

**OPTN/UNOS Organ Procurement Organization Committee
Report to the Board of Directors
December 1-2, 2015
Richmond, Virginia**

**Sean F. Van Slyck, MPA/HSA, CPTC, Chair
Jennifer K. Prinz, RN, BSN, MPH, CPTC, Vice Chair**

Contents

Contents	1
Action Items.....	2
1. Proposal to Reduce Documentation Shipped with Organs.....	2
2. Imminent and Eligible Death Data Definitions	3
Committee Projects.....	3
3. HIV Organ Policy Equity Act	3
Committee Projects Pending Implementation.....	4
4. Deceased Donor Registration Completion	4
Review of Public Comment Proposals	4
5. Proposal to Revise OPTN/UNOS Data Release Policies (Data Advisory Committee).....	4
6. Proposal to Increase OPTN/UNOS Committee Terms to Three Years (Policy Oversight Committee).....	5
7. Proposal to Revise Facilitated Pancreas Allocation Policy (Pancreas Transplantation Committee).....	5
8. Simultaneous Liver Kidney (SLK) Allocation Policy (Kidney Transplantation Committee).....	5
9. Proposal to Modify Pediatric Lung Allocation Policy (Thoracic Organ Transplantation Committee).....	5
Other Committee Work	6
10. Memorandum from the Membership and Professional Standards Committee.....	6
11. Documentation Requirements for Additive and Preservation Solutions.....	6
12. Kidney Allocation System Update	6
13. Infectious Disease Verification	6
14. TransNet sm Project Update	6
15. OPTN Research Study	6
16. Brainstorming Session.....	7
17. Member Quality Site Survey Process.....	7
Meeting Summaries	7

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This report reflects the work of the OPTN/UNOS OPO Committee during the May 2015 to November 2015 period.

Action Items

1. Proposal to Reduce Documentation Shipped with Organs

Public Comment: [August - October 2015](#)

OPTN/UNOS Policy 16.5.A: *Organ Documentation* states that members must send the complete donor record in the container with each transported organ. These requirements originated prior to the availability of electronic medical records and functionality to upload information into DonorNet®. As a part of the TransNetsm project, the entire donor process from the intensive care unit to the recovery of organs in the operating room was studied to identify where the process could be made safer and more efficient. After studying multiple donor cases at nine OPOs, the TransNetsm project team, as well as the Ad Hoc Organ Tracking Committee, came to the conclusion that the amount of time coordinators spent making copies of documents, often at very time-sensitive moments, took the coordinators' time and attention away from critical aspects of their job. The practice of including these documents, most of which were already in DonorNet®, in the package with the organ is inefficient and a potential safety hazard. The current requirements can also delay the departure of the transplant teams while donor records are being copied, thereby unnecessarily increasing cold ischemic time.

This proposal will make the organ procurement and allocation system more efficient without increasing patient safety risks or increasing costs. Providing donor information electronically is a well-established practice in the transplantation community, provides the most updated information, and allows transplant teams to review important information in advance of the arrival of an organ at the transplant hospital. The proposed solution does not affect the current practice of OPOs providing all the necessary donor information to transplant hospitals; it merely reduces redundancies in required documentation and reduces paper documentation.

The OPO Committee reviewed public comments and policy language during its October 29, 2015, conference call and unanimously approved the language for consideration by the Board of Directors (16 support; 0 oppose; 0 abstentions).

RESOLVED, that additions and modifications to Policy 2.2 (OPO Responsibilities), Policy 16.1 (Organs Recovered by Living Donor Recovery Hospitals), and Policy 16.4 (Documentation Accompanying the Organ or Vessel) as set forth in Exhibit A of the OPO Committee's report to the Board, are hereby approved, effective March 1, 2016.

2. Imminent and Eligible Death Data Definitions

Public Comment: [September 2012](#)

Board Approval: [June 2013](#) (Proposal)

Board Approval: [November 2013](#) (Revised effective date)

Board Approval: [November 2014](#) (Revised effective date)

Projected Implementation: January 1, 2017

The Committee discussed the upcoming January 1, 2016 effective date for the new imminent and eligible death data definitions. The Board of Directors approved the new definitions in June of 2013; however, the Committee has delayed the effective date twice in order to allow CMS time to make the necessary regulatory changes. One of the main concerns raised during public comment was the potential requirement for OPOs to maintain two sets of data for imminent and eligible deaths. The Committee has actively engaged HRSA and CMS; however, there was no guarantee of a regulation change before the end of 2015. The Committee voted unanimously to delay the effective date until January 1, 2017.

RESOLVED, that the effective date for changes to the definitions of Eligible Death and Imminent Neurological Death in Policy 1.2, as set forth in Exhibit B of the OPO Committee's report to the Board, be changed from January 1, 2016 to January 1, 2017.

Committee Projects

3. HIV Organ Policy Equity Act

Public Comment: [September 29 – December 5, 2014](#)

Public Comment: [January 27 – March 27, 2015](#)

Board Approval: [June 2015](#)

Implementation: November 21, 2015

Policy Updates

The Committee was provided with an update on policy language changes necessary to allow for the conduct of research as outlined in the HOPE (HIV Organ Policy Equity) Act. During the June 2015 Board of Directors meeting, a Board member expressed concern that the proposed language in *Policy 15.6: Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors* addressing the allocation of HIV positive organs to HIV positive candidates not appearing on the match run did not specifically limit the practice to directed donations. The Committee approved a policy language change that clarified allocation of HIV positive organs to HIV positive candidates not on the match run can only occur in cases of directed donation. There are also safeguards in place within the policy that require verification that the donor is HIV positive and the intended candidate is registered at a transplant hospital that meets the requirements for transplanting HIV positive candidates with HIV positive organs.

Two additional policy language changes being proposed are an expiration date for the open variance as well as a requirement for HOPE Act researchers to provide institutional review board (IRB) data safety monitoring board reports to the OPTN. These changes did not

require OPO Committee action. The OPTN/UNOS Executive Committee approved all three items during a conference call on October 19, 2015. The requirement to submit institutional review board data safety monitoring reports was approved with a sunset date of September 1, 2016. This policy change will be distributed for public comment in January 2016 and submitted to the Board of Directors in June 2016. For more information about these changes please refer to **Exhibit C**.

Programming Updates

UNOS staff provided the Committee with an overview of the programming changes necessary to allocate livers and kidneys from HIV positive donors to those HIV positive candidates participating in a HOPE Act research study. One Committee member expressed concern that reported false positive HIV test results could lead to organs being lost. UNOS staff noted that in order to ensure patient safety, a candidate would be considered HIV positive if any of the three screening tests for HIV were positive. UNOS staff agreed to forward the concern to the internal work group in order to identify the best way to handle these situations.

