At-a-Glance

Proposal to Address the Requirements Outlined in the HIV Organ Policy Equity Act

- **Affected Policies:** Policy 2.7 (HIV Screening of Potential Deceased Donors), Policy 15 (Identification of Transmissible Diseases), and Policy 16.7.B (Vessel Storage)

- **Organ Procurement Organization Committee**

  Current federal rules and OPTN policy prohibit the recovery and transplantation of organs from deceased donors infected with the human immunodeficiency virus (HIV). The HIV Organ Policy Equity Act, enacted on November 21, 2013, will allow for the development and publication of criteria for the conduct of research relating to transplantation of organs from donors infected with HIV into individuals who are infected with HIV before receiving such organ. The goal of this proposal is to concurrently amend OPTN policies to allow members to participate in the research study in accordance with upcoming changes to the Final Rule and criteria developed by the Secretary of Health and Human Services (HHS).

- **Affected Groups**
  Directors of Organ Procurement
  Lab Directors/Supervisors
  OPO Executive Directors
  OPO Medical Directors
  OPO Coordinators
  Transplant Administrators
  Transplant Data Coordinators
  Transplant Physicians/Surgeons
  PR/Public Education Staff
  Transplant Program Directors
  Transplant Social Workers
  Organ Recipients
  Organ Candidates
  Living Donors
  Donor Family Members
  General Public

- **Number of Potential Candidates Affected**
  Over the past several years there has been a steady increase in the number of transplants performed each year for reported HIV positive recipients, from 15 in 2001 to 137 in 2013. There are likely many more patients awaiting transplants. Boyarsky et al determined that annually there are as many as 500-600 potential HIV positive deceased donors that could result in several hundred additional kidney and liver transplants each year[1].

- **Compliance with OPTN Strategic Plan and Final Rule**
  This proposal supports the OPTN's Strategic Plan by increasing the number of transplants and increasing access to transplants. This proposal will also address future changes to the Final Rule that will allow for the development and publication of criteria for the conduct of research relating to transplantation of organs from donors infected with HIV into individuals who are infected with HIV before receiving such organs.

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Organ Procurement Organization Committee

Public comment response period: September 29, 2014 – December 5, 2014

Summary and Goals of the Proposal:

Current federal rules and OPTN policy prohibit the recovery and transplantation of organs from deceased donors infected with the human immunodeficiency virus (HIV). The HIV Organ Policy Equity Act, enacted on November 21, 2013, will allow for the development and publication of criteria for the conduct of research relating to transplantation of organs from donors infected with HIV into individuals who are infected with HIV before receiving such organ. The goal of this proposal is to concurrently amend OPTN policies to allow members to participate in the research study in accordance with upcoming changes to the Final Rule and criteria developed by the Secretary of Health and Human Services (HHS).

Background and Significance of the Proposal:

The HIV Organ Policy Equity Act outlines future changes to the Final Rule and contains a schedule of deliverable deadlines. The initial requirements are:

- By November 21, 2015, the Secretary of HHS must develop and publish criteria for the conduct of research relating to transplantation of organs from donors infected with HIV into individuals who are infected with HIV before receiving such organ.
- By November 21, 2015, the Secretary of HHS must revise the section of the OPTN Final Rule (42 CFR 121.6) that presently requires the OPTN to adopt and use standards to prevent the recovery of HIV-infected organs.
- By November 21, 2015, to the extent determined by the Secretary to be necessary to allow the conduct of research, the OPTN shall revise standards of quality (i.e. policies) for acquisition and transportation of donated organs infected with HIV in accordance with the criteria developed by the Secretary as described above. This must begin concurrently with the Secretary's development of criteria for research in order to meet the two year deadline.

By November 21, 2017, and each year thereafter the Secretary of HHS will**:**

- Review the results of scientific research in conjunction with the OPTN to determine whether the results warrant revision of the standards;
- Determine if participation in clinical research, as a requirement for such transplants, is no longer warranted;
- Review the results of scientific research in conjunction with the OPTN to determine whether the results warrant revision of the standards of quality 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;

[1] Boyarsky, B. J., Hall, E. C., Singer, A. L., Montgomery, R. A., Gebo, K. A. and Segev, D. L. (2011), Estimating the Potential Pool of HIV-Infected Deceased Organ Donors in the United States. American Journal of Transplantation, 11: 1209–1217. doi: 10.1111/j.1600-6143.2011.03506.x

- Determine necessary conduct of research in accordance with the criteria developed;
- Determine if results warrant revision of the standards of quality; and
- Direct the OPTN to revise such OPTN standards in a way that ensures the changes will not reduce the safety of organ transplantation.

