

**OPTN/UNOS Ethics Committee
Report to the Board of Directors
June 28-29, 2011
Richmond, VA**

Summary

I. Action Items for Board Consideration

- None

II. Other Significant Items

- Modifications to Policy 6.0 (Transplantation of Non-Resident Aliens). The Committee is collaborating with the Ad Hoc International Relations Committee to develop proposed 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 6)
- Uncontrolled Donation after Circulatory Death (UDCD). The Committee is working on a position paper describing the ethical considerations for UDCD organ recovery to provide guidance for the development of UDCD recovery protocols. (Item 4, Page 7)

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**OPTN/UNOS Ethics Committee
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**Michael E. Shapiro, M.D., Chair
Alexandra Glazier, MPH, JD, Vice-Chair**

This report presents a summary of the deliberations of the joint meeting of the Ethics Committee and the Ad Hoc International Relations Committee (AHIRC), which occurred on April 10-11, 2011, and of the Ethics Committee conference calls, which occurred on March 17, 2011, and May 26, 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 referenced *Declaration of Istanbul on Organ Trafficking and Transplant Tourism*, and specifically, the following definitions, which have been adopted by the OPTN:

“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.

The group wanted to quantify the number of individuals who are traveling to the United States for purposes of receiving an organ transplant, which could assist in determining the magnitude of “transplant tourism” in the United States. To accompany this quantification, the AHIRC is considering recommending that the Board adopt a policy that will enable it to review listings and transplants of non-residents/non-citizens traveling to the United States for transplant. Any such recommendation would need to be distributed for public comment prior to consideration by the Board of Directors. The AHIRC anticipates learning whether the number of individuals travelling to the United States for transplantation make the United States unable to provide for the transplantation needs of its residents.

It was noted that per NOTA, the OPTN cannot do anything about allocation to “fly ins.” Also, those “fly ins” cannot be counted because the present data collection doesn’t distinguish those transplant candidates/recipients. It has been suggested that a “fly in” is bad but “fly ins” have not been defined. If there is a reason for counting “fly ins” in a precise way, it is because there is a public trust concern. Last, politically, people may want to know the citizenship of candidates receiving organs and we have an obligation to gather that data.

The group also discussed the 5% audit rule and its practical application to transplant centers who transplant non-resident aliens. A motion was made to remove the 5% rule and that any center wishing to transplant a non-US Citizen needs to prospectively report all such transplants from the OPTN/UNOS prior to adding such patient to the waiting list. The motion failed for lack of a second.

Concerns were shared about present undocumented residents, which don’t fit into either category, and that the present categories don’t describe everyone that the group wants to track. It was suggested that illegal aliens are “the elephant in the room” and that the group is fashioning a data collection system that will hide that group. Is that the intent of this group?

It was noted that the current policy does not address illegal aliens. There were significant concerns that there is no need to collect citizenship and immigration status at all and that this data collection may lead to backlash and prejudice. Who really needs this information and will the OPTN be the only entity who will be using this data? Why do we need to know citizenship?

The group spent much time discussing the need to distinguish between the non-resident aliens living in the United States from those who came to the United States for the sole purpose of receiving a transplant. The latter group is not likely to contribute to the population of organ

donors whereas the former group may. Thus, the group considered citizens, resident aliens, documented non-resident aliens, and undocumented non-resident aliens to belong in the category of “residents.” The group did not want to eliminate data collection fields that already exist, but rather, add to it. The group did eliminate the term “alien” as it seemed inappropriate of a label for a person.

The group proposed that the citizenship field ask whether the deceased or living donor or potential candidate is a:

- a) US Citizen/US Resident
- b) US Citizen/Non-US Resident
- c) Non-US Citizen/US Resident
- d) Non-US Citizen/ Non-US Resident, Traveled to US for Reason Other Than Transplant
- e) Non-US Citizen/Non-US Resident, Traveled to US for Transplant

The group also requested the collection of “country of permanent domicile” for non-resident/non-citizen in the TCR, DDR, and LDR forms. The intent of this data collection is also to delineate those who are traveling for transplant from those foreign nationals who reside here in the United States. The collection of this additional data element will require approval by the OPTN/UNOS Board of Directors, but will not need to be distributed for public comment as it will be a component of an existing field in the three forms.