Committee Projects Pending Implementation

4. Deceased Donor Registration Completion

Public Comment: [September 29 – December 5, 2014](#)

Board Approval: [June 2015](#)

Projected Implementation: *May 2016*

Policy 18.1: Data Submission Requirements requires all OPOs to complete the deceased donor registration (DDR) for all deceased donors and authorized but not recovered potential deceased donors. Prior to 2001, information on non-donors was collected on the cadaver donor referral form. When this form was eliminated, only the DDR remained. The OPO Committee observed inconsistent data reporting on potential donors that do not proceed to donation. The Committee discussed the purpose of collecting data on authorized but not recovered donors or those for whom authorization was not obtained. Because there is limited information available on non-donors, the Committee agreed that it was appropriate to eliminate the requirement. During the discussions, the Committee also agreed to propose a minor modification to the definition of a deceased donor.

During a conference call on September 5, 2014, the Committee reviewed the final policy language and unanimously supported the proposal moving forward to public comment on September 29, 2014. The proposal received unanimous support from all the regions, committees, and organizations. The OPO Committee reviewed the final policy language during its March 31, 2015, meeting and unanimously approved the language for consideration by the Board of Directors (12 support; 0 oppose; 0 abstentions). The Board approved the proposal during its June 2015 meeting, and the changes to the form will be implemented in May 2016.

Review of Public Comment Proposals

The Committee reviewed 5 of the 12 proposals released for public comment from August 14, 2015 – October 14, 2015.

5. Proposal to Revise OPTN/UNOS Data Release Policies (Data Advisory Committee)

The OPO Committee supported this proposal with the following questions:

OPTN/UNOS Organ Procurement Organization Committee

- What is the definition of “reasonableness” and how will the OPTN evaluate the “reasonableness” of requests?
- What additional OPO data will be released outside of what is currently released by the OPTN and SRTR?
- Will this proposal improve the process for OPOs to obtain information? For example, OPOs currently contact the transplant centers to obtain information about the results of the transplants when the same information could be obtained directly from UNOS.

6. Proposal to Increase OPTN/UNOS Committee Terms to Three Years (Policy Oversight Committee)

The OPO Committee supported this proposal but questioned how the transition plan will impact current members and whether the proposal affects the current process for extensions.

7. Proposal to Revise Facilitated Pancreas Allocation Policy (Pancreas Transplantation Committee)

The OPO Committee supported the efforts of the Pancreas Committee to improve facilitated pancreas allocation. Allowing OPOs to manage the process is an improvement to the system and changing the timeframe from one hour to three hours (from donor organ recovery) will allow for additional time to identify transplant centers willing to accept the organ. The OPO Committee had the following comments:

- OPOs might not be aware of facilitated pancreas allocation so additional communication might be beneficial.
- The proposal is not clear on whether a new match run needs to be executed.
- The data indicates that OPOs are allocating pancreata for an average of 19 hours and it is unclear if this proposal will increase utilization since only 14% of all pancreata were recovered last year and 31% of those were discarded. There was a recommendation to review data on why organs are being discarded or declined to determine if sufficient time to receive offers was a factor. Additionally, the data do not account for pancreata that were aborted and not recovered.
- For transplant centers to qualify for the facilitated pancreas allocation list, there was a recommendation to create a more dynamic system to allow for the variability in volume of transplants.
- There was a recommendation to evaluate the broader allocation system (i.e. DonorNet[®]) for areas of improvement across all organ systems.

8. Simultaneous Liver Kidney (SLK) Allocation Policy (Kidney Transplantation Committee)

The OPO Committee supported the proposal but remains concerned about the variability of practice for sharing kidneys regionally. This variability in practice is not always OPO-driven and can be influenced by local transplant programs.

9. Proposal to Modify Pediatric Lung Allocation Policy (Thoracic Organ Transplantation Committee)

The OPO Committee reviewed the proposal and offered no comments.

Other Committee Work

10. Memorandum from the Membership and Professional Standards Committee (MPSC)

The Committee reviewed a memorandum from the MPSC regarding Policy 8.2.A: *Exceptions Due to Medical Urgency*. As written, the policy could be interpreted as an exception to mandatory kidney sharing policies. The Committee agreed that the exception should only be applied to bypass the local list and that the policy language should be clarified in order to provide OPOs clear guidance for kidney allocation when made aware of local, medically urgent, potential kidney recipient. The Committee will submit a formal response to the MPSC.

11. Documentation Requirements for Additive and Preservation Solutions

The Committee discussed how OPOs should handle documentation of additive and preservation lot numbers for solutions provided by transplant center procurement teams. The Committee agreed that while it is ultimately the OPO's responsibility based on Policy 2.15.B: Organ Procurement Procedures, there should be shared responsibility with the transplant hospitals to provide the required information.

The Committee agreed to reach out to the Transplant Administrators Committee and Transplant Coordinators Committee in an effort to make them aware of this issue and get feedback on potential policy changes. Additionally, the Committee agreed it would be helpful to identify OPOs with "best practices" that can be shared with the OPO community.

12. Kidney Allocation System Update

The Committee was provided with an update on the new kidney allocation system. The OPO Committee will continue to work with the Kidney Transplantation Committee on the logistical challenges in allocation and look forward to further analysis of the increase in discard rates, cold ischemia time, and delayed graft failure.

13. Infectious Disease Verification

The Committee was provided with an update from the infectious disease work group. This joint work group with the Operations and Safety Committee has been developing requirements for the pre-recovery verification of infectious disease test results. The Committee reviewed and provided feedback on draft policy language. The Committee also agreed to complete a brief survey to provide additional information for an upcoming work group conference call. The Committee will continue to provide input on this proposal as it moves forward to public comment in January 2016.

14. TransNetsm Project Update

The Committee was provided with an update on the TransNetsm project. This included an updated project timeline, OPO training, usage data, and transplant hospital functionality. The Committee briefly discussed the need for a "multi-organ" label and reviewed a prototype label. The Committee will provide additional input on the label as it is being developed for use in packaging "en bloc" organs.

15. OPTN Research Study

The Committee was provided with an overview of a recent modification to the OPTN contract to conduct a study examining the feasibility of the OPTN collecting in-hospital

ventilated death referral data. Some initial research questions include standardized definitions, availability of patient-level data, level of effort to collect the data, verifying data, and data collection tools. As the project continues, the OPO Committee will receive updates.

16. Brainstorming Session

The new OPTN Strategic Plan approved by the Board of Directors in June 2015 included benchmarks for resource allocations towards each of the five strategic goals. This was based on feedback from the community and resulted in an emphasis on increasing the number of transplants and increasing equity in transplant access. The Committee participated in a brainstorming session to identify project ideas that have the potential to increase the number of transplants. The Committee identified a list of potential projects that included the following:

- Facilitated placement of all organs
- Improvements in DonorNet[®]
- Pumping standards
- Use of ex-vivo lungs
- Increase DCD
- Regulatory changes to increase use of marginal organs
- Reducing discards
- Financial assistance – living and deceased donors
- Expanding DSA recovery teams

The Committee will work to further define the projects, draft problem statements, and identify proposed solutions.

