

POLICY NOTICE

Modify HOPE Act Variance to Include Other Organs

Sponsoring Committee:	Ad Hoc Disease Transmission Advisory Committee (DTAC)
Policies Affected:	<i>5.3.B: Infectious Disease Screening Criteria</i> <i>5.4.E: Allocation to Candidates Not on the Match Run</i> <i>5.5.C: OPO Requirements for Positive HIV Results</i> <i>15.7.C: Transplant Hospital Requirements for Transplantation of HIV-Positive Organs</i> <i>16.6.A Extra Vessels Use and Sharing</i>
Public Comment:	January 22, 2019 – March 22, 2019
Board Approved:	June 10, 2019
Board Amended:	June 7, 2020
Effective:	Pending programming and notice to OPTN Members (Implemented May 21, 2020)

Note: The OPTN Executive Committee approved a technical correction at its meeting in June 2020. This correction is noted by a corresponding footnote. For more information regarding this technical correction, please contact member.questions@unos.org.

Problem Statement

The HIV Organ Policy Equity Act was enacted on November 21, 2013, permitting use of organs from HIV-positive donors for transplantation into HIV-positive candidates under approved research protocols designed to evaluate the feasibility, effectiveness, and safety of such organ transplants. The OPTN variance to accommodate this legislation, implemented in 2015, limited HIV-positive donors for transplantation into HIV-positive candidates to liver and kidney recipients. This updated variance will allow all additional organs to be transplanted from HIV-positive donors into HIV-positive candidates, while still ensuring patient safety by adherence to policy requirements and federal research criteria. It is intended to increase the number of transplants with broader use of HIV-positive donor organs.

Summary of Changes

This proposal changes policy language to include additional organs in the infectious disease screening and verification process for donors that are HIV-positive and also clarifies language regarding use and storage prohibition of HIV-positive extra vessels.

What Members Need to Do

Transplant Programs

Transplant hospitals must continue to meet required experience, participate in a research study, develop organ-specific protocol for HOPE Act transplants, and submit data to the OPTN.

OPOs

Organ Procurement Organizations must train staff to expand pool of organs evaluated and recovered.

Affected Policy Language

New language is underlined (example) and language that is deleted is struck through (~~example~~).

5.3 Additional Acceptance and Screening Criteria

5.3.B Infectious Disease Screening Criteria

A transplant hospital may specify whether a candidate is willing to accept an organ from a donor known to have certain infectious diseases, according to *Table 5-1* below:

Table 5-1: Donor Infectious Disease Screening Options

If the donor tests positive for:	Then candidates may choose not to receive offers on the following match runs:
Cytomegalovirus (CMV)	Intestine
Hepatitis B core antibody (HBcAb)	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas
Hepatitis B Nucleic Acid Test (NAT)	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas
Hepatitis C (HCV) Antibody	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas
Hepatitis C Nucleic Acid Test (NAT)	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas
Human Immunodeficiency Virus (HIV); Organs from HIV-positive donors may only be recovered and transplanted according to the requirements in the Final Rule.	<u>Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas</u> Kidney, Liver; Use of HIV-positive donor organs is only permissible for kidney and liver transplantation at this time.

5.4.E Allocation to Candidates Not on the Match Run

When a candidate does not appear on at least one of the deceased donor's match runs for at least one organ type, the transplant hospital must document the reason the candidate does not appear and ensure that the organ is safe and appropriate for the candidate. Acceptable reasons for allocation to the candidate may include, but are not limited to, directed donations or to prevent organ waste.

In such an event, the transplant hospital must document *all* of the following:

1. The reason for transplanting an organ into a candidate who did not appear on the match run
2. The reason the candidate did not appear on the match run
3. Whether the transplant hospital is willing to accept a kidney from a deceased donor with a KDPI score greater than 85% or from a donation after circulatory death (DCD) donor, if applicable

4. Prior to transplant, the transplant hospital must verify the medical suitability between the deceased donor organ and recipient in at least, but not limited to, *all* the following areas according to organ type:
 - Blood type
 - Blood subtype, when used for allocation
 - Donor HLA and candidate's unacceptable antigens
 - Donor height
 - Donor weight
 - Infectious disease test results
 - For HIV-positive deceased donors ~~kidneys and livers~~, the OPO and transplant hospital must also do *both* of the following:
 - a. Verify that the potential recipient is registered as a HIV-positive candidate at a transplant hospital that meets the requirements in *Policy 15.7.C Transplant Hospital Requirements for Transplantation of HIV-positive Organs*
 - b. Meet the requirements in *Policy 15.7: Open Variance for the Recovery and Transplantation of Organs from HIV-positive Donors*

The transplant hospital must maintain all related documentation.

5.5.C OPO Requirements for Positive HIV Results

If a donor is found to be positive for HIV after any match run has been executed, the host OPO must report the updated information to the OPTN Contractor and do *all* of the following for each organ being allocated:

1. Stop allocation on the original match run for this donor
2. Re-execute ~~the kidney and liver~~¹ match runs in order to include *only* HIV-positive candidates participating in an institutional review board approved research protocol that meets the requirements in the Final Rule regarding the recovery of organs from individuals known to be infected with HIV according to *Policy 15.7.A: Requirements for Allocating HIV-positive Deceased Donor Organs*
3. Withdraw any pending offers to candidates who are not HIV-positive *and* also participating in an institutional review board approved research protocol that meets the requirements in the OPTN Final Rule according to *Policy 15.7.C: Transplant Hospital Requirements for Transplantation of HIV-positive Organs*
4. Continue allocating organs using the re-executed match run. Only recover and send extra vessels from this donor with an organ allocated from this donor.

~~Allocate *only* kidneys and livers from HIV-positive donors. Extra vessels from these donors must only be allocated with the kidneys or liver and must only be used for transplantation of these organs. Members must not share or store extra vessels from HIV-positive donors.~~

¹ On June 7, 2020, the OPTN Executive Committee approved a technical correction to Policy 5.5.C. This policy correction removed the language "the kidney and liver" requiring OPOs to re-execute the match run in order for HIV-positive candidates to receive organ offers, other than kidneys and livers, consistent with the type of HOPE Act approved transplant program at which they are listed. This language was omitted instead of using strikethrough in original proposal.

15.7.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 an organ from a 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.

16.6 Extra Vessels Transplant and Storage

16.6.A Extra Vessels Use and Sharing

Extra vessels must only be used for organ transplantation or modification of an organ transplant.

Transplant hospitals may share deceased donor extra vessels with other transplant hospitals, unless storage is prohibited by *Policy 16.6.B: Extra Vessels Storage*. Extra vessels from a living donor must only be used for transplant or modification of an organ transplant for the original intended recipient and must not be shared. Extra vessels from a HIV-positive donor must only be used for transplant for the original intended recipient.