

**OPTN/UNOS Ethics Committee  
Report to the Board of Directors  
June 21-22, 2010  
Richmond, VA**

**Summary**

**I. Action Item for Board Consideration**

- DCD – Declaration of Death Protocols. The Board is asked to reaffirm that it is ethically acceptable and appropriate to recover organs after cardiac death is pronounced in both adult and pediatric patients, with consent and in accordance with the “dead donor rule.” (Item 1, Page 3)
- Restatement of Principles of Allocation White Paper. The Board is asked to approve the paper titled, “Ethical Principles to be Considered in the Allocation of Human Organs.” (Item 2, Page 4)

**II. Other Significant Items**

- None

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**OPTN/UNOS ETHICS COMMITTEE**  
**Report to the Board of Directors**  
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**Richmond, VA**

**Michael Shapiro, M.D., Chair**  
**Alexandra Glazier, J.D., MPH, Vice-Chair**

*The following report represents the Ethics Committee's deliberations and discussions at its in-person meetings held on April 11-12, 2010, and December 7, 2009:*

1. DCD – Declaration of Death Protocols. Based on recently reported DCD pediatric cases, the Committee discussed Donation after Cardiac Death and ECMO Issues at its October 2008. The Committee reviewed articles regarding a pediatric death protocol where the pediatric donor organs were recovered beginning only 75 seconds following the declaration of death. The Report of the National Conference on Donation after Cardiac Death recommended a period of two minutes following declaration of cardiac death prior to commencing organ recovery in order to confirm that there was no autoresuscitation.

At the time, the Committee developed the following proposal for consideration by the Board of Directors:

*RESOLVED, that it is ethically acceptable and appropriate to recover organs after cardiac death is pronounced in both adult and pediatric patients, with consent and in accordance with the "dead donor rule." Death should be established using current empirical data and standards established by the Institute of Medicine (IOM) and the Report of the National Conference on Donation after Cardiac Death. Further scientific investigation in adult and pediatric populations should be conducted to determine more precisely the minimum time needed to ensure the permanent cessation of circulatory function in the donor.*

The Committee discussed the declaration of death process and at what point a person is declared dead. The Committee discussed the Uniform Declaration of Death Act and the distinction of this proposal where a time limit is necessary for a DCD donor. There is a need to focus on the fact that there is a lethal condition and a withdrawal of support is not the cause of the decedent's death. There is a need to be clear about the dead donor rule.

Upon review by OPTN leadership, there were concerns that this proposal might be interpreted as the OPTN prescribing medical practice and the Committee was asked to reconsider this proposal. It was suggested striking the language regarding specific standards in the above resolution, and the Committee agreed with this suggestion.

After additional discussion, by a vote of 18 for, 0 against, and 0 abstentions, the Committee recommends the following proposal for consideration by the Board of Directors:

**\*\*RESOLVED, that it is ethically acceptable and appropriate to recover organs after cardiac death is pronounced in both adult and pediatric patients, with consent and in accordance with the "dead donor rule." Death should be established using current empirical data and accepted medical standards ~~established by the Institute of Medicine (IOM) and the Report of the National Conference on Donation after Cardiac Death.~~ Further scientific investigation in adult and pediatric populations should be conducted to determine more precisely the minimum time needed to ensure the permanent cessation of circulatory function in the donor.**

2. Restatement of Principles of Allocation White Paper. At its December 2009 meeting, Dr. Shapiro recounted the procedural status of this project, which has been in process for several years. The Ethics Committee was originally charged with revisiting prior Ethics Committee Statements and White Papers. After much work and revisions, the Committee proposed several versions of an updated Restatement of Principles of Allocation of Human Organs. Most recently, the Committee proposed revisions to be considered by the Board of Directors at its June 2009 meeting. This is the most recent version and is attached as **Exhibit A**. Representatives of HRSA had concerns about the paper and asked that the proposal not be presented to the Board of Directors. Dr. Shapiro has been working to communicate with OPTN leadership and HRSA to resolve their concerns.

It was suggested that this paper should be published independently without the endorsement of the OPTN. By the April 2010 meeting, whether this paper is presented to the Board, this remains OPTN/UNOS work-product, and those identifiers should be removed if that option is pursued further.

Dr. Shapiro indicated that he will continue to work with leadership to determine the concerns and address those appropriately.

HRSA is concerned that there is another document that may compete with the OPTN Final Rule. It was noted that the 1991 white paper was created and approved prior to the development of the OPTN Final Rule. HRSA was concerned that any such document from the Ethics Committee comports with and reflects the OPTN Final Rule. There also was concern as to whether a revision of the 1991 White Paper is the proper approach as the Final Rule on which it should be based did not exist at the time. Section 121.8 of the Final Rule is very specific regarding policies of equitable allocation and states 8 principles allocation policies “shall” be based upon. It is felt that any contemporary allocation white paper must discuss and focus on these 8 principles in relation to the overarching ethical principles. The concern is that rather than continuing on the present direction, a document should be written taking more into consideration the specifics of the Final Rule. Once a path forward was determined, there would be opportunities to revise and fine tune the paper as appropriate.

At its April 2010 meeting, Dr. Shapiro advised the Committee on the status of the white paper draft and about a recent teleconference with OPTN and HRSA leadership. He explained that the Committee is working with OPTN leadership and HRSA representatives to determine the remaining concerns with the draft white paper and appropriately address those concerns. HRSA agreed to provide documentation of those concerns to the Committee, which would be addressed at a separate conference call. The Committee would like to receive this feedback and make appropriate revisions to present the paper for approval at the June 2010 Board of Directors meeting.

The Committee planned to have a conference call on Monday, May 24, 2010, to address those concerns and make appropriate modifications to the draft paper. The Committee did not receive any documentation, and the May 24 conference call was postponed until feedback from HRSA has been received and distributed to the Committee.

Subsequent to the preparation of the Committee report, which was distributed to the Board of Directors on a CD-ROM on June 2, 2010, HRSA provided thorough feedback to the Committee detailing its concerns with the paper. The Committee convened a conference call and LiveMeeting on June 10, 2010, to review the feedback. Due to the short notice, only nine members of the Committee were available for the call but the group unanimously agreed to incorporate the language suggestions and approved other modifications to respond appropriately to those concerns. The revised document has been retitled, “Ethical Principles to be Considered in the Allocation of Human Organs,” and a complete copy is attached hereto as Exhibit A.

The document was forwarded electronically to the full Committee with a request to vote electronically on the final product and recommend that the Board approve the paper at its June 21-22, 2010, meeting in Richmond, Virginia.

Therefore, the Committee recommends the following resolution for consideration by the Board of Directors:

**RESOLVED, that the Board of Directors hereby approves the paper titled, “Ethical Principles to be Considered in the Allocation of Human Organs” set forth in Exhibit A, effective June 22, 2010.**