17. Member Quality Site Survey Process

The Committee was provided with an update from Membership Quality staff regarding recent changes to the site survey process and the OPTN evaluation plan. The Member Quality department is currently undergoing a comprehensive evaluation of their processes due to a change in leadership. Member Quality staff noted that there is interest in working collaboratively with the OPO Committee as they move forward with process changes.

Meeting Summaries

The Committee held meetings on the following dates:

- October 29, 2015

Meetings summaries for this Committee are available on the OPTN website at: <http://optn.transplant.hrsa.gov/converge/members/committeesDetail.asp?ID=18>.

OPTN/UNOS Organ Procurement Organization Committee

Proposal to Reduce the Documentation Shipped with Organs

*Prepared by:
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Executive Summary	2
What problem will this proposal solve?	3
Why should you support this proposal?	3
Which populations are impacted by this proposal?	6
How does this proposal support the OPTN Strategic Plan?	6
How will the sponsoring Committee evaluate whether this proposal was successful post implementation?	7
How will the OPTN implement this proposal?	7
How will members implement this proposal?	7
How will members be evaluated for compliance with this proposal?	7
Policy or Bylaw Language	8

Proposal to Reduce the Documentation Shipped with Organs

Executive Summary

OPTN/UNOS Policy 16.4.A: Organ Documentation states that members must send the complete donor record in the container with each transported organ. These requirements originated prior to the availability of electronic medical records and the functionality to upload information into DonorNet®. The Organ Procurement Organization (OPO) Committee discussed strategies to reduce the amount of documentation that is packaged and shipped with each organ, to allow OPO transplant coordinators more time to focus on donor management. The OPO Committee proposes limiting the required documentation to blood type source documentation and infectious disease testing results. OPOs will continue to provide all other pertinent donor information electronically.

Proposal to Reduce the Documentation Shipped with Organs

Affected Policies: Policy 2.2: OPO Responsibilities; Policy 16.1: Organs Recovered by Living Donor Recovery Hospitals; and Policy 16.4: Documentation Accompanying the Organ or Vessel

Sponsoring Committee: Organ Procurement Organization Committee

Public Comment Period: August 14, 2015 – October 14, 2015

What problem will this proposal solve?

OPTN/UNOS Policy 16.4.A: Organ Documentation states that members must send the complete donor record in the container with each transported organ. These requirements originated prior to the availability of electronic medical records and functionality to upload information into DonorNet®. As a part of the TransNetsm project, the project team studied the entire donor process from the intensive care unit to the recovery of organs in the operating room to identify where the process could be safer and more efficient. After studying multiple donor cases at nine organ procurement organizations (OPOs), the project team and the Ad Hoc Organ Tracking Committee concluded that the amount of time coordinators spent making copies of documents took the coordinators' time and attention away from critical, time-sensitive aspects of their job. The practice of including these documents, most of which were already in DonorNet®, in the package with the organ was inefficient and a potential safety hazard by taking the coordinators' attention away from managing the donor. The current requirements can also delay the departure of the transplant teams and unnecessarily increase cold ischemic time.

Why should you support this proposal?

This proposal will make the organ recovery and allocation system more efficient without increasing patient safety risks or increasing costs. Providing donor information electronically is a well-established practice in the transplantation community, provides the most updated information, and allows transplant teams to review important information in advance of the arrival of an organ at the transplant hospital. The OPO Committee (the Committee) proposes limiting the required documentation to blood type source documentation and infectious disease testing results. OPOs will continue to provide all other pertinent donor information electronically. The proposed solution does not affect the current practice of OPOs providing all the necessary donor information to transplant hospitals; it merely decreases redundancy in required documentation and reduces the amount of paper documentation.

How was this proposal developed?

OPOs expressed that current paper documentation requirements are burdensome. The burden became even more apparent during the development of TransNetsm, when project staff observed donor management and organ procurement practices in six OPOs and seven transplant hospitals. The Committee discussed strategies to reduce the amount of paper documentation that is packaged and shipped with each organ. The Committee agreed OPO staff time is inefficiently used for copying voluminous documents and the transplant coordinator is removed from focused donor management.

The Committee requested feedback from the Transplant Administrators Committee (TAC) and Transplant Coordinators Committee (TCC) in order to evaluate the potential impact on transplant hospitals with the proposed reduction of paper documentation. Highlights of the feedback include:

Transplant Coordinators Committee

- Utilizing DonorNet® will allow for the communication of current information
- Decreasing the paper documentation packaged with organs decreases the chance of errors and allows coordinators to focus on donor patient care
- Including UNOS ID, match run, ABO source documentation, and serology results in paper form for verification purposes in case DonorNet® is not accessible
- Uploading documents in PDF format to allow for easy accessibility by transplant hospitals
- Verbally notifying transplant hospital of important changes such as updated testing results
- Uploading all necessary information and additional organ-specific information into DonorNet® by the OPO to allow the transplant hospital to view the information and print it out if necessary.

Transplant Administrators Committee

- TAC supported the vision of paperless charts but understands the sequential plan to achieve this goal will require the interim use of paper documentation.
- TAC noted that paper documentation included with the organs are not the “final chart” because final test results might not be available at the time of organ packaging.
- TAC expressed concern that DonorNet® is not always accessible in the operating room and some staff are not familiar with how to access the available information.

The Committee discussed this feedback and agreed to retain the requirement to include blood type and infectious disease results source documentation with the shipped organ. The Committee agreed that this information was important for transplant hospital personnel to verify when receiving organs. OPOs will continue to provide all required information and source documentation in DonorNet®.

The Committee discussed adding a requirement to upload all other relevant information, including intraoperative findings, within two hours of completion of organ recovery. However, upon further review of OPTN/UNOS Policy 16.4.A, the Committee determined that the additional information such as medical and behavioral information, donor evaluation information, donor authorization, and organ quality information are already required to be provided electronically or verbally *prior to* organ packaging. Because OPTN/UNOS Policy 16.4 addresses documentation accompanying the organ or vessel and most of the information is also required by OPTN/UNOS Policy 2.2: OPO Responsibilities, the Committee agreed to remove all the required documentation, except blood type and infectious disease results source documentation. The Committee also proposes modifying the title of OPTN/UNOS Policy 16.4.A to make it clear the policy is addressing organ packaging documentation requirements.

OPTN/UNOS Policy 2.2 states that one of the OPO responsibilities is to “report to the OPTN Contractor all deceased donor information required for organ placement, including the donor’s human leukocyte antigen (HLA) type.” The policy does not include requirements for when or how OPOs report this information. Additionally, the policy is vague regarding what is considered “donor information” but specific when referencing HLA. Therefore, the Committee is proposing that this vague language be removed and HLA type be included with the other required documentation addressed in Policy 2.2 (14). The Committee also proposes that OPOs be required to submit the information “upon receipt” in order for transplant programs to assess donors and respond to offers in a timely manner. The donor information reporting requirements proposed in this document are not exhaustive. OPOs are still required to provide additional information as outlined in OPTN/UNOS Policy 2: Deceased Donor Organ Procurement.

