered body parts specific to VCA transplantation.
- The Board approved changes to OPTN Bylaws Articles 2.3 (Terms) and 2.4 (Regional Representatives) to address regional councillor vacancies on the OPTN/UNOS Board of Directors.

The Histocompatibility Committee withdrew from Board consideration a proposed guidance document entitled "Histocompatibility Testing Guidance Document."

Richard Pietroski, Treasurer, gave a report from the Finance Committee. The Board approved the 2016-2017 OPTN Operating Budget and Registration Fee.

Brian Shepard, OPTN Executive Director gave a report of OPTN strategic plan updates. Following the update, Mr. Shepard along with Alex Tulchinsky, UNOS CTO, provided the Board an update on the KDPI mapping table implementation error.

The Board received a presentation from the OPTN/UNOS Living Donor Committee, ASTS, and AST on Living Donation.

In December 2015, the Board directed the MPSC to provide the Board with a proposal for an improved program specific reporting system that identifies substantive clinical differences in patient and graft outcomes. The Board received a report from the MPSC on its recommendations for improving the OPTN Transplant Program Outcomes Review System.

The Board received a presentation regarding the status of the Collaborative Improvement Innovation Network (COIIN) project.

In the second day of the meeting, the Board met in closed session to consider three member adverse actions recommended by the Membership and Professional Standards Committee. The Board placed a transplant hospital on Probation, and released a transplant hospital and an OPO from Probation and restored them to full membership.

Ms. Walsh gave her Presidential Address.

The Board approved changes to Policies 5.10.B (Allocation of Liver-Kidneys), 5.10.C (Other Multi-Organ Combinations), 9.7 (Administrative Rules), 8.5.H (Allocation of Kidneys from Deceased Donors with KDPI Scores less than or equal to 20%), 8.5.I (Allocation of Kidneys from Deceased Donors with KDPI Scores Greater Than 20% but Less Than 35%), 8.5.J (Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than or Equal to 35%), and 8.5.K (Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than 85%) that provide clarity and consistency in the rules for simultaneous liver-kidney allocation.

The Board approved changes to Policies 2.9 (Required Deceased Donor Infectious Disease Testing), 2.11.C (Required Information for Deceased Heart Donors), 2.13 (Post Recovery Follow Up and Reporting), 15.4 (Reporting of Potential and Proven Disease Transmissions), 15.5 (Requirements for Post-Transplant Discovery of Donor Disease or Malignancy), and 15.6 (Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors) that add clarity and essential details for the reporting of new donor information learned post-transplant and reduce unnecessary reporting to the OPTN Contractor and transplant hospital patient safety contacts.

The Board received a presentation on the proposal to modify the Adult Heart Allocation System.

The Board received a presentation from the Liver and Intestinal Organ Transplantation Committee on Liver redistricting, the National Liver Review Board, and related projects.

Ms. Walsh gave a report from the Executive Committee and the OPTN guidance document working group.

The Board received a presentation on the first year post implementation of Kidney Allocation System (KAS).

The Board received presentations on the discussions of three breakout sessions attended by the Directors on the prior day.

In the final item of the meeting, the Board received a UNOS Information Technology presentation from Mr. Tulchinsky.