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

September 17-18, 2007

Los Angeles, California

Dr. Pruett called the meeting to order at 2:50 p.m. on September 17, 2007. A quorum was present, and 34 of the Board members were in attendance during the meeting.

The Board appointed Thomas A. Gonwa, M.D. to fill the vacancy created by the relocation of Dr. Alan I. Reed, the Region 3 Councillor Representative to the Board of Directors.

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 a proposed alternative renal allocation system for sensitized kidney waiting list candidates within the state of Tennessee. Those candidates with defined unacceptable HLA antigens that yield an 80 percent or greater probability of incompatibility with deceased donors (CPRA) would be assigned four points (the same as the national system) and candidates who have a CPRA value between 40 percent and 79 percent will be assigned two points.

2. The Board approved the minutes of the June 26, 2007, Meeting of the Board of Directors held in Richmond, Virginia.

3. The Board approved modifications to the Bylaws, Appendix 3A – HLA A, B and DR Antigen Values and Split Equivalences Table.

4. The Board approved modifications to Policy 3.6.6 (Removal of Liver Transplant Candidates from Liver Waiting Lists When Transplanted or Deceased) that will provide clarification to members regarding the removal of liver candidates from the waiting lists following a living donor transplant.

Following passage of the Consent Agenda and after extensive discussion, the Board approved modifications to OPTN/UNOS Bylaws, Appendix B, Attachment I, Section XIII(C)(2)(Kidney Transplant Programs that Perform Living Donor Kidney Transplantation), to establish within the bylaws designated program criteria for live donor kidney transplantation programs. Specifically, the bylaws require that programs that perform living donor transplantation must have the resources available to assess the medical condition of and specific risks to the individual of potential living donation including a psychosocial assessment of the donor. The center must have an independent donor advocate (IDA) who is not involved with the recipient evaluation, is independent of the decision to transplant the potential recipient and, is a knowledgeable advocate for the potential living donor, with the goals of: promoting the best interests of the potential living donor; advocating the

rights of the living donor; and assisting the potential donor in obtaining and understanding information regarding the donation and follow-up process. Transplant programs that perform living donor transplants must demonstrate that they have protocols to address all phases of the living donation process and must document that all phases of the living donation process were performed in adherence to the center's protocol. Written protocols must include: i) a description of the duties and primary responsibilities of the IDA; ii) a thorough medical evaluation by a physician and/or surgeon experienced in living donation; iii) a psychosocial evaluation of the potential living donor by a psychiatrist, psychologist, or social worker with experience in transplantation; iv) screening for evidence of transmissible diseases; and v) anatomic assessment of the suitability of the organ for transplant purposes. In addition, centers must have written protocols for the Informed Consent for the Donor Evaluation Process that include: (i) discussion of the potential risks of the procedure including the medical, psychological and financial risks associated with being a living donor; (ii) assurance that all communication between the potential donor and the transplant center will remain confidential; (iii) discussion of the donor's right to opt out at any time during the donation process; (iv) discussion that the medical evaluation or donation may impact the donor's ability to obtain health, life and disability insurance; and (v) disclosure by the transplant center that it is required, at a minimum, to submit Living Donor Follow-up forms addressing the health information on each living donor at 6 months, one-year, and two-years post donation.

The Board approved modifications to OPTN/UNOS Bylaws, Attachment I, Section XIII(C)(4) (Liver Transplant Programs that Perform Living Donor Liver Transplants) to establish within the bylaws designated program criteria for live donor liver transplantation programs. Specifically, the bylaws require that programs that perform living donor transplantation must have the resources available to assess the medical condition of and specific risks to the individual of potential living donation including a psychosocial assessment of the donor. The center must have an independent donor advocate (IDA) who is not involved with the recipient evaluation, is independent of the decision to transplant the potential recipient and, is a knowledgeable advocate for the potential living donor, with the goals of: promoting the best interests of the potential living donor; advocating the rights of the living donor; and assisting the potential donor in obtaining and understanding information regarding the donation and follow-up process. Transplant programs that perform living donor transplants must demonstrate that they have protocols to address all phases of the living donation process and must document that all phases of the living donation process were performed in adherence to the center's protocol. Written protocols must include: i) a description of the duties and primary responsibilities of the IDA; ii) a thorough medical evaluation by a physician and/or surgeon experienced in living donation; iii) a psychosocial evaluation of the potential living donor by a psychiatrist, psychologist, or social worker with experience in transplantation; iv) a radiographic assessment to ensure adequate anatomy and volume of the donor and of the remnant liver; and v) screening for evidence of transmissible diseases. In addition, centers must have written protocols for the Informed Consent for the Donor Evaluation Process that include: (i) discussion of the potential risks of the procedure including the medical, psychological and financial risks associated with being a living donor; (ii) assurance that all communication between the potential donor and the transplant center will remain confidential; (iii) discussion of the donor's right to opt out at any time during the donation process; (iv) discussion that the medical evaluation or donation may impact the donor's ability to obtain health, life and disability insurance; and (v) disclosure by the transplant center that it is required, at a minimum, to submit Living Donor Follow-up forms addressing the health