CMS Regulations

The Committee is aware that changes to OPTN policies will not eliminate the requirements to submit donor documentation with the organs as outlined in CMS (Centers for Medicare and Medicaid Services) regulation 42 CFR § 486.346(b) and the supporting interpretive guidelines §486.346(b).¹ The Committee will work with Health Resources and Services Administration (HRSA) staff to determine if changes can be made to the CMS interpretive guidelines to allow regulatory compliance to align with the proposed OPTN/UNOS policy changes. The Committee agreed to proceed with the OPTN policy change since it will not create additional requirements on OPOs.

How well does this proposal address the problem statement?

Digital technology, including DonorNet[®], smart phones, tablets, and web-based devices, has changed the way we communicate and share information. Health care systems have embraced the use of electronic health records (EHR) as a method to provide information and improve patient care. Hospital adoption of EHR systems has increased more than five-fold since 2008.² OPOs and transplant hospitals have increased the use of EHR, and sending information electronically allows for better communication between OPOs and transplant hospitals. This proposal will reduce the need to copy and ship documentation already provided to the transplant hospitals, which can lead to fatigue, potential errors, and distraction from other donor management tasks including organ labeling and packaging. All OPOs currently report donor information to DonorNet[®] in order to provide transplant centers with the necessary information to make informed decisions about donors and to provide access to donor records at any time from any location.

Was this proposal changed in response to public comment?

The OPO Committee received a number of comments and questions in response to this proposal. The main themes and the responses by the OPO Committee are included below.

DonorNet[®] Accessibility

Some responders expressed concern that transplant hospital personnel might not have access to DonorNet[®] at certain times, and therefore may not be able to obtain the information that will only be submitted to DonorNet[®] and not packaged with organ. The Committee understands the concern about access to DonorNet[®]; however, the required donor information is currently provided by OPOs through DonorNet[®] and includes information that is communicated to the transplant hospitals well in advance of organ packaging and shipping. The Committee believes that providing paper copies of this information, which can be voluminous at times, is unnecessary. The information is provided well in advance of the organs arriving at the recipient transplant hospital and staff have the opportunity to print copies of the information if needed.

The Committee discussed the VCA Committee's concern about VCA programs having limited access to DonorNet[®] and did not believe an exception should be included in the proposed policies. The proposed policy language does not prohibit the use of paper documentation or other means to provide information. VCA programs should continue to work with their OPOs to identify the best method for receiving donor information. The Committee has plans to develop training tools to review DonorNet[®] access, in addition to existing training materials available in UNetsm and is willing to work with the VCA Committee to address these issues.

¹ Available at http://www.ecfr.gov/cgi-bin/text-idx?SID=f68a8e754cb03dca1b17c702936f9211&node=42:5.0.1.1.5&rgn=div5#se42.5.486_1346 and <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R115SOMA.pdf>

² Charles D, Gabriel M, Furukawa MF. "Adoption of Electronic Health Record Systems among U.S. Non-federal Acute Care Hospitals: 2008-2013," ONC Data Brief, no. 16. Washington, DC: Office of the National Coordinator for Health Information Technology. May 2014.

Donor Record Retention

Some responders requested that the OPO Committee further define the requirements to maintain donor records and determine whether DonorNet® can serve as the permanent record of OPO documentation. It is the opinion of the Committee that these concerns, while pertinent, are outside the scope of the proposed policy revisions. Additionally, the Committee believes that the proposed policy would provide a more efficient and effective venue for transplant programs to receive and process donor records as they will all be available electronically on DonorNet® or can be electronically sent by the host OPO via secure email.

Complete Donor Record

One respondent suggested requiring OPOs to upload the entire donor record into DonorNet®. The Committee agreed that OPOs should upload the entire donor record to DonorNet® and will work to develop guidance documents on naming structures for the files to reinforce ease of access for the transplant community.

The OPO Committee reviewed and approved responses to the public comments during its October 29, 2015, conference call. The comments received for this proposal are on the Organ Procurement and Transplantation Network (OPTN) website at <http://optn.transplant.hrsa.gov/governance/public-comment>. The Committee unanimously approved the policy language for consideration by the Board of Directors (16 support; 0 oppose; 0 abstentions).

Updated Donor Information

Some responders questioned how the OPO will communicate last minute updates to the donor's information. The host OPO is required to communicate all pertinent information to the accepting transplant center, and will be required to post all relevant information to DonorNet® as soon as it is received.

Conflict with Living Donor Packaging Policy

The Transplant Administrators Committee noted there is a conflict between the *Organ Packaging Documentation* policy and 16.2(3): *Organs Recovered by Living Donor Recovery Hospitals*. The OPO Committee agreed that the two policies are in conflict and is proposing the following modification to Policy 16.1 (3): “~~Instead of~~ In addition to the list of documents in *Policy 16.4...*” Additionally, Policy 16.1 still requires the complete living donor record to be included with living donor organs.

Which populations are impacted by this proposal?

OPOs and transplant hospitals will be impacted by this proposal. The proposed changes will only reduce the documentation shipped with each organ and will not impact the current methods used by OPOs to communicate donor information to the transplant hospitals.

How does this proposal support the OPTN Strategic Plan?

1. *Increase the number of transplants:* There is no impact to this goal
2. *Improve equity in access to transplants:* There is no impact to this goal
3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* There is no impact to this goal
4. *Promote living donor and transplant recipient safety:* There is no impact to this goal

5. *Promote the efficient management of the OPTN:* This proposal will allow for more efficient and timely communication of donor information to transplant centers by utilizing current technology instead of paper documentation.

How will the sponsoring Committee evaluate whether this proposal was successful post implementation?

The Committee will develop a survey to collect information from OPOs and transplant hospitals to assess efficiencies associated with the policy change. This will include any problems identified during the first six months of implementation that might require additional changes or education.

How will the OPTN implement this proposal?

UNOS IT provides cost estimates for each public comment proposal that will require programming to implement. As this proposal will not require programming in UNetSM, no IT complexity was assigned.

The Committee discussed the effective date for this policy change and the potential for the OPTN to delay it in order to allow time for alignment with CMS regulations or interpretive guidelines. The Committee ultimately decided to move forward with the standard effective date of March 1, 2016 if the Board of Directors approves the proposal during its December 2015 meeting.

The Committee plans to develop an educational document to identify best practices and establish standard naming conventions for use by OPOs when uploading files. The Committee agreed that the file names should accurately describe the documents contained in the file and OPOs should upload documents individually whenever possible.

How will members implement this proposal?

OPOs must report all required information to the OPTN Contractor upon receipt by uploading the information to DonorNet[®]. Transplant hospitals will need to be aware that donor information is available in DonorNet[®] and OPOs will only include the blood type and infectious disease source documentation in the shipping container with each organ. If paper copies of donor information are required, transplant hospitals will need to print the information.