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 document 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 will propose this data collection to the OPTN/UNOS Board of Directors in June, 2011. As the primary sponsoring committee, the AHIRC will recommend the following resolution for consideration by the Board of Directors at its June 2011 meeting:

****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, and as described in Exhibit B [to the report of the AHIRC], 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). 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 individuals who travel 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 AHIRC-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
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.

3. **Non-OPTN Contract Discussions.** On April 10, 2011, the group briefly discussed whether laws, such as NOTA, should be changed to enable differential treatment of US citizens from non-citizens for the purposes of allocation. The group reviewed a legal opinion stating that the current regulations prohibit different allocation algorithms based on legal citizenship status. NOTA and the OPTN Final Rule require that allocation systems be based on objective medical criteria, and whether an individual is in the United States illegally is not a medical criterion. The group felt that developing a tiered allocation system is not desirable. Transplantation remains a humanitarian act, and residents in the United States should be treated equally regardless of legal status – they are all potential donors.

4. **Uncontrolled Donation after Cardiac Death (UDCD).** At the April 2011 meeting, the Ethics Committee met separately from the Ad Hoc International Relations Committee to consider additional matters. The Committee discussed the appropriate sequence for the pronouncement of death and when additional organ preservation methods may be instituted such as ECMO and chest compressions. The Committee also discussed appropriate designation on a document of gift.

It was asked whether there is an ethical legitimacy to employing extreme organ preservation techniques when there are not any conflicts with the known wishes of the donor. It was also asked whether local hospitals prepared for success, i.e. to double the number of donors recovered. Is there sufficient equipment, OR space, staff, etc.

It was noted that there is a level of uncertainty about whether an individual can be declared dead by circulatory criteria if circulation is being restored. With respect to the practice of balloon occlusion, the Committee questioned why a balloon is required to make sure that the brain is not perfused for a patient who has been declared dead.

The Committee discussed several existing protocols for UDCD and began the following draft statement of Ethical Considerations for Uncontrolled Donation after Circulatory Death Organ Recovery:

**Ethical Considerations for
Uncontrolled Donation after Circulatory Death (UDCD) Organ Recovery**

1. UDCD is ethically acceptable and appropriate.
2. Resuscitation measures on the potential donor must meet or exceed current accepted medical standards, to the extent such measures are consistent with the patient's directions.
3. Death must be appropriately declared. Death by circulatory criteria is not appropriately pronounced until medical interventions that may continue or restore circulation have ceased.
4. Before implementing a rapid organ recovery protocol, there should be community education.
5. Authorization for organ preservation is required. Inclusion in a donor registry is appropriate authorization. Other forms of authorization may be appropriate.

This statement was posted on the Committee SharePoint site for informal review and comment by the Committee. A follow up conference call was scheduled to discuss the statement further.

On May 26, 2011, the Committee convened a conference call to revise further the draft statement and to determine a path forward. Modifications (noted in double underlines and double strikethroughs below) were proposed to the statement and discussed at length.

**Ethical Considerations for
Uncontrolled Donation after Circulatory Death (UDCD) Organ Recovery**

Uncontrolled donation after a circulatory determination of death (UDCD) or rapid organ recovery involves the recovery of organs following an unexpected circulatory arrest, typically outside of the hospital. Various UDCD protocols have been implemented in the Netherlands, Spain, and more recently in the U.S. The Institute of Medicine and other groups have observed that UDCD greatly expands ~~could greatly expand~~ the pool of potential deceased organ donors.

UDCD, in principle, is ethically acceptable and appropriate. The following elements provide guidance for the development of ethically acceptable UDCD protocols:

1. Education in the community in which the UDCD protocol is applicable
~~Community education~~ should precede implementation of a rapid organ recovery protocol.

2. Resuscitation measures ~~on the potential UDCD donor~~ must meet or exceed current accepted medical and legal standards ~~to the extent such measures are consistent with the patient's known wishes, insofar as they are known.~~
3. Protocols should address compliance with the patient's known wishes and surrogate decision making.
4. Organ preservation should occur only if authorized. Acceptable authorization may include a first person document such as designation in a donor registry; a proxy/surrogate decision; or by statute. Authorization for organ donation ethically authorizes organ preservation. Authorization for organ preservation, such as designation in an organ and tissue donor registry, is required and shall be obtained in a manner consistent with the Uniform Anatomical Gift Act or other applicable law.
5. Death must be appropriately declared. Death by circulatory criteria is not appropriately pronounced until medical interventions that may continue or restore circulation have ceased.

