

**OPTN/UNOS Ethics Committee  
Report to the Board of Directors  
June 1-2, 2015  
Atlanta, GA**

**Peter Reese, MD, Chair  
Elisa Gordon, PhD, MPH, Vice Chair**

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*This report reflects of the work of the OPTN/UNOS Ethics Committee between September 2014 and April 2015.*

## **Action Items**

### 1. Ethical Principles to be Considered in the Allocation of Human Organs

The OPTN website provides access to thirteen white papers developed by the Ethics Committee. The oldest white paper on the site was approved in 1993, and it is unclear when the resources have been reviewed for accuracy and relevancy. The Committee will review each of the white papers. Four papers have been reviewed and determined not to require revision. One white paper is ready for Board reconsideration. A mini-brief for this white paper is provided (**Exhibit A**) and the updated white paper is provided as **Exhibit B**.

This revised white paper on the allocation of human organs includes two conceptual changes from the paper as written in 2010:

- The ethical principles of utility and justice (equity) are weighted equally, and
- It considers the principle of “respect for persons, including respect for autonomy”, rather than “autonomy”

In addition, this revised version refines the language, remove redundancies, and overall make the paper more user friendly.

The remaining white papers will be updated and prepared for Board reconsideration over the next year.

## **Committee Projects**

### 2. Imminent Death Donation

Public Comment: *N/A*

Board Consideration: *December 2015*

The Committee continues to examine the ethical considerations of imminent death donation. Imminent death donation has occurred in the past but is currently prohibited under existing policy. Imminent death donation involves the removal of transplantable organs prior to an imminent, planned withdrawal of support expected to result in death and is a donation alternative to donation after cardiac death for patients who are not brain dead.

The Committee is leading a work group with representatives from the OPO, Living Donor, and Operations and Safety Committees to investigate this issue. At this point, the path forward is unclear, as there is no consensus on the workgroup regarding when, if ever, IDD may be appropriate. In response, the work group has identified the ethical or practical

concerns that may need to be addressed in order to IDD to be considered as a potential new option for organ donation, including:

- Would IDD violate the dead donor rule;
- How should the option for IDD be introduced to the donor family
- Who would provide surrogate consent; and
- Whether concerns in the public's perception of IDD would decrease traditional deceased donations and outweigh any potential benefits of IDD

The work group is expected to prepare a report outlining areas of concern and proposed solutions that will be provided to the Committees represented on the work group for review and feedback.

The Committee plans to prepare a report for Board consideration in December 2015 and may need to consult the Board regarding the future direction of this project.

### 3. Review White Papers for Accuracy and Relevancy

Public Comment: *N/A*

Board Consideration: *December 2015*

Over several years, the Board has approved a series of white papers on bioethical issues that the Committee developed. These are available on the [OPTN website](#). Some of the topics addressed in the white papers include:

- An Evaluation of the Ethics of Presumed Consent
- Financial Incentives for Organ Donation
- The Ethics of Organ Donation from Condemned Prisoners

These resources have not been regularly reviewed to ensure they remain accurate and relevant. In response, the Committee has reviewed the white papers for accuracy and relevancy, and has determined if each white paper should be maintained in its current form, is in need of minor or major revision or should be eliminated because it is no longer relevant.

Some of the other questions being considered for each white paper include:

- Overall purpose (i.e. inform UNOS policy versus educational purposes)
- Target audiences
- Does the resource continue to reflect and inform current practice?
- Is the resource written in plain simple language?
- Are the citations and data current, and
- To determine if the Committee supports the resource.

The Committee reviewed the status of each white paper during its spring 2015 meeting and will continue to work on the white papers during a series on monthly conference calls. The Committee plans to have other revised white papers ready for Board consideration in December 2015.

4. Consider if Living Donor Recovery Programs Should be Responsible for Post- Operative Complications

Public Comment: N/A

Board Consideration June 2016

This is a new project that should result in the development of a white paper or guidance document addressing the ethical issues concerning if and when living donor recovery hospitals should be responsible for providing care for post-operative complications. The resource could address who should be responsible for the cost of postoperative care.

When the Policy Oversight Committee approved this project, it commented that the proposed project lacked evidence that a problem with donors not receiving post-operative care for complications existed. In response, the Committee consulted the Transplant Administrators, Transplant Coordinators, Patient Affairs, and Living Donor Committees to ask these groups if they had knowledge or evidence of living donors who were either denied or were required to cover the cost of care for post-donation complications. All of these Committees responded commenting on the importance of this project. The Living Donor Committee responded that it had previously surveyed transplant programs that responded they would not cover the cost of post-operative complications.

The Committee had a lengthy discussion regarding how to advance this project during its spring 2015 meeting, and several Committee members volunteered to work on this project.

**Committee Projects Pending Implementation**

None

**Implemented Committee Projects**

None

**Review of Public Comment Proposals**

The Committee reviewed 2 of the 13 proposals released for public comment from January and March 2015.

5. Membership Requirements for VCA Transplant Programs

The Chair of the VCA Committee provided a presentation on the proposal to the Committee. The Committee did not prepare a formal response regarding this proposal.

6. Proposal to Address the Requirements Outlined in the HIV Organ Policy Equity Act

The Ethics Committee limited its review of the proposal to aspects of the proposal relevant to living donors.

The Committee supports the proposed policy modification of Table 14-9 (Living Donor Exclusion Criteria) which would be modified to read:

- HIV, unless the requirements for a variance are met, according to Policy 15.5 Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors

The Ethics Committee is concerned that the proposal does not address the special informed consent and medical evaluation requirements that should be necessary for potential HIV positive living donors.

Additionally, the Committee is concerned that the proposal does not address post-donation follow-up requirements for HIV positive living donors. The two-years of required follow-up for living donors required under current policy will not be sufficient to understand the longer term effects of organ donation for HIV positive living donors.

### **Other Committee Work**

#### **7. VCA Guidance Documents**

Members of the Ethics Committee are participating on a multi-committee work group developing a resource to provide guidance on VCA living donation. The Committee reviewed the current draft and was invited to send comments to the Committee leadership who will combine the comments and submit feedback to the VCA guidance document work group.

#### **8. Pediatric Lung Policy Preview**

A member of the Pediatric Committee presented an overview of a pediatric lung allocation policy during the Committee April in-person meeting. The Committee was asked to provide feedback concerning the ethical implication of two different allocation sequences under consideration by the Pediatric and Thoracic Committees.

#### **9. Redesigning Liver Distribution to Address Geographical Disparities in Access**

The Vice Chair of the Liver Committee provided a liver redistricting update during the Committee's April in-person meeting. The Committee will continue to monitor future changes to the liver allocation system focusing on potential ethical implications.

### **Meeting Summaries**

The committee held meetings on the following dates:

- April 13, 2015

Meetings summaries for this Committee are available on the OPTN website at:  
<http://optn.transplant.hrsa.gov/converge/members/committeesDetail.asp?ID=3>.