

**OPTN/UNOS Ethics Committee  
Report to the Board of Directors  
November 12-13, 2012  
St. Louis, MO**

**Summary**

**I. Action Items for Board Consideration**

- None

**II. Other Significant Items**

- Response to the Policy Oversight Committee (POC) on Multi Organ Transplantation (Item 1, Page 2)
- Review of Proposals Released for Public Comment (Item 2, Page 2)
- Request from the OPO Committee to respond to key issues raised during public comment on the Changes to the Donation after Cardiac Death (DCD) Model Elements (OPO Committee) proposal that ended June 25, 2012 (Item 3, Page 3)
- Committee Feedback and Planning (Item 4, Page 3)
- Vascular Composite Allografts (VCA) (Item 5, Page 4)
- New Projects for Consideration (Item 6, Page 4)

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**Alexandra Glazier, MPH, JD, Chair  
Peter Reese, MD, Vice-Chair**

This report details the discussions had and decisions made by the Ethics Committee during the teleconference meeting on July 19, 2012 and in-person meeting on October 3, 2012.

1. ***Response to the Policy Oversight Committee (POC) on Multi Organ Transplantation***

The POC requested that the Committee respond to the following question:

*If the concept of lifesaving organ is removed, are there key ethical principles your committee feels should be included in a framework for allocating the second organ based on a balance between equity and utility?*

The Multi-organ Allocation Subcommittee considered the ethical implications of multi-organ allocation and transplantation and created a response memo as requested by the POC.

The response was presented to the entire Ethics Committee at a July 2012 conference call where the Committee voted on the response to the POC (15 For, 0 Against, 0 Abstentions). See **Exhibit A**.

2. ***Review of Proposals Released for Public Comment***

At its October 2012 meeting, the Committee reviewed proposals that were distributed for public comment on September 21, 2012, particularly focusing on the *Proposal to Substantially Revise the National Kidney Allocation System (Kidney Transplantation Committee)* which was presented to the Committee.

The presentation briefly discussed the course of the development of a kidney policy from 2003 to present, and then proceeded to present the specifics of the allocation proposal. Ethic Committee members asked many detailed questions and evaluated the proposal thoroughly, outlining some concerns. Of note is that the Committee expressed a desire that there be a discussion in the proposal of the ethical reasoning supporting the policy decisions, and specifically, the extent to which the policy advances the separate and distinct considerations of equity and utility.

The Committee voted on the proposal and approved the proposal by a vote of 15 For, 0 Against, and 1 Abstention. Despite its approval of the proposal, the Committee strongly felt that a Subcommittee should be formed to communicate to the Kidney Committee its ethical concerns about the proposal and suggestions for future consideration and improvement of the allocation policy.

The Committee determined that none of the other proposals that went out for public comment on September 21, 2012 presented ethical issues that the Committee should review.

3. ***Request from the OPO Committee to respond to key issues raised during public comment on the proposed Changes to the Donation after Cardiac Death (DCD) Model Elements (OPO Committee) proposal***

The Chair of OPO Committee gave a presentation by telephone to the Committee at its October 3, 2012 meeting in Chicago. The OPO Committee's proposal on DCD Model Elements resulted in many comments, and the OPO Committee was specifically looking for feedback from the Ethics Committee about some of the key issues raised during the comment period.

The Committee discussed two key issues that arose during public comment about the DCD Model Elements proposal:

1. Failure to Restore the Ethical Safeguard of Separation Between Organ Procurement and Decision to Withdraw Life-Sustaining Treatment
2. Failure to Provide Safeguards for Conscious Individuals

In discussing these key issues, the Committee agrees that:

- The hospital must notify OPO of impending death
- Donor evaluation should occur in advance to be prepared if the family makes the decision to withdraw support
- The model elements do not necessarily need to address the issue of when families are approached. Right now, the model elements are silent on this but the Committee thinks the model elements should:
  - Discuss the approach of families in a positive way and not to this level of detail
  - Be aware that families often bring up donation in the context of withdrawal of life support, so timing is important
- Ultimately, it needs to be a collaborative process that works for that hospital and that donor family
- Transplant programs and OPOs should approach and honor the wishes of conscious patients who desire to be donors. It is also important when dealing with conscious patients to have a clear separation between the decision to withdraw care and the separate decision to donate

The Ethics Committee Chair will summarize the conversation and recommendations of the Committee and send a memo to the OPO Committee.