OPOs will remain responsible for "arranging for testing with respect to identifying organs that are infected with human immunodeficiency virus (HIV)" Per 42 USC 273(b)(3)(C)

Formation of a joint work group

The OPTN formed a joint work group with representation from the Organ Procurement Organization (OPO) Committee, Operations and Safety Committee, Ad Hoc Disease Transmission Advisory Committee (DTAC), SRTR, and HRSA. The initial conference call was held on January 31, 2014, during which four subgroups were formed to address policy, patient safety, allocation, and labeling/transport. Each of these subgroups were assigned policies to determine if changes are required to address the use of HIV infected organs as well as identifying other issues that could be impacted by the new law.

The four subgroups met individually by conference call and provided initial recommendations to the full work group on April 2, 2014. The subgroups identified the key policies that need to be modified in order to allow for the recovery and transplantation of HIV-infected organs. The work group also determined that the current prohibition on the storage of hepatitis C antibody positive and hepatitis B surface antigen positive (HBsAg) extra vessels should be extended to HIV-infected extra vessels. During the review of the policies, several minor language issues were identified such as numerous references to serology results and the use of informed authorization instead of consent. These will be addressed during a future proposal or other means outside the scope of this project.

The work group discussed the operational issues that will need to be addressed once more information about the research protocols becomes available from the National Institutes of Health (NIH), the organization that is developing the criteria for the research study. Overall, the work group agreed that current testing for infectious diseases provides the appropriate safeguards to prevent disease transmission. However, unlike current practice, organs known to be infected with HIV will now be allocated and appropriate safeguards need to be in place to ensure that HIV-infected organs get allocated only to those HIV-positive candidates willing to accept the organ.

Future proposal

The work group will continue to evaluate policy and operational issues in preparation for the next public comment period in January 2015. The next proposal will address informed consent, living donation issues, patient safety, and other issues identified by the work group.

Supporting Evidence and/or Modeling:

The OPTN does not currently collect the HIV status of candidates on the waiting list. For this reason, the exact number of potential candidates that could benefit from this policy change is unknown. However, over the past several years there has been a steady increase in the number of transplants performed each year for reported HIV positive recipients, from 15 in 2001 to 137 in 2013. There are likely many more patients awaiting transplants. Boyarsky et al maintain that

annually there are as many as 500-600 potential HIV positive deceased donors that could result in several hundred additional kidney and liver transplants each year[1].

Expected Impact on Living Donors or Living Donation:

It is anticipated that living donors will be included in the research protocols being developed by the NIH. However, before removing HIV from the exclusion criteria listed in Table 14-2 (Requirements for Living Kidney Donor Medical Evaluations) the group will seek input from the Living Donor Committee and the transplant community.

Expected Impact on Specific Patient Populations:

This proposal will lead to the increased availability of organs for candidates with HIV. Boyarsky et al maintain that annually there are as many as 500-600 potential HIV positive deceased donors that could result in several hundred additional kidney and liver transplants each year[2].

Expected Impact on OPTN Strategic Plan, and Adherence to OPTN Final Rule:

This proposal supports the OPTN's Strategic Plan by increasing the number of transplants and increasing access to transplants. This proposal will also address future changes to the Final Rule that will allow for the development and publication of criteria for the conduct of research relating to transplantation of organs from donors infected with HIV into individuals who are infected with HIV before receiving such organs.

Plan for Evaluating the Proposal:

This proposal is the first step to amend OPTN policies to allow members to participate in the research study in accordance with upcoming changes to the Final Rule and criteria developed by the Secretary of Health and Human Services (HHS). According to the HIV Organ Policy Equity Act, the Secretary of HHS will work in conjunction with the OPTN to review the results of scientific research by November 21, 2017.

Six months after the first HIV positive donor transplant is performed as part of the research study the committee will request the following information:

- The number of HIV positive donor transplants performed by organ type
- The number of transplant programs approved, and the number performing these transplants
- The number of OPOs with at least one HIV positive deceased donor recovered
- The number of candidates indicated as willing to accept an organ from an HIV positive donor
- The number of unintended HIV donor transmissions.

These data will be updated twice a year for at least three years after the first transplant is performed. Once enough HIV positive donor transplants have been performed, Kaplan-Meier

[1] Boyarsky, B. J., Hall, E. C., Singer, A. L., Montgomery, R. A., Gebo, K. A. and Segev, D. L. (2011), Estimating the Potential Pool of HIV-Infected Deceased Organ Donors in the United States. American Journal of Transplantation, 11: 1209–1217. doi: 10.1111/j.1600-6143.2011.03506.x

patient and graft survival rates at 6 months and one year post-transplant will be included along with the other data points.

Additional evaluation planning will be required as more information is known about the research protocols.

