

OPTN/UNOS Ad Hoc International Relations Committee
Report to the Board of Directors
June 28-29, 2011
Richmond, Virginia

Summary

I. Action Item For Board Consideration

- Modification to the Existing Citizenship Categories in the Transplant Candidate Registration (TCR) Form, Deceased Donor Registration (DDR) Form, and Living Donor Registration (LDR) Form.

The Board of Directors is asked to approve a modified list of items that will appear in the existing dropdown list of items to select in response to the “citizenship” data entry question in the DDR, LDR, and TCR forms. (Item 1, page 3)

II. Other Significant Items

- Modifications to Policy 6.0 (Transplantation of Non-Resident Aliens).

The Committee is collaborating with the OPTN/UNOS Ethics Committee to propose revisions to Policy 6.0. The revisions include the elimination of policies that cannot be measured, including as one category residents and citizens, elimination of the greater than 5% audit trigger, and broadening of the audit policy to include a retrospective review of listings and transplants of foreign nationals who enter the United States for transplant. (Item 2, page 5)

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**Gabriel Danovitch, MD (Chair)
Marian O'Rourke, RN, CCTC (Vice-Chair)**

The following is a summary of the joint meeting of the Ethics Committee and the Ad Hoc International Relations Committee (AHIRC), which occurred on April 10-11, 2011.

1. Modification to the Existing Citizenship Categories in the Transplant Candidate Registration (TCR) Form, Deceased Donor Registration (DDR) Form, and Living Donor Registration (LDR) Form.

The AHIRC and the Ethics Committee (AHIRC-EC) discussed the need to distinguish between individuals who are not citizens of the United States, but living in the United States, from those who came to this country for the sole purpose of receiving a transplant. The latter group is not likely to contribute to the population of organ donors in the United States, whereas the former group may. Thus, the AHIRC-EC considered citizens and resident aliens – documented or undocumented – to belong in the category of “citizens/residents.” AHIRC-EC did not want to eliminate data collection fields that already exist, but rather, modify the selections for the current citizenship fields. However, the AHIRC-EC eliminated the term “alien” as it seemed a pejorative label for a person, even though a few members argued that “alien” is a legal term.

Currently, the TCR and the LDR forms collect the following categories of citizenship: U.S. Citizen; Resident Alien; and, Non-Resident Alien, Year Entered US. If the transplant program selects Non-Resident Alien, the transplant program specifies the candidate’s “Year of Entry to the US.” The DDR form collects the following categories of citizenship: U.S. Citizen; Resident Alien, and Non-Resident Alien, Specify Country.” If the OPO selects Non-Resident Alien, it is asked to provide the name of the “Home Country.”

Per Policy 6.3 (Audit), the AHIRC audits programs whose annual deceased donor recipient population includes more than 5% non-resident aliens. The AHIRC-EC opined that the audit policy is problematic as it tends to prevent the transplantation of residents of the United States due to their documentation to reside in the country. The current citizenship categories do not provide guidance on how to classify undocumented individuals in the United States – either candidates or deceased donors.

The philosophical tenor of the AHIRC-EC is to ensure complete transparency with regard to the transplantation of foreign nationals who travel to the United States for the purpose of transplant. It is not the purpose of the proposed changes to prohibit such transplants, although some members supported such a prohibition. The AHIRC-EC was cognizant of the dramatic changes that had taken place in the relative availability of transplants since Policy 6.0 was first enacted and were greatly concerned that both the letter and spirit of Policy 6.0 with respect to “community participation” were not being honored. The AHIRC-EC were influenced by the Principles of the *Declaration of Istanbul on Organ Trafficking and Transplant Tourism (Exhibit A)*, and specifically, the following constructs:

“Travel for transplantation is the movement of organs, donors, recipients or transplant professionals across jurisdictional borders for transplantation purposes. Travel for

transplantation becomes **transplant tourism** if it involves organ trafficking and/or transplant commercialism or if the resources (organs, professionals and transplant centers) devoted to providing transplants to patients from outside a country undermine the country's ability to provide transplant services for its own population.”

If the OPTN continues to allow foreign nationals to enter the United States and receive organs from deceased residents, then the United States impairs its ability to provide for its residents. The AHIRC-EC acknowledged that Americans should not travel overseas for transplant if that transplant had a similar impact on the provision of transplant services in the destination country. However, the AHIRC-EC did not propose this policy change due to concern about the lack of accurate data on the actual number of foreign nationals who travel to the United States for transplant.

Interested in quantifying the number of individuals who are traveling to the United States for Transplant, the AHIRC-EC sought to understand the magnitude of “transplant tourism” in the United States. To accompany this quantification, the AHIRC is considering adopting a policy that will enable it to review listings and transplants of non-residents/non-citizens traveling to the United States for transplant; and, the AHIRC anticipates learning whether the numbers of such individuals indeed make the United States unable to provide for its residents.