information on each living donor at 6 months, one-year, and two-years post donation.

The Board approved a Resource Document for Obtaining Informed Consent of Living Donors. In summary, the consent process for any potential living donor should include, but is not limited to: The assurance that the potential donor is willing to donate, free from inducement and coercion, and understands that he or she may decline to donate at any time; A psychosocial evaluation of the potential donor; disclosure of alternate procedures or courses of treatment for the potential donor and recipient, including deceased donation; an evaluation of the potential donor's ability to comprehend the donation process; providing printed materials that explain all phases of the living donation process; ensure that the potential donor has time to reflect after consenting to donate; offer any potential donor a general, nonspecific statement of unsuitability for donation should they wish not to proceed with donation; explain that a decision by the potential donor not to proceed with the donation will only be disclosed after obtaining the consent of the potential donor; an understanding that the donor undertakes risk and receives no medical benefit from the operative procedure of donation; a specification of the medical, psychological, and financial risks associated with being a living donor; disclosure that transplant centers are required to report living donor follow-up information for at least two years; specification of who is responsible for the cost of follow-up care; agreement of the potential donor to commit to postoperative follow-up testing for a minimum of two years; disclosure that donors may not receive valuable consideration for agreeing to be a donor; disclosure that living donor follow-up is the only method for the collections of information on the long-term health implications of living donation; and the stipulation that transplant centers will provide potential donors with outcomes information including one-year patient and graft survival, National one-year patient and graft survival, and notification about all Medicare outcome requirements not being met by the transplant center.

The Board engaged in an extensive discussion of the Living Donor Committee's proposed Resource Document for the Medical Evaluation of Living Kidney Donors. The Board commended the Living Donor Committee for its excellent work in preparing recommendations for the medical evaluation of Living Donors and approved the Introduction and Purpose sections of the proposed recommendations. The Board further directed that the recommendations should be further revised, resubmitted for public comment, and presented to the Board in February 2008 for final adoption.

The Board approved amendments to the Bylaws, Article II (Board of Directors), Section 2.2 (Election/Term), and Section 2.3 (Number) to provide that other directors may be elected in the event that there are an insufficient number of candidates recommended by voluntary health organizations.

The Board approved the composition of the OPTN/UNOS Board of Directors for the term beginning at the conclusion of the last regular meeting prior to July 1, 2008.

The Board approved the slate of nominees for the election of members of the Board of Directors for the term beginning at the conclusion of the last regular meeting of the Board of Directors prior to July 1, 2008, with the addition of Deborah Surlas, AEE, and Dolph Chianchiano, J.D. as candidates for the Transplant Recipients/Candidate/Family Members Representative on the Board of Directors.

The Board approved a proposal to implement a task force study and then request that the HHS

Secretary's Advisory Committee on Transplantation (ACOT) review: (1) the current HHS Program Goals for the OPTN for organs transplanted per donor; (2) the data used to establish these goals; (3) how these goals might be impacted by the program performance and/or OPO performance standards set by CMS; and (4) to review these goals to determine if the goals have internal conflicts due to current practices.

The Board approved in principle the white paper entitled, "White Paper on Charges for Pancreata Recovered for Islet Transplantation," with direction to the Pancreas Transplantation Committee to return the final version to the Executive Committee for its approval prior to submission to CMS.

The Board approved modifications to the RRB Guidelines that change the appeal process for MELD/PELD exceptions, as well as the review of Status 1A and 1B cases that do not meet standard criteria.

The Board approved modifications to Policies 3.3.3 (Renal Acceptance Criteria) and 3.5.3.5 (Time Limit) that will allow OPOs to apply additional screening criteria prior to making regional and national kidney offers.