Will this proposal require members to submit additional data?

No, this proposal does not require additional data collection.

How will members be evaluated for compliance with this proposal?

Members will be expected to comply with requirements in the proposed language; however, the proposed language will not change the current routine site surveys of OPTN members. The proposed policy language does not restrict OPOs from providing paper documentation in order to comply with CMS regulations. Any data submitted to the OPTN Contractor may be subject to OPTN review, and members are required to provide documentation as requested.

Policy or Bylaw Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~)

RESOLVED, that changes to Policy 2.2 (OPO Responsibilities), Policy 16.1 (Organs Recovered by Living Donor Recovery Hospitals), and Policy 16.4 (Documentation Accompanying the Organ or Vessel) as set forth below, are hereby approved, effective March 1, 2016.

2.2 OPO Responsibilities

The host OPO is also responsible for *all* of the following:

1. Identifying potential deceased donors.
2. Providing evidence of authorization for donation.
3. Evaluating deceased donors.
4. Maintaining documentation used to exclude any patient from the imminent neurological death data definition or the eligible data definition.
5. Verifying that death is pronounced according to applicable laws.
6. Establishing and then implementing a plan to address organ donation for diverse cultures and ethnic populations.
7. Clinical management of the deceased donor.
8. Assuring that the necessary tissue-typing material is procured, divided, and packaged.
9. Assessing deceased donor organ quality.
10. Preserving, packaging, and transporting the organs.
- ~~11. Reporting to the OPTN Contractor all deceased donor information required for organ placement, including the donor's human leukocyte antigen (HLA) type.~~
- ~~12.11.~~ 11. Executing the match run and using the resulting match for each deceased donor organ allocation. The previous sentence does not apply to VCA transplants; instead, members must allocate VCAs according to *Policy 12.2: VCA Allocation*.
- ~~13.~~ 12. Documenting and maintaining complete deceased donor information for seven years for all organs procured.
- ~~14.~~ 13. Ensuring that ~~written~~ documentation for all of the following deceased donor information is submitted to the OPTN Contractor upon receipt to enable complete and accurate evaluation of donor suitability by transplant programs: ~~of the deceased donor evaluation, donor management, authorization for donation, death pronouncement, and organ procurement quality accompanies the organ as described in *Policy 16: Organ and Vessel Packaging, Labeling, Shipping, and Storage*.~~
 - a. ABO source documentation
 - b. ABO subtype source documentation
 - c. Infectious disease results source documentation
 - d. Death pronouncement source documentation
 - e. Authorization for donation source documentation
 - f. Human leukocyte antigen (HLA) type
 - g. Donor evaluation and management
 - h. Donor medical and behavioral history
 - i. Organ intraoperative findings

37 ~~15.~~ 14. Maintaining blood specimens appropriate for serologic and nucleic acid testing (NAT), as available, for
 38 each deceased donor for at least 10 years after the date of organ transplant, and ensuring these samples
 39 are available for retrospective testing. The host OPO must document the type of sample in the deceased
 40 donor medical record and, if possible, should use qualified specimens.

41

42 16.1 Organs Recovered by Living Donor Recovery Hospitals

43

44 Living donor recovery hospitals must follow all of the requirements for packaging, labeling, and
 45 transporting organs, tissue typing material, and vessels according to this Policy, with these differences:

46

- 47 1. While OPOs are responsible for packaging, labeling, and transporting deceased donor organs,
 48 vessels, and tissue typing samples, recovery hospitals are responsible for packaging, labeling, and
 49 transporting living donor organs, vessels, and tissue typing samples.
- 50 2. When a member repackages a living donor organ, they are not required to notify the member that
 51 originally packaged the organ.
- 52 3. ~~Instead of~~ In addition to the list of documents in *Policy 16.4: Documentation Accompanying the Organ or*
 53 *Vessel*, living donor organs must contain the blood type source documents, donor informed consent form,
 54 and the complete medical record of the living donor. Vessels that are shipped separately from living donor
 55 organs must include the same documents as are required for shipping living donor organs.
- 56 4. Blood samples must contain the donor ID and *one* of the following three identifiers: donor date of
 57 birth, donor initials, or a locally assigned unique ID. Each sample must contain the donor's blood
 58 type and subtype, the type of tissue, and the date and time when the sample was obtained.
 59 The recovery hospital must document in the donor record all unique identifiers used to label
 60 blood samples and tissue typing materials.
- 61 5. The recovery hospital will provide specimens for tissue typing if requested. The minimum
 62 typing materials for living donor kidneys are: two ACD (yellow top) tubes per kidney.

63

64 16.4 Documentation Accompanying the Organ or Vessel

65 16.4.A Organ Packaging Documentation Requirements

66 Each external deceased and living donor transport container holding an organ must be sent with
 67 ~~the complete deceased and living donor record that includes~~ all of the following source
 68 documentation:

69

- 70 1. Blood type ~~source documentation~~
- 71 2. Blood subtype ~~source documentation~~, if used for allocation
- 72 3. Infectious disease testing results available at the time of organ packaging
- 73 4. ~~Medical and behavioral history information~~
- 74 5. ~~Donor evaluation information~~
- 75 6. ~~Donor authorization form~~
- 76 7. ~~Organ quality information as noted in Policy 2.15.C: Organ Procurement Procedures~~

77

78 ~~Donor~~ The source documentation must be placed in a watertight container in *either* of the
 79 following:

80

- 81 • A location specifically designed for documentation
- 82 • Between the inner and external transport containers

83

84 ~~When a deceased or living donor organ is transported, the host OPO or the transplant hospital~~
 85 ~~must include the source documentation with the donor information.~~

86

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OPTN/UNOS Organ Procurement Organization Committee

Imminent and Eligible Death Data Definitions – Change Effective Date

*Committee Liaison
Robert A. Hunter
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Executive Summary 2

What problem will this proposal solve?..... 3

Why should you support this proposal? 3

How does this proposal support the OPTN Strategic Plan?..... 3

How will the OPTN implement this proposal?..... 3

How will members implement this proposal?..... 3

How will members be evaluated for compliance with this proposal? 4

Policy or Bylaw Language..... 4

Imminent and Eligible Death Data Definitions – Change Effective Date

Mini-Brief

Executive Summary

This proposal, approved by the Board of Directors in June 2013, clarifies the data collection definitions for determining whether or not a death can be classified as “imminent” or “eligible.” The approved language eliminates multi-system organ failure (MSOF) as an exclusionary criterion for classifying a death as “eligible” and adds a list of organ-specific exclusionary criteria to give OPOs more guidance. The Committee also changed the definition of “imminent” to restrict it to those deaths that would most likely be classified as “eligible” had brain death been legally declared. The OPO Committee is requesting the effective date be changed from January 1, 2016 to January 1, 2017.

Imminent and Eligible Death Data Definitions – Change Effective Date

Affected Policy: Policy 1.2 (Definitions)

Sponsoring Committee: Organ Procurement Organization Committee

What problem will this proposal solve?

