

**Ad Hoc International Relations Committee and the Ethics Committee**  
**March 21, 2012 (11 am to 1 pm, eastern)**  
**Teleconference and Live Meeting**  
**Interim Report**

*Leadership of the Ad Hoc International Relations Committee and the Ethics Committee*

- Gabriel M. Danovitch, MD (Chairman of the Ad Hoc International Relations Committee)
- Alexandra K. Glazier, JD, MPH (Chairwoman of the Ethics Committee)
- Marian O'Rourke, RN, CCTC (Vice-Chairwoman of the Ad Hoc International Relations Committee)
- Peter P. Reese, MD (Vice-Chairman of the Ethics Committee )

On March 21, 2012, the Ad Hoc International Relations Committee and the Ethics Committee (Committees) met by telephone and Internet to discuss comments submitted by the public, OPTN/UNOS Committees, and the OPTN/UNOS Regions about the revisions to Policy 6 (Transplantation of Non-Resident Aliens). The Committees received the opportunity to evaluate these comments (Exhibit A) and during this meeting, discuss select policy revisions proposed by the Committees' leadership to address the comments submitted. The following were the primary issues raised by those who reviewed the policy revisions during the comment cycle (9/16/2012 to 12/23/2012).

- **Issue I: Retain Language about Valuable Consideration**

The revisions to Policy 6, distributed for public comment in September, 2011, deleted language about valuable consideration. This language was part of the "ethical practices" policy. During public comment, concerns were raised that the removal of the policy altogether, especially language about valuable consideration, may not be prudent.

Removing this language may suggest that the OPTN is not concerned about valuable consideration in organ transplantation

- **Issue II: Modify the Organ Export Policy**

Define "exhausting the match run"

- **Issue III: Modify the Residency Definitions**

How is residency best reported?

Current residency definitions may place transplant programs in a position of sorting through immigration information.

- **Issue IV: Modify Language in the Nondiscrimination in Organ Allocation Policy**

During the public comment cycle, UNOS staff reviewed this policy and recommended editorial suggestions.

- **Issue V: Modify the Proposed Audit Policy**

Various comments were submitted about the proposed audit policy, they were mostly supportive of the suggested changes. Concerns were expressed that the proposed audit

policy was the first step in making it a policy violation to transplant non-residents. There were concerns that the proposed policy lacked an explanation about the audit process, thereby leaving the transplant community wary of the proposed audit. The review itself may be burdensome to the transplant centers. If a review were to occur, perhaps the submission of data should be voluntary. The proposed audit policy may give too much oversight to the Ad Hoc International Relations Committee. Some suggested retaining the greater than 5% audit trigger policy, because it sets a concrete threshold by which transplant programs can decide when to stop listing or transplanting non-residents during a given calendar year. Because of this perceived “limit” some suggested that the greater than 5% audit trigger policy may better achieve the goal of reducing transplant tourism in the US than the proposed audit policy, which has no limit to the number of non-residents that may be transplanted. Some responders suggested edits to the proposed audit policy language; others suggested that the proposed policy focus only on data collection.

- **Issue VI: Modify Proposed Reporting Policy**

Focus on the data or only collect the data. Report all data, not just about those who traveled to the US for transplant

Ensure that individually identifiable patient data remains private.

How will the data be treated?

- **Issue VII: Define Ad Hoc Deceased Donor Organ Import**

UNOS staff reviewed the policy and suggested that an ad hoc deceased donor organ import be defined.

The Committees discussed further policy modifications to address each issue described above. During this discussion, the Committees agreed to include the following policy text changes in the final version of Policy 6 that they will submit to the OPTN/UNOS Board of Directors to review June, 2012:

- *Include language that recovery or transplantation of an organ for valuable consideration is not legal in the United States (See [Issue I](#); [Proposed Policy 1.1](#))*

Policy 6.4.4 (Ethical Practices) currently includes the valuable consideration concept. Proposed revisions to Policy 6 struck Policy 6.4.4 in its entirety, because it: 1) is illegal to recover and transplant organs for valuable consideration and a Member’s violation in this area would involve other federal agencies, it may not be necessary to continue to include this concept in policy; 2) makes no mention that Members may not import a living donor who has valuable consideration; 3) contradicts Policy 12.6 (Center Acceptance of Living Donor Organs) that requires recovery of living donor organs for transplant in the United States to occur only at Member transplant centers; and, 4) includes but does not define the phrases “ethical practices” and “practices which might discredit the transplant community.” A definition of “ethical practices” and “practices which discredit the transplant community” would be subjective and arbitrary, leading to inconsistent

interpretations of this phrase over time. A few comments from the public, however, suggested retention of the valuable consideration concept in Policy 6.4.4.

