Interim Report of the
OPTN/UNOS Thoracic Organ Transplantation Committee
Live Meeting/Teleconference
January 11, 2012

***Committee Members*:** Steve Webber, Joe Rogers, Gordon Yung, Rocky Daly, Leway Chen, Brad Dyke, Kevin Chan, Dorrie Dils, Kevin Dushay, Bill Mahle, Laurie Loza, Dan Meyer, Mark Zucker

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On January 11, 2013 the Thoracic Organ Transplantation Committee (the Committee) met by LiveMeeting teleconference to discuss proposals that were distributed during the Fall 2012 public comment period, and to discuss a heart Regional Review Board (RRB) case that was referred to the Committee.

Discussion of Public Comment Proposals

The Committee first discussed the Proposal to Change the OPTN/UNOS Bylaws to Better Define Notification Requirements for Periods of Functional Inactivity. The Committee suggested minor edits for clarity: on page 6 of the proposal document, under "Expected Implementation Plan," the proposal says: "If this proposal is approved, transplant programs must notify the OPTN in writing and send a representative copy of the notification and a list of all patients that received the notification." The Committee felt the term "representative" copy was confusing, and could be replaced with another word such as "example." Additionally, in the policy language section, on page 8, the proposal says: "No changes to Sections D.1 through D.10," but the Committee noted this is confusing because D.9 is being changed, which falls within that range. The Committee voted unanimously to approve this proposal (13 yes, 0 no, 0 abstentions).

Next, the Committee discussed the Proposal to Modify the Imminent and Eligible (I & E) Neurological Death Data Reporting Definitions. The Committee suggested redefining the Summary and Goals section to make the proposal more understandable. Overall, the Committee understands the logic of the proposal, but does not think the concepts are intuitive or clearly explained. For example, in section 7.1.6 the Committee believes it is confusing to define imminent neurological death using "a death of a patient who meets the eligible death definition."

The Committee also did not agree with certain exclusions included in the proposal. Including "congenital defects" for hearts may be too exclusionary, because some very minor defects do not, or should not, ever exclude donors (e.g. patent foramen ovale). The Committee also agreed that some of the lung criteria listed as exclusions in the proposal are controversial. For example, a previous lobectomy shouldn't exclude a donor because the other lung from the donor may still be donated. Lastly, the Committee does not think that varicella zoster should be criteria for exclusion since all patients with prior chickenpox will carry the virus for life, though the Committee recognized that their interpretation of the section might be incorrect due to the way it was written (perhaps the proposal is referring to an active system infection). The

Committee's main concern is that the proposal is written in a confusing manner that will not be easily understood by the vast majority of readers, including professionals familiar with the field of transplantation. The Committee voted unanimously against proposing this policy to the Board of Directors in its current form. (0 yes, 13 no, 0 abstentions)

Discussion of RRB Case

Next, the Committee reviewed a case that was referred to the Committee for closure after the transplant program declined to appeal the RRB's decision. On May 13, 2012, the transplant center registered a heart transplant candidate as Status 1A(b). After reviewing the status justification form, on May 16, 2012 the RRB disapproved the status by a vote of 4 No, 1 Yes, and 2 No Responses. UNOS mistakenly did not inform the center of the RRB's decision until August 28, 2012. By then, the center had already transplanted the candidate as a Status 1A(b) on May 25, 2012. UNOS offered the center the option to appeal the decision to the RRB, or to submit the case for review by the Thoracic Committee. The center did not appeal the case.

The Committee unanimously agreed that the center did not provide sufficient information on the patient to justify the Status 1A(b) listing. The center did not provide enough details regarding the severity of the candidate's aortic insufficiency. The Committee noted that the criterion (b) guidelines will help prevent this type of situation in the future. However, in the Committee's view, the center's transplant of this candidate prior to learning the RRB's decision is not cause for referral to the Membership and Professional Standards Committee (MPSC) in this case. Therefore, the Committee voted in favor of not taking any adverse action against the center (13 yes, 0 no, 0 abstentions).