This proposal is an effort to establish clear imminent and eligible death data definitions to improve the consistency of reporting across OPOs.

Why should you support this proposal?

One of the main concerns raised during public comment was the potential requirement for OPOs to maintain two sets of data for imminent and eligible deaths. The Committee discussed the upcoming January 1, 2016 effective date for the new imminent and eligible death data definitions. The Board of Directors approved the new definitions in June of 2013; however, the Committee has delayed the effective date twice in order to allow CMS time to make the necessary regulatory changes. One of the main concerns raised during public comment was the potential requirement for OPOs to maintain two sets of data for imminent and eligible deaths.

The Committee has actively engaged HRSA and CMS in an effort to move this policy change forward; however, there was no guarantee of a regulation change before the end of 2015. The Committee will work with HRSA staff to continue discussions with CMS on a path forward. In order to avoid creating unnecessary data burden on OPOs, the Committee is requesting a change to the effective date.

How does this proposal support the OPTN Strategic Plan?

1. *Increase the number of transplants:* There is no impact to this goal
2. *Improve equity in access to transplants:* There is no impact to this goal
3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* There is no impact to this goal
4. *Promote living donor and transplant recipient safety:* There is no impact to this goal
5. *Promote the efficient management of the OPTN:* This proposal promotes this goal by increasing the accuracy of data reporting that supports critical network functions of data collection.

How will the OPTN implement this proposal?

The Committee will continue to provide periodic updates on the status of this proposal. The Committee has developed an education plan which includes an e-learning module.

This proposal will require programming in UNetSM. There will be a minor change to the Online Help Documentation; however, no changes will be required to any of the data fields.

How will members implement this proposal?

When this proposal goes into effect, OPOs will need to be familiar with the new definitions in order to accurately indicate imminent and eligible status on the death notification registration form.

Will this proposal require members to submit additional data?

This proposal does not require additional data collection.

How will members be evaluated for compliance with this proposal?

UNOS Member Quality staff will review death referral information reported to the OPTN during OPO onsite reviews. Member Quality staff will verify that OPOs are using the definitions in policy to report death referral information to the OPTN.

Policy Language

1 **RESOLVED, that the effective date for changes to the definitions of Eligible Death and Imminent**
 2 **Neurological Death in Policy 1.2, which were approved by the Board of Directors on June 24, 2013,**
 3 **be changed from January 1, 2016 to January 1, 2017.**
 4

5 **1.2 Definitions**

6 The definitions that follow are used to define terms specific to the OPTN Policies.

7 **Eligible death**

8 For reporting purposes of DSA performance assessments, an eligible death for deceased organ donation
 9 is defined as the death of a patient who meets *all* the following characteristics:
 10

- 11 • Is 75 years old or less
- 12 • Is legally declared dead by neurologic criteria according to the current standards of accepted medical
 13 practice and state or local law
- 14 • Has body weight of 5 kg or greater
- 15 • Has a body mass index (BMI) of 50 kg/m² or less
- 16 • Has at least one kidney, liver, heart or lung that is deemed to meet the eligible data definition as
 17 defined below:
 - 18 ○ The kidney would initially meet the eligible data definition unless the donor meets *any* of the
 19 following criteria:
 - 20 • Greater than 70 years old
 - 21 • Age 50-69 years with history of type 1 diabetes for more than 20 years
 - 22 • Polycystic kidney disease
 - 23 • Glomerulosclerosis greater than or equal to 20% by kidney biopsy
 - 24 • Terminal serum creatinine greater than 4.0 mg/dL
 - 25 • Chronic renal failure
 - 26 • No urine output for 24 hours or longer
 - 27 ○ The liver would initially meet the eligible data definition unless the donor meets *any* of the
 28 following criteria:
 - 29 • Cirrhosis
 - 30 • Terminal total bilirubin greater than or equal to 4 mg/dL
 - 31 • Portal hypertension
 - 32 • Macrosteatosis greater than or equal to 50%
 - 33 • Fibrosis greater than or equal to stage II
 - 34 • Fulminant hepatic failure
 - 35 • Terminal AST/ALT greater than 700 U/L
 - 36 ○ The heart would initially meet the eligible data definition unless the donor meets *any* of the
 37 following criteria:
 - 38 • 60 years old or older

- 39 • 45 years old or older with a history of 10 or more years of HTN or 10 or more years of type 1
- 40 diabetes
- 41 • History of coronary artery bypass graft (CABG)
- 42 • History of coronary stent/intervention
- 43 • Current or past medical history of myocardial infarction (MI)
- 44 • Severe vessel diagnosis as supported by cardiac catheterization
- 45 • Acute myocarditis or endocarditis, or both
- 46 • Heart failure due to cardiomyopathy
- 47 • Internal defibrillator or pacemaker
- 48 • Moderate to severe single valve or 2-valve disease documented by echo or cardiac
- 49 catheterization, or previous valve repair
- 50 • Serial echo results showing severe global hypokinesis
- 51 • Myxoma
- 52 • Congenital defects (surgically corrected or not)
- 53 ○ The lung would initially meet the eligible data definition unless the donor meets *any* of the
- 54 following criteria:
- 55 • Age 65 years or older
- 56 • Diagnosed with COPD
- 57 • Terminal PaO₂/FiO₂ less than 250 mmHg
- 58 • Asthma (with daily prescription)
- 59 • Asthma is the cause of death
- 60 • Pulmonary fibrosis
- 61 • Previous lobectomy
- 62 • Multiple blebs documented on computed axial tomography (CAT) scan
- 63 • Pneumonia as indicated on computed tomography (CT), X-ray, bronchoscopy, or cultures
- 64 • Bilateral severe pulmonary contusions as per CT

65
66 If a deceased patient meets the above criteria they would be classified as an eligible death unless the
67 donor meets *any* of the following criteria:

- 68
- 69 • The donor has no suitable organ for transplant (as defined above)
- 70 • The donor goes to the operating room with intent to recover organs for transplant and all organs are
- 71 deemed not medically suitable for transplant
- 72 • The donor exhibits *any* of the following:
- 73 ○ Active infections (with a specific diagnosis)
- 74 ○ Bacterial: tuberculosis, gangrenous bowel or perforated bowel or intra-abdominal sepsis
- 75 ○ Viral: HIV infection by serologic or molecular detection, rabies, reactive hepatitis B surface
- 76 antigen, retroviral infections including viral encephalitis or meningitis, active herpes simplex,
- 77 varicella zoster, or cytomegalovirus viremia or pneumonia, acute epstein barr virus
- 78 (mononucleosis), West Nile virus infection, SARS
- 79 ○ Fungal: active infection with cryptococcus, aspergillus, histoplasma, coccidioides, active
- 80 candidemia or invasive yeast infection
- 81 ○ Parasites: active infection with trypanosoma cruzi (Chagas'), Leishmania, strongyloides, or
- 82 malaria (*plasmodium sp.*)
- 83 ○ Prion: Creutzfeldt-Jacob disease
- 84 ○ General [Exclusions to the Definition of Eligible]: aplastic anemia, agranulocytosis
- 85 ○ Current malignant neoplasms, except non-melanoma skin cancers such as basal cell and
- 86 squamous cell cancer and primary CNS tumors without evident metastatic disease
- 87 ○ Previous malignant neoplasms with current evident metastatic disease
- 88 ○ A history of melanoma
- 89 ○ Hematologic malignancies: leukemia, Hodgkin's disease, lymphoma, multiple myeloma
- 90 ○ Active fungal or parasitic meningitis or encephalitis
- 91 ○ No discernible cause of death