Legal prohibition to recover or transplant organs due to valuable consideration, however, is not restricted to the recovery of organs from or transplants of non-resident aliens. The foreign status of an organ procured for transplant is not relevant, because OPTN Members must not procure or transplant an organ for valuable consideration. Therefore, Policy 1.1 (Obligation to the National Organ Transplantation Act) includes only the valuable consideration concept from Policy 6.4.4.

- *Edit the proposed organ export policy (See [Issue II](#); Proposed [Policy 3.2.1.4](#))*

The proposed and post-public comment revisions to the export policy continue to allow living donor organs to be exported, however, a recent question posed by a community member has created a project for the Ad Hoc International Relations Committee and the Living Donor Committee to determine if policy should continue to enable living donor organs to be exported.

- *Edit the definition of non-US citizen/US resident and non-US citizen/non-US resident (See [Issue III](#); Proposed [Policies 6.1.1 and 6.1.2](#))*

The Committees edited the definitions of non-US citizen/US resident and non-US citizen/non-US resident for readability.

- *Revise the proposed audit policy (See [Issues V and VI](#); Proposed [Policies 6.3 and 6.3.1](#))*

The proposed revisions to Policy 6.3 include the following modifications: 1) remove the term “audit” from the policy’s title; 2) Instruct the Ad Hoc International Relations Committee to review all citizenship data submitted per board-approved modification of data entry introduced March 2012 3) remove the term “justification” regarding listing or transplantation of a non-resident non-citizen; and, 4) allow the Ad Hoc International Relations Committee to request that transplant programs voluntarily provide additional data related to their listings or transplants of non-resident aliens. In making these revisions the Committees avoided any mandatory reporting requirements over and above that which is already in place while retaining the ability to review and analyze data regarding the listing and transplantation of non-citizen non-residents. . The Ad Hoc International Committee will make public access to an annual report of the listings and transplants of non-residents (with patient de-identified data).

The proposed review of non-resident listings or transplants as a policy path will provide a significant degree of transparency to the American public regarding the number of individuals who travel to the United States for transplant. This information may guide future policy considerations. The Committees rejected the suggestion to retain the “greater than 5%” audit policy since this policy is widely misunderstood, does not provide transparency and, in some transplant programs, prevents foreign nationals in need of transplants from being listed.

- Define “ad hoc import” of deceased donors (See [Issue VII](#); Proposed [Policy 6.4.2](#))

The Committees, per request from UNOS staff members, defined “ad hoc” deceased donor organ import.

The proposed policy modifications presented below include post-public comment changes to policy text, based on the discussion described above. Text with double underlines (example) denotes changes proposed by the Committees after the public comment cycle. The Committees voted in favor of the following modification for submission to the OPTN/UNOS Board of Directors: 24-supported; 0-opposed; and, 0-abstained.

## **1.0 Member Rights and Obligations**

The Organ Procurement and Transplantation Network (OPTN) is a private non-profit entity that has an expertise in organ procurement and transplantation. The purposes for which the OPTN is organized are detailed in the OPTN Charter. Membership in the Corporation is voluntary; rights and obligations of Members of the OPTN are set forth in the OPTN Bylaws and in OPTN Policies adopted by the OPTN Board of Directors.

OPTN Policies govern the various areas of OPTN operations. Amendments and additions to OPTN Policies are adopted by the Board of Directors and may be incorporated into the Bylaws. Policy Amendments and additions are binding upon OPTN Members after adoption by the Board of Directors and after notice to Members, whether or not such amendments and additions are incorporated into the Bylaws. Copies of OPTN Policies are distributed to Members upon request, and policy updates are available subsequent to adoption of policy changes.

By accepting membership in the OPTN, each Member agrees to be bound by all provisions of the OPTN Charter, Bylaws, and Policies, including amendments thereto. A Member who does not comply with such provisions will be afforded the appropriate due process as described in the OPTN Bylaws.