The AHIRC-EC proposed the modification to the existing categories in the citizenship field in the TCR and LDR forms. The new categories proposed by the committees are:

- US Citizen
- Non-US Citizen/US Resident
- Non-US Citizen/Non-US Resident, Traveled to US for Reason Other than Transplant
- Non-US Citizen/Non-US Resident, Traveled to US for Transplant

The AHIRC-EC proposed the following modification to the existing categories in the citizenship field in the DDR form:

- US Citizen
- Non-US Citizen/US Resident
- Non-US Citizen/Non-US Resident

A few members noted that once policy allows the AHIRC to review, retrospectively, listings and transplants of non-US citizens/non-US residents who traveled to the US for transplant, it is possible that foreign nationals will self-identify as non-US citizen/non-US resident who traveled to the US for a reason other than transplant. Nevertheless, the AHIRC-EC voted in favor of the modification to the citizenship categories: 21-supported; 2-opposed; and, 3-abstained.

To determine about the country from where person traveled to the United States for Transplant, the AHIRC-EC previously requested the collection of “country of permanent residence” for those listed as non-resident aliens. The request for this additional field was previously approved by the OPTN/UNOS Board of Directors as part of the OMB proposal in November, 2010. The modification to the citizenship categories requires approval by the OPTN/UNOS Board of Directors, but will not require public comment as it will be a component of an existing field in the three forms. The AHIRC recommends the following programming for consideration – the cost estimate for which is in **Exhibit B** – by the Board of Directors:

****RESOLVED, that the categories in the existing “Citizenship” field in the Living Donor Registration and Transplant Candidate Registration forms be modified as set forth below, pending programming:**

- **US Citizen**
- **Non-US Citizen/US Resident**
- **Non-US Citizen/ Non-US Resident, Traveled to US for Reason Other than Transplant**
- **Non-US Citizen/Non-US Resident, Traveled to US for Transplant;**

that the categories in the existing “Citizenship” field in the Deceased Donor Registration form be modified as set forth below, pending programming:

- **US Citizen**
- **Non-US Citizen/US Resident**
- **Non-US Citizen/ Non-US Resident**

and, that the selection of the “Non-US Citizen/Non-US Resident, Traveled to US for Transplant” category or the “Non-US Citizen/Non-US Resident, Traveled to US for Reason Other than Transplant” category will require the “year of entry to the US,” pending programming.

OPTN data analysis supported, in part, the AHIRC-EC’s rationale to modify data collection in the DDR, LDR, and the TCR forms, as well changes to the Policy 6.0 (Transplantation of Non-Resident Aliens) (**Exhibit C**). The committees also asked for further analyses: non-resident alien transplantation data by region, accommodating for the population within that region.

The AHIRC-EC considered whether to enlist the assistance of the UNOS Department of Evaluation and Quality or the OPTN Regional or National Review Boards to evaluate, retrospectively, listings and transplants of non-resident/non-citizen who travels to the US for transplants. However, the AHIRC-EC opined that the actual numbers of candidates and recipients may not be too large given the proposed citizenship categories. So, the AHIRC would not review any non-residents who are, in fact, actual residents of the United States, as it does now.

2. Modifications to Policy 6.0 (Transplantation of Non-Resident Aliens).

The AHRIC-EC jointly reviewed all policies in 6.0 with the exception of those pertaining to ethical practices, importation, and exportation. The latter concepts the AHIRC discussed on its own after the two Committees separated to conduct their respective meetings. The AHIRC suggested leaving the export policy as is, but modify the exchange policy section to address the importation of organs. The AHIRC will work with the Ad Hoc Disease Transmission Advisory Committee, the Organ Procurement Organization Committee, and the Transplant Administrators Committee to further revise the organ import policy.

Proposed modifications to Policy 6 include:

1. Change in the title;
2. Inclusion of a preamble that borrows language from the *Declaration of Istanbul on Organ Trafficking and Transplant Tourism*;

3. Revisions to the citizenship definitions;
4. Deletion of policies that cannot be measured or are antiquated – 6.2.2, 6.2.3, 6.2.5, 6.2.6;
5. Allow the AHIRC to audit any transplant program that lists or transplants candidates who are in the “non-US citizen/non-US resident, traveled to US for transplant” category;
6. Delete Policy 6.5 (Violation), as all policy violations are subject to review by the OPTN/UNOS Membership and Professional Standards Committee;
7. Refocus the current organ exchange section to only organ imports;
8. Retain the ability to import organs ad hoc and through a formal arrangement;
9. Retain the ability to export organs as stated currently; and,
10. Delete the policy on ethical practices (decision made in 2010), because defining “ethical practices” could be problematic, and the import of an organ for valuable consideration is a criminal offense, which is not under the purview of the OPTN.

The AHIRC-EC voted in favor of modifications 1 through 4: 27-supported; 0-opposed; and, 1-abstained. The AHIRC-EC voted in favor of modification #5: 27-supported; 0-opposed; and, 1-abstained.