The Committee did not complete its discussion of the proposed revisions and a path forward, nor was there a quorum present to vote on approving the statement. Another follow up call will be scheduled to complete this project and determine the appropriate path forward, including potential recommendation to the Board of Directors.

5. **Review Concepts for Kidney Allocation.** At its March 17, 2011, meeting, Dr. Shapiro gave a brief introduction to the Committee about the Concepts for Kidney Allocation document issued by the Kidney Transplantation Committee ("Kidney Committee"). He explained that the Kidney Committee has been working for many years on an evolving set of concepts for a new kidney allocation system.

There are valid concerns with the mechanics of the proposal. There could be extensive discussion by the Committee on the merits and flaws of the proposal without ever reaching a consensus.

The Committee briefly discussed two recent articles in the NEJM by Lainie Ross et al and Alan Leichtman et al. regarding arguments for and against the proposed kidney allocation concepts. The issues were well-developed in those articles so the Committee sought instead to find areas of common ground with respect to the proposal.

It was noted very clearly that the proposed kidney allocation concept document does not address the issues of geography. It was suggested that this proposal is not the right proposal, right now. All of the simulation modeling has been using national data that has sharing regionally and nationally so the data are not appropriate.

The NEJM article points out that the current system varies in terms of impact of the way points are distributed. In certain DSAs, the effects of the additional points for allocation vary widely.

The Kidney Committee originally planned to develop an allocation system and then address the problem of geography because it is a large problem. The core issue is that allocation of high quality kidneys to patients whose lifespan is biologically limited does not make sense. A system should be developed to do a better job at maximizing the life years of the limited supply of kidneys. Leaving geography out is a mistake but the current algorithm is not acceptable either.

It is important to acknowledge that there is no control over living donors who provide 40% of the total donor kidneys. There are likely to be unintended consequences of having fewer total living donor kidneys, and second, that living donor kidneys are going to be going into older recipients. Nationally, historically fewer than 2% of all kidneys go to recipients older than age 70. Based on the post Share 35 policy behavior with respect to living donors, the number of living donors decreased and living donor kidneys were allocated to older recipients.

In Los Angeles, the waiting times are so long that the fears are not likely to materialize but in Oregon where waiting times are short, the unintended consequences are very relevant.

It was argued that since whites live longer than blacks; wealthy live longer than poor people; women live longer than men - why is it okay to discriminate on the basis of age when those other characteristics also indicate expected life years? There is a lack of transparency in the modeling. There is a significant ethical difference in using age as a strong predictor of survival than using gender, race, or socioeconomic characteristics.

It was suggested that it may be illegal discrimination to use age as a factor in organ allocation. It was noted that presently immunosuppressant medications are only covered for three years, which results in a significant number of graft failures per year. It was suggested that the system should address geography first, and then other system issues such as providing lifetime coverage for immunosuppressants.

Concerns were also shared about the arbitrariness in determining the top 20% of potential recipients. We cannot determine with specificity the difference between a patient in the top 20.1% versus a patient at 19.9% based on the current modeling based on national data.

Generally, younger patients lose their graft because the graft fails while older patients lose their allograft because they die. The age matching portion of the proposal makes sense and eliminates the SCD and ECD distinction.

It was asked what is the role of the Ethics Committee with respect to this proposal, and specifically, what is unethical about the proposal? There may be legitimate objections to the proposal but those may not be ethical objections. It may not be intrinsically unethical or ethical.

It was suggested that the proposal may be unethical because it discriminates on the basis of age. There is no justification for distinguishing between individuals at certain levels since we cannot do that with any certainty. Third, it ignores living donors and fails to consider the overarching issue of justice. The living donor system will either reduce overall or shift living donor kidneys to older recipients.

In general, this policy has a reasonable ethical basis. Concerns were shared by several members about the effect of this system on the behavior of living donors, as well as the number and projected recipients of living donor kidneys.

Concerns were also shared that the kidney proposal is trying to do survival matching. Survival matching is easy to do at the extreme age ranges, but very difficult to accomplish in the middle range where most of the transplants will occur. This proposal may succeed in extending the lives of people who need a transplant but a fairly large proportion of people would be misclassified, because the models are limited at the individual level.