4. ***Committee Feedback and Planning***

The Ethics Committee reviewed the upcoming OPTN/UNOS Committee activities for opportunities for collaboration and ethical input. The Committee believes that it can best inform the policy development process through earlier involvement with the traditional

policymaking committees. The Committee reviewed the complete list of approved Committee projects and identified areas that it believes could benefit from early input from the Ethics Committee as follows:

- Uncontrolled DCD project with the OPO Committee. Several Committee members volunteered to participate in a working group to consider this project and provide feedback
- Define Exhausting the Match Run project with the AHIRC and OPO Committees
- Import/Export of living donor organs with the Living Donor Committee. Committee members volunteered to participate in a working group to consider this project and provide feedback
- Consideration of Which Living Donor Program Metrics should be available to the general public with the Living Donor Committee. Committee members volunteered to participate in a working group to consider this project and provide feedback

**5. *Vascular Composite Allografts (VCA)***

The U.S. Department of Health and Human Services issued a notice in the Federal Register indicating its intent to designate Vascular Composite Allografts (VCA) to be organs and within the purview of the OPTN. The Committee asked what the status is of VCA determination as an organ and covered by the OPTN Final Rule. Comment period closed on February 14, 2012 and the Secretary is considering comments. It is anticipated that VCA would be a separate OPTN/UNOS Committee that might be a component of the next OPTN RFP.

**6. *New Projects for Consideration***

- The Committee will consider a proposed white paper for references for high spinal cord alive and aware donors. This whitepaper would be an overview of what resources are available to help guide that process.
- Imminent Death Donation considerations: This involves recovering a single or double kidney from patients who would become DCD candidates, and would be considered a living donor donation.

## Ethics Committee

Name	Position	July 19, 2012 Teleconference	October 3, 2012 Chicago, Illinois
Alexandra K. Glazier, JD, MPH	Chair	X	X
Peter Reese, MD	Vice-Chair	X	X
Manuel Rodriguez-Davalos, MD	Region 1		X
Peter Reese, MD	Region 2	X	X
Carlos F Zayas, MD	Region 3		X
Mark Fox, MD, PHD, MPH	Region 4		
Donald Stouder, M.Div.,PCS	Region 5	X	X
Lisa S Florence, MD	Region 6	X	
Edward Garrity Jr., MD, MBA	Region 7	X	X (by phone)
Scott Biggins	Region 8	X	X
Antonio DiCarlo, MD	Region 9		X
Ann Eshelman, PhD	Region 10	X	X
Lance Stell, PhD	Region 11	X	X
Michael E. Shapiro, MD	Immediate Past Chair	X	X
Bonnie Boulanger, Esq.	At Large	X	
Kay Kendall, MSW, LISW	At Large		X
Robert Veatch, MD	At Large	X	X
Elisa Gordon, PhD	At Large	X	X
Robert Truog, MD	At Large		X
Richard Demme, MD	At Large	X	X
Isabel Stenzel-Byrnes, MSW	At Large		X
Deborah Adey, MD	At Large		X
Keren Ledin, PhD	At Large		X
Teresa Beigay, DrPH	Ex Officio – HRSA	X	
Bernie Kozlovsky, MD	Ex Officio – HRSA	X	
James Bowman	Ex Officio – HRSA		X
Tabitha Leighton	SRTR	X	
Martin Smith, S.T.D., Cleveland Clinic	Guest		X
Richard Pietroski	OPTN OPO Committee Chair		X (by phone)
John Fredewald, MD, Kidney Committee	OPTN Kidney Committee Chair		X (by phone)
Leigh Kades	UNOS Staff	X	X
Jason Livingston	UNOS Staff – Liaison	X	X
James Alcorn	UNOS Staff		X
Gloria Taylor	UNOS Staff		X
Ciara Samana	UNOS Staff		X (by phone)