92 Imminent neurological death

93 Imminent Neurological Death is defined as the death of a patient who meets *both* of the following criteria:

94

- 95 • Meets the eligible death definition with the exception that the patient has not been declared legally
- 96 dead by neurologic criteria according to current standards of accepted medical practice and state or
- 97 local law.
- 98 • Has a severe neurological injury requiring ventilator support who, upon clinical evaluation
- 99 documented in the OPO record or donor hospital chart, has no observed spontaneous breathing and
- 100 is lacking at least *two* of the additional brain stem reflexes that follow:

101

- 102 ○ Pupillary reaction
- 103 ○ Response to iced caloric
- 104 ○ Gag Reflex
- 105 ○ Cough Reflex
- 106 ○ Corneal Reflex
- 107 ○ Doll's eyes reflex
- 108 ○ Response to painful stimuli

109

110 A patient who is unable to be assessed neurologically due to administration of sedation or

111 hypothermia protocol does not meet the definition of an imminent neurological death.

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Modifications to the Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors

*Committee Liaison
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Executive Summary	2
What problem will this proposal solve?.....	3
Why should you support this proposal?.....	3
How does this proposal support the OPTN Strategic Plan?.....	4
How will the OPTN implement this proposal?.....	5
How will members implement this proposal?.....	5
How will members be evaluated for compliance with this proposal?	5
Policy Language.....	6

Modifications to the Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors

Mini-Brief

Executive Summary

This proposal addresses three distinct issues:

1. During the June 2015 Board of Directors meeting, a Board member expressed concern that the proposed language in *Policy 15.6: Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors* addressing the allocation of HIV positive organs to HIV positive recipients not appearing on the match run did not specifically limit the practice to directed donations. This proposal modifies the policy language to clarify that allocation of HIV positive organs to HIV positive recipients not on the match run can only occur in the event of a directed donation.
2. The HOPE Act states that “not later than 4 years after the date of enactment and annually thereafter, the Secretary shall review the results of scientific research in conjunction with the Organ Procurement and Transplant Network to determine whether the results warrant revision of the standards of quality.” UNOS leadership discussed the OPTN’s role in this review and how to best meet the statutory requirements. These discussions resulted in a recommended modification to the variance to require members participating in a HOPE Act research study to provide periodic reports from their data safety monitoring boards to the OPTN.
3. According to OPTN/UNOS policies, variances are to have defined expiration dates for when the sponsoring Committee will evaluate the impact of the variance. When the Board adopted this variance, it did not contain a defined expiration date. This proposal sets a defined expiration date for the variance.

Modifications to the Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors

Affected Policy: Policy 15.6: Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors

Sponsoring Committee: Organ Procurement Organization Committee

What problem will this proposal solve?

This proposal solves three distinct problems. First, during the June 2015 Board of Directors meeting the Board of Directors approved policy changes to create a variance for the allocation and transplantation of HIV positive organs into HIV positive recipients. However, a Board member expressed concern that the language in *Policy 15.6: Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors* addressing the allocation of HIV positive organs to HIV positive recipients not appearing on the match run did not clearly limit the practice to directed donations. During the development of the policy language, it was the OPO Committee's intent to only allow for an exception in cases where an HIV positive donor or legal next of kin wishes to directly donate organs to an HIV positive candidate, even if the candidate does not appear on the match run due to ABO incompatibility. This proposal modifies policy language to clarify that allocation of HIV positive organs to HIV positive recipients not on the match run can only occur in the event of a directed donation. Additionally, UNOS staff revised the introductory paragraph of Policy 15.6 to remove the parentheses.

Second, the HOPE Act states that "not later than 4 years after the date of enactment and annually thereafter, the Secretary shall review the results of scientific research in conjunction with the Organ Procurement and Transplant Network to determine whether the results warrant revision of the standards of quality." UNOS leadership discussed the OPTN's role in this review and how to best meet the statutory requirements. These discussions resulted in a recommended modification to the variance to require members participating in a HOPE Act research study to provide periodic reports from their data safety monitoring boards to the OPTN.

Third, according to OPTN/UNOS policies, variances are to have defined expiration dates for when the sponsoring Committee will evaluate the impact of the variance. When the Board adopted this variance, it did not contain a defined expiration date. This proposal sets a defined expiration date for the variance.

Why should you support this proposal?

The proposed changes to Policy 15.6 addressing allocation to candidates not appearing on the match run clarify policy language to meet the Committee's original intent that the practice is allowed for directed donation only. There are safeguards in place within the policy that require verification that the donor is HIV positive and the intended candidate is registered at a transplant hospital that meets the requirements for transplanting HIV positive candidates with HIV positive organs. OPTN Bylaws Article XI: *Adoption of Policies* grants the Executive Committee the authority to approve this policy change request. Section 11.1.A states that "some policy proposals do not require public comment," including "proposals that clarify

or correct existing policy rather than changing the intent or adding to the policy.” The OPO Committee approved the language modification during its September 23, 2015 meeting.

The second proposed change to the policy language addresses the OPTN’s requirement under the HOPE Act to review the results of the scientific research “to determine whether the results warrant revision of the standards of quality.” In order to conduct such a review, UNOS leadership believes it is important to work with HOPE Act researchers to monitor the safety of the transplants performed as part of the research studies. *Policy 1.3.D: Reporting Requirements for Variances* states that “members participating in a variance must submit data and status reports to the sponsoring Committee at least annually.” Therefore, this proposal includes a requirement for researchers to submit periodic data safety monitoring board reports to the OPTN. This will allow the OPTN Contractor to identify issues or trends across multiple research studies and proactively address potential problems.

In order to meet the statutory requirements outlined in the HOPE Act, this proposal requires approval under *Bylaw 11.7: Emergency Action* which states “a proposal that is necessitated by a pending statutory or regulatory change” may be adopted by the Board of Directors prior to public comment. The Bylaw also requires that a proposal “designates a future date upon which the policy will expire, not more than 12 months beyond the policy’s effective date.” The proposal will be distributed for public comment after the December 2015 Board meeting, and is expected to be brought to the Board for approval once again during the June 2016 Board meeting. Policy proposals considered during the June Board of Directors meeting typically become effective on September 1 if no programming is required. Therefore, the proposed sunset date for this section of policy is September 1, 2016.