The Membership application and review process is set forth in the OPTN Bylaws. Permanent Standing Committees and Ad Hoc Committees, develop OPTN Policies and propose such Policies, amendments, and additions for consideration and adoption by the Board of Directors. All OPTN Members are invited and encouraged to participate in OPTN activities through OPTN committee service and through consultation with OPTN Committee Members and members of the Board of Directors.

### **1.1 Obligation to the National Organ Transplantation Act**

An OPTN member may not knowingly permit donation, recovery, or transplantation of deceased or living donor organs for valuable consideration.

**3.2.1.4 Prohibition for Organ Offers to Non-Members.** ~~Members shall not provide organs to non-member transplant centers except to transplant centers in foreign countries as described in Policy 6.4 (Exportation and Importation of Organs – Developmental Status). Members can only share organs with Members or countries. However, Members may only export deceased donor organs United States after a well documented and verifiable effort, coordinated through the Organ Center, has been made to hospitals in foreign countries after having offered offer these organs to all potential recipients on match runs. Prior to exporting deceased donor organs, Members must submit the organ export verification form to the OPTN Contractor contractor prior to exporting deceased donor organs.~~

**6.0 Deceased Donor Organ Transplantation of Non-US Residents/Non-US Citizens, and the Importation of Deceased Donor Organs from Foreign Sources**

**6.1 Definitions.** The following definitions apply to this policy:

**6.1.1 Non-US Citizen/US Resident** – ~~A person who is not a non-citizen of the United States, who is present in the United States, and for whom the United States is the primary place of residence.~~

**6.1.2 Non-US Citizen/Non-US Resident** – ~~A person who is not a non-citizen of the United States and for whom the United States is not the primary place of residence.~~

**6.2 Guidelines.** ~~Any member transplant center that places a non-US citizen/non-US resident on its waiting list shall adhere to the following guidelines:~~

**6.2.1 Nondiscrimination in Organ Allocation.** ~~Selection from the waiting list of non-US citizen/non-US resident candidates for transplantation shall be based on the same allocation policies (Section 3.0) mandated by the Board of Directors for selection of candidates who are citizens or residents. Deceased donor organ allocation to candidates for transplantation shall not differ on the basis of a candidate’s citizenship or residency status in the US. Such selection~~ Allocation shall not be influenced by favoritism or discrimination based on political influence, national origin, race, sex, religion, or financial status.

**6.2.2 Referrals.** ~~Members shall not enter into formal contractual arrangements with foreign agencies or governments for the transplantation of non-US residents/non-US citizens in the United States. Members may negotiate the terms and conditions under which any individual candidate would be treated with the~~

understanding that each candidate must be referred on a case-by-case and physician-to-physician basis.

**6.3 Audit Review and Reporting of Non-US Citizens/Non-US Residents Listings and Transplants.** ~~As a condition of membership, all member transplant centers agree to allow the Ad Hoc International Relations Committee to review and, at its discretion, audit all member transplant center activities pertaining to transplantation of non-US residents/non-US citizens. At member transplant centers where non-US residents/non-US citizens are listed for transplant, the Ad Hoc International Relations Committee shall review the circumstance and justification for listing any non-US resident/non-US citizen traveling to the United States for transplant. The Ad Hoc International Relations Committee will review all citizenship data submitted to the OPTN Contractor. The Ad Hoc International Relations Committee may request that Member transplant centers voluntarily provide additional information about listings or transplants of non-US citizens/non-US residents.~~

**6.3.1 Transparency in Reporting Listings and Transplants of Non-US Citizens/Non-US Residents.** The Ad Hoc International Relations Committee shall prepare and provide public access to an annual report of member Member transplant center activities related to the listings and transplantation of non-US citizens/non-US residents.

**6.4 Importation of Deceased Donor Organs from Foreign Sources.** Members may import deceased donor organs from foreign sources, and in doing so, must adhere to the related policies below.

**6.4.1 Formal Deceased Donor Organ Import Agreement.** Upon approval by the Board of Directors, a Member may enter into formal, deceased donor organ import agreement with a foreign entity. Each formal agreement cannot exceed two years in duration. A Member that wishes to enter into a formal, deceased donor organ import agreement with a foreign entity must submit a proposal to the Ad Hoc International Relations Committee for review. The proposed deceased donor organ import agreement must:

- 1) Describe the basis for the agreement.
- 2) Describe the expected benefits to the foreign and domestic participants.
- 3) Include credentials of the foreign entity.
- 4) State the number and type of deceased donor organs anticipated for import.
- 5) Outline a plan for reporting the results of the agreement.
- 6) Include a requirement for the donor organization to submit documentation certifying the ~~informed consent~~ authorization of

- the donor or his or her legal representative.
- 7) Include a requirement for the donor organization to submit documentation certifying that the donor has met the met brain death or donation after ~~cardiac~~ circulatory death (DCD) protocols that are in compliance with recognized US standards for domestic organ procurement.
  - 8) Include a requirement for the donor organization to submit documentation of the donor's ABO.