To determine whether a consensus exists, the Ethics Committee unanimously agreed that the Committee remains concerned with the lack of consideration given to the broader geographic sharing of kidneys and recommends that the Kidney Transplantation Committee make consideration of broader geographic sharing of kidneys a high priority.

By consensus, the Ethics Committee finds no overt ethical problems with the proposed kidney concept. The current system may be unethical and the proposed system is no more unethical than the current system. It was suggested that the proposed system is more unethical because it discriminates on the basis of disease. While the Committee finds the proposal is ethical, there are still concerns about the effects on living donation rates which may render this proposal ethically suspect. Further simulation modeling should be done in order to allay these potential ethical concerns.

Finally, the Ethics Committee has significant concerns over the potential effects of the proposed kidney allocation system on living donation. There were concerns that the effects on living donors may be an ethical problem or may simply be deemed a statistical problem.

The Committee offered the following three motions which were circulated electronically to the Ethics Committee for their votes. The final votes follow each respective Motion.

Motion 1:

In reviewing the new kidney allocation proposals, the Ethics Committee remains concerned with the lack of attention to geographic disparities in access to kidney transplantation. The Ethics Committee recommends that the KI committee make broader geographic sharing of kidneys a high priority when proposing any new system for kidney allocation.

Approved: 11 for, 3 against, and 0 abstentions

Motion 2:

The Ethics Committee finds no overt ethical problems with the proposed kidney allocation concept document.

Approved: 10 for, 4 against, and 0 abstentions

Motion 3:

Implementation of a kidney allocation system based on survival matching could lead to decreased kidney donation from live donors. Decreased living donation would decrease the overall pool of kidneys available for transplantation and therefore impede access to kidney transplantation. The Ethics Committee believes that live donation rates must be closely monitored following implementation of any new kidney allocation system.

Approved: 14 for, 0 against, and 0 abstentions

6. **Recognition of Outgoing Committee Members.** At its April 11, 2011, meeting, Alexandra Glazier, Vice-Chair, presented certificates of appreciation to members of the Committee whose terms were expiring.

Ethics Committee				
Name	Position	March 17, 2011 Conference Call	April 10-11, 2011 Chicago, Illinois	May 26, 2011 Conference Call
Michael E. Shapiro, MD	Chair	X	X	X
Alexandra K. Glazier	Vice-Chair	X	X	X
Matthew G Nuhn, MD	Region 1 Representative		X	
Peter Reese, MD	Region 2 Representative	X	X	X
Carlos F Zayas, MD	Region 3 Representative		X (4/11 only)	X
Natalie G Murray, MD	Region 4 Representative	X	X	
Gabriel M Danovitch, MD	Region 5 Representative	X	X	
Lisa S Florence, MD	Region 6 Representative	X	X	
Bhargav M Mistry, MD	Region 7 Representative			
Erik Schadde, MD	Region 8 Representative			
Deborah B Adey, MD	Region 9 Representative	X	X	X
Amy Pope-Harman, MD	Region 10 Representative	X	X	
Robert Sade, MD	Region 11 Representative		By phone (4/10) X (4/11)	X
Jack Berry	At Large Member	X	X	
Lainie F. Ross, MD	At Large Member	X	By phone (4/10) X (4/11)	X
Kay Kendall, MSW, LISW	At Large Member	X		
Dane Sommer, D.Min., BCC	At Large Member	X	X	
Robert M Veatch, MD	At Large Member		X	X
Liz Lehr, BSN, MHA	At Large Member		X	
Rachel Mackey	At Large Member		X	
Richard Demme, MD	At Large Member	X		
Ronald E Domen	At Large Member			
James M DuBois, PhD, DSc	At Large Member		X	X
Teresa M Beigay, DrPH	Ex Officio – HRSA		By phone	X
Bernie Kozlovsky, MD	Ex Officio – HRSA	X	By phone	X
James Bowman	Ex Officio – HRSA			X
Tabitha Leighton	SRTR	X	By phone	X
Maryam Valapour, MD	SRTR	X	By phone	
Jason Livingston	UNOS Staff – Liaison	X	X	X
Gloria Taylor	UNOS Staff	X	X	X