Finally, the third section of this proposal sets an expiration date for the HOPE Act variance. The HOPE Act contains a review period for the HOPE Act.

(c) Revision of Standards and Regulations Generally.--Not later than 4 years after the date of the enactment of the HIV Organ Policy Equity Act, and annually thereafter, the Secretary, shall--

(1) review the results of scientific research in conjunction with the Organ Procurement and Transplantation Network to determine whether the results warrant revision of the standards of quality adopted under section 372(b)(2)(E) with respect to donated organs infected with HIV and with respect to the safety of transplanting an organ with a particular strain of HIV into a recipient with a different strain of HIV

When the underlying HOPE Act proposal was sent to the Board, staff had planned to use this statutory review period as the review period for this variance. For the sake of transparency, this expiration is being applied to the variance in the OPTN/UNOS policies. Four years after the date of the enactment of the HOPE Act would be November 2017. Since the Board is planning to meet in December 2017, it is proposed that the expiration date be after the Board’s meeting. Therefore, this proposal includes an expiration date of January 1, 2018.

How does this proposal support the OPTN Strategic Plan?

1. *Increase the number of transplants:* This specific proposal does not impact this strategic goal but the previously approved proposal supports the goal by allowing HIV positive recipients to utilize kidneys or livers from HIV positive donors, thus increasing the pool of organs available for transplant.
2. *Improve equity in access to transplants:* This proposal will increase access to transplants for HIV positive candidates willing to accept an HIV positive kidney or liver as part of a Hope Act research study.
3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* There is no impact to this goal.

4. *Promote living donor and transplant recipient safety:* This proposal before the Executive Committee will promote transplant recipient safety by allowing the OPTN review IRB data safety monitoring reports to identify issues or trends across multiple research studies.
5. *Promote the efficient management of the OPTN:* There is no impact to this goal.

How will the OPTN implement this proposal?

Programming requirements include updates to the membership database to identify those transplant centers with institutional review board approval to participate in a research study and changes in UNetSM to address donor and candidate screening. Standard match runs for kidneys and livers from HIV positive donors will be used with screening of candidates based on HIV positive status and willingness to accept an HIV positive organ. The OPTN has a statutory requirement to review the results of Hope Act research studies. The OPTN will review data that it currently collects and the long term plan is to review published literature. Additionally, this current proposal will allow the OPTN to review patient safety data in order to identify national trends.

Staff will prepare a public comment proposal related to the substantive changes in this proposal. The Board will be asked to review and approve those at a future Board meeting.

How will members implement this proposal?

OPOs may allocate organs to candidates not appearing on the match run only after they determine that the potential deceased donor is HIV positive and the HIV positive candidate is willing to accept an HIV positive organ as part of a research protocol.

Transplant hospitals participating in a HOPE Act IRB approved research study must provide a schedule of deadlines for data safety monitoring reports and provide reports according to the schedule.

Will this proposal require members to submit additional data?

Members will be required to submit IRB data safety monitoring reports to the OPTN. Additionally, there are data being requested as part of the NIH research criteria that will require communication between the OPO and transplant hospitals to evaluate donors and donor organs.

How will members be evaluated for compliance with this proposal?

Before a transplant hospital can have HIV positive organs allocated to their candidates, the hospital will have to submit a request for an open variance that will include: 1. A plan for submitting the IRB data safety monitoring board reports to the OPTN contractor. 2. A copy of the IRB approval letter.

Policy Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~)

RESOLVED, that modifications to Policy 15.6 (Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors) and 15.6.A (Requirements for Allocating HIV Positive Deceased Donor Organs), as set forth below, are hereby approved, effective November 21, 2015.

FURTHER RESOLVED, that modifications to lines 12-17 in Policy 15.6 (Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors), as set below, are hereby approved, will expire September 1, 2016.

FURTHER RESOLVED, Policies 15.6 (Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors) through 15.6.C (Transplant Hospital Requirements for Transplantation of HIV Positive Organs), will expire on January 1, 2018.

15.6 Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors

This variance applies to members participating in an institutional review board (IRB) approved research protocol that meets the requirements in the OPTN Final Rule regarding the recovery of organs from donors that test positive for human immunodeficiency virus (HIV) and the transplantation of these organs into HIV positive recipients, (including Health and Human Services (HHS) research criteria pertaining to the transplantation of organs from HIV positive donors, as applicable.) ~~regarding the recovery of organs from donors that test positive for human immunodeficiency virus (HIV) and the transplantation of these organs into HIV positive recipients.~~

Transplant hospitals participating in this variance must submit *all* of the following to the OPTN Contractor:

1. A detailed schedule of required deadlines for IRB data safety monitoring reports that addresses the requirements in the HHS research criteria.
2. IRB data safety monitoring reports at each deadline in the schedule.

15.6.A Requirements for Allocating HIV Positive Deceased Donor Organs

In addition to the requirements of the OPTN Final Rule, the OPO may allocate HIV positive organs only after determining the potential deceased donor is HIV positive and the HIV positive candidate is willing to accept an HIV positive organ as part of a research protocol. The OPO must only allocate HIV positive organs to HIV positive candidates appearing on the match run, except in cases of directed donation. ~~In the case of a directed donation and prior to transplant, the~~ The OPO must verify that the potential recipient is registered as an HIV positive candidate at a transplant hospital that meets the requirements in *Policy 15.6.C Transplant Hospital Requirements for Transplantation of HIV Positive Organs*.

15.6.B Requirements for Allocating HIV Positive Living Donor Organs

In addition to the requirements of the OPTN Final Rule, the recovery hospital must confirm that the potential living donor is HIV positive and the potential recipient is willing to accept an HIV positive organ as part of a research protocol.

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15.6.C Transplant Hospital Requirements for Transplantation of HIV Positive Organs

In addition to the requirements of the OPTN Final Rule, transplant hospitals may transplant HIV positive organs only if *all* of the following conditions are true:

1. The transplant hospital notifies and provides documentation to the OPTN Contractor that it is participating in an institutional review board approved research protocol that meets the requirements in the OPTN Final Rule regarding the recovery and transplantation of organs from HIV positive individuals.
2. The transplant hospital obtains informed consent from the potential transplant recipient to participate in the institutional review board protocol that meets requirements in the OPTN Final Rule.
3. The transplant hospital meets the informed consent requirements according to *Policy 15.3 Informed Consent of Transmissible Disease Risk*.

In order for an HIV positive candidate to appear on a match run for HIV positive donor kidneys or livers, the transplant hospital must complete a two-person reporting and verification process. This process must include two different individuals who each make an independent report to the OPTN Contractor that the candidate is willing to accept an HIV positive organ as part of a research protocol.

Transplant hospitals must notify the OPTN Contractor if it is no longer participating in an IRB approved research protocol that meets the requirements in the OPTN Final Rule regarding the recovery and transplantation of organs from HIV positive individuals.

The OPTN Contractor may release to the public the names of members participating in this variance.

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