The Ad Hoc International Relations Committee will review each formal agreement every two years.

Each organ imported through a formal agreement must adhere to the requirements listed in 6.4.1.1.

**6.4.1.1 Requirements for Importing Deceased Donor Organs through a Formal Agreement.** The Member importing any deceased donor organ from a foreign entity must:

- Report the event within 72 hours to the Organ Center.
- Allocate the organ using the Match System, ~~and~~ in accordance with the allocation policy for that organ.
- Provide the minimum required information about the foreign deceased donor organ, as specified in Policies 2 (Minimum Procurement Standards for an Organ Procurement Organization (OPO), 3.5.9 (Minimum Information/ Tissue for Kidney Offer), 3.6.9 (Minimum Information for Liver Offers), 3.7.12 (Minimum Information for Thoracic Organ Offers, and 3.8.2 (Required Information).
- Comply with the ABO verification requirements in Policies 2 and 3.2.4 (Match System Access).
- Evaluate the organ for transmissible diseases as specified in Policy 4 (Identification of Transmissible Diseases in Organ Recipients).
- Verify that the foreign entity is authorized as a transplant center or organ procurement program by an appropriate agency of its national government.
- Obtain official documentation from the exporting party that it is a medical center authorized to export organs for transplantation.

**6.4.2 ~~Ad Hoc~~ Deceased Donor Organs Imported from outside of the United States.** A Member may import a deceased donor organ recovered outside of the United States without a formal agreement (6.4.1). An ~~ad hoc~~ imported of a deceased donor organ must meet all the requirements in 6.4.1.1. ~~Except, the~~ The Member must notify

the Organ Center immediately so that the OPTN contractor Contractor can allocate the organ using the Match System, and in accordance with the allocation policy for that organ.

If the The Member importing the organ is an OPO, in addition to the requirements listed above, the OPO must provide the following to the OPTN contractor:

- Documentation certifying that the donor has met brain death or donation after cardiac circulatory death (DCD) protocols that are in compliance with recognized standards for domestic organ procurement;
- Documentation from the donor organization certifying the informed consent authorization of the donor or his or her legal representative; and,
- Documentation from the donor organization verifying the donor's ABO.

The Ad Hoc International Relations Committee will review the circumstances of each deceased donor organ imported without a formal agreement. each Ad Hoc deceased donor import

Ethics Committee Members Who Participated on March 21, 2012:

1. Alexandra Glazier, JD, MPH (Chairwoman)
2. Peter Reese, MD (Vice-Chairman)
3. Deborah Adey, MD
4. Jack Berry
5. Dan Bruggemeyer, MS
6. Antonio Di Carlo, MD
7. Lisa Florence, MD
8. Mark Fox, MD, PhD, MPH
9. Kay Kendall, MSW, LISW
10. Bernie Kozlovsky (HRSA)
11. Keren Ladin, MSc
12. Liz Lehr, BSN, MHA
13. Amy Pope-Harman, MD
14. Michael Shapiro, MD
15. Isabel Stenzel-Byrnes, MSW, MPH
16. Robert Veatch, MD
17. Maryam Valapour, MD (SRTR)
18. Carlos Zayas, MD

Ad Hoc International Relations Committee Members Who Participated on March 21, 2012:

1. Gabriel M. Danovitch, MD (Chairman )
2. Marian O'Rourke, RN, CCTC (Vice-Chairwoman )
3. Mark Barr, MD
4. Gloria Bohrer
5. Bill Fiser, MD
6. Bert Kasiske, MD (SRTR)
7. Kay Kendall, MSW, LISW
8. Tabitha Leighton (SRTR)
9. Lisa McMurdo, RN, MPH
10. Jill McMaster, MA, CAPT-USNR(Ret) (BOD Liaison to the Committee)
11. Linda Ohler, RN, MSN, CCTC, FAAN
12. Jorge Reyes, MD
13. Bob Walsh (HRSA)