The AHIRC alone discussed modifications 6-9, and had discussed #10 over the past two years. The AHIRC still needs to identify the time during which a member may import an organ six times – as an ad hoc exchange – before the member can only import organs through a memorandum of agreement. The AHIRC will meet on June 20, 2011 to continue its discussion of Policy 6. The AHIRC-EC allowed UNOS staff to make technical edits to the language edits made during the meeting on April 10-11. The AHIRC-EC anticipates distributing a proposal for public comment in September, 2011.

In 2011, the AHIRC sought comments on the current Policy 6.0 from several OPTN/UNOS committees. At its meeting in June, 2011, the AHIRC will review these comments and consider their inclusion in the revised policy.

3. Living Donation

The AHIRC considered the import of living donor organs for transplant in the United States as part of international living donor exchange programs. This concept speaks to the globalization of medicine but current policy does not allow for the transplant of living donor organs not recovered at an OPTN transplant hospital.¹ However, the issue also of importance is the consent process used to identify a living donor. The OPTN/UNOS Living Donor Committee made significant efforts over the past several years to improve the living donor consent process in the United States.

¹ **12.6 Center Acceptance of Living Donor Organs.** Transplant Centers that perform living donor transplants must only accept and transplant living donor organs recovered at OPTN member transplant hospitals.

Ad Hoc International Relations Committee (AHIRC)	April 10-11, 2011 [Joint Meeting of the AHIRC and the Ethics Committee] Chicago, Illinois	
Name	Position	Attendance
Gabriel Danovitch, MD	Chair	X
Marian O'Rourke, RN, CCTC	Vice-Chair	X
Gloria Garcia Bohrer	Ex Officio (Voting)	By phone
Mark Barr, MD	At Large Member	X
Linda Bowes, RN	At Large Member	X
B. Ann Butts, MHSA	At Large Member	By phone
Angela Carlton, RN	At Large Member	
Bill Fiser, MD	At Large Member	By phone (4/10) X (4/11)
Kay Kendall, MSW, LISW	At Large Member	
Bob Kormos, MD	At Large Member	
Rich Luskin, MPA	At Large Member	X
Dennis Martin, RN	At Large Member	X
M. Jill McMaster, MA, CAPT-USNR	Liaison to the Board of Directors	X
Lisa McMurdo, RN, MPH	At Large Member	X
Jorge Reyes, MD	At Large Member	X
Paul Volek, MPH	At Large Member	X (left at 1 pm on 4/11)
Jim Bowman, MD	Ex Officio – HRSA	By phone (4/11)
Bob Walsh	Ex Officio – HRSA	By phone
Bert Kasiske	SRTR	
Manny Carwile	UNOS Staff	X
Vipra Ghimire	UNOS Staff – Liaison	X
John Persons	UNOS Staff	X
Brian Shepard	UNOS Staff	X
Sarah Taranto	UNOS Staff	X
Kerrie Cobb	UNOS Staff	By phone (4/11)

Ethics Committee	April 10-11, 2011 [Joint Meeting of the AHIRC and the Ethics Committee] Chicago, Illinois	
Name	Position	Attendance
Michael E. Shapiro, MD	Chair	X (left mid-day on 4/11)
Alexandra K. Glazier	Vice-Chair	X
Gloria Garcia Bohrer	Ex Officio (Voting)	X
Deborah B Adey, MD	Region 9 Representative	X
Jack Berry	At Large Member	X
Gabriel M Danovitch, MD	Region 5 Representative	X
Richard Demme, MD	At Large Member	
Ronald E Domen	At Large Member	
James M DuBois, PhD, DSc	At Large Member	X
Lisa S Florence, MD	Region 6 Representative	X
Amy Pope-Harman, MD	Region 9 Representative	X
Kay Kendall, MSW, LISW	At Large Member	
Liz Lehr, BSN, MHA	At Large Member	X
Rachel Mackey	At Large Member	X
Bhargav M Mistry, MD	Region 7 Representative	
Natalie G Murray, MD	Region 4 Representative	X
Matthew G Nuhn, MD	Region 1 Representative	X
Peter Reese, MD	Region 2 Representative	X
Lainie F. Ross, MD	At Large Member	By phone (4/10) X (4/11)
Robert Sade, MD	Region 11 Representative	By phone (4/10) X (4/11)
Erik Schadde, MD	Region 8 Representative	
Dane Sommer, D.Min., BCC	At Large Member	X
Robert M Veatch, MD	At Large Member	X
Carlos F Zayas, MD	Region 3 Representative	X (4/11 only)
Teresa M Beigay, DrPH	Ex Officio – HRSA	By phone
Bernie Kozlovsky, MD	Ex Officio – HRSA	By phone
Chris J. McLaughlin	Ex Officio – HRSA	
Tabitha Leighton	SRTR	By phone
Maryam Valapour, MD	SRTR	By phone
Jason Livingston	UNOS Staff – Liaison	X
Gloria Taylor	UNOS Staff	X