Additional Data Collection:

At this time it is unknown what additional data elements will be required for participation in the research study. When these become available these will be addressed in a future proposal.

Expected Implementation Plan:

If public comment on this proposal is favorable, this proposal will be submitted to the OPTN Board of Directors in June 2015. If passed, the proposal would go into effect concurrent with the implementation of the HOPE Act (November, 2015).

This proposal is only one step in changing policy to allow for the recovery and transplantation of HIV-infected organs. Once HHS publishes the research protocols required by the HOPE Act, the OPTN workgroup will discuss whether additional policy modifications are necessary. Those changes will be released for public comment in 2015.

Communication and Education Plan:

The proposal would apply to hospitals performing HIV positive transplants and OPOs that would recover HIV positive organs. Communication and education efforts would thus focus on the specific details of the policy modifications and support members may need to revise their processes.

Information about the policy modifications would be included in an effort to provide communication and instruction to members, with emphasis on impacted practices at transplant programs and OPOs.

In addition, notification of the policy modifications would be included in the following routine communication vehicles:

- Policy notice
- System notice
- Member e-newsletter/member communicaitons
- Communication to appropriate listservs

Compliance Monitoring:

The following changes may apply to existing routine monitoring of OPTN members:

Policy 2.7 *HIV Screening of Potential Deceased Donors*
At OPOs, site surveyors will review a sample of deceased donor records for the following documentation:

- The results of all HIV testing performed on the donor

Policy 16.7.B *Vessel Storage*
At transplant hospitals, site surveyors will review the transplant hospital's internal policies, procedures, and/or protocols and/or interview key clinical personnel to verify that they address:

- That HIV+, HCV+ and HbSAg+ vessels are not stored for later use

The following new routine monitoring may apply to OPTN members:

Policy 15.3 *Recovery and Transplantation of HIV-infected Organs*
At transplant hospitals, site surveyors will:

Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that:

- The recipient of any organ from a donor infected with HIV was known to be infected with HIV prior to transplant

OPTN staff will continue to review all deceased donor match runs resulting in a transplanted organ to ensure that allocation was carried out according to OPTN policy. Staff will request evidence of participation in an institutional review board-approved research protocol for recovering organs from donors known to be infected with HIV from any transplant program that has transplanted an organ from a donor known to be infected with HIV.

Policy or Bylaw Proposal:

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

2.7 HIV Screening of Potential Deceased Donors

~~Members may not participate in the recovery or transplantation of organs from deceased donors known to be infected with HIV. Members may only recover organs if the laboratory data, medical history, and behavioral history indicate that the donor is not HIV infected.~~

The host OPO must accurately document HIV test results for every deceased donor. All deceased donors must be tested for HIV according to *Policy 2.9: Required Deceased Donor Infectious Disease Testing*.

The host OPO must report the results of all HIV tests it performs directly to all receiving OPOs and transplant programs.

Policy 15: ~~Identification of~~ Transmissible Diseases

15.3 Recovery and Transplantation of HIV-infected Organs

Members may recover and transplant organs known to be infected with human immunodeficiency virus (HIV) only if *all* of the following are true:

- The potential recipient is known to be HIV-infected before receiving the organ

- The transplant hospital is participating in an institutional review board approved research protocol that meets the requirements in the Final Rule, 42 CFR 121 *et seq*., regarding the recovery of organs from individuals known to be infected with HIV.

~~15.3~~15.4 Informed Consent of Transmissible Disease Risk

Subsequent headings affected by the re-numbering of this policy will also be changed as necessary.

16.7.B Vessel Storage

Transplant hospitals may not store for later use any HIV positive, hepatitis C antibody positive (HCV) or hepatitis B surface antigen positive (HBsAg) extra vessels. If the transplant hospital stores vessels and later uses the vessels for the intended recipient or another recipient, it must notify the OPTN Contractor.

The Transplant hospital must designate a person to do *all* of the following:

1. Monitor and maintain all records relating to the use and management of vessels
2. Monitor the refrigerator where the vessels are stored
3. Destroy expired vessels
4. Notify the OPTN

Additionally, the transplant hospitals must do *all* of the following:

1. Store vessels in a Food and Drug Administration (FDA) approved preservation solution
2. Package and label vessels as required by *Policy 16.4: Packaging and Labeling*
3. Store vessels in a secured refrigerator with a temperature monitor and maintain the temperature no colder than 2 degrees Celsius and no warmer than 8 degrees Celsius
4. Monitor vessels daily with documented security and temperature checks
5. Destroy unused vessels within 14 days after the recovery date
6. Maintain a log of stored vessels
7. Have accessible at all times the vessel deceased donor information for the transplant surgeon prior to using the vessels in any recipient other than the originally intended recipient