

## *Notice of OPTN Variance Extension*

# **Extend HIV Organ Policy Equity (HOPE) Act Variance**

<b>Sponsoring Committee:</b>	<b>Ad Hoc Disease Transmission Advisory</b>
<b>Policies Affected:</b>	<b><i>15.7: Open Variance for the Recovery and Transplantation of Organs from HIV-positive Donors</i></b>
<b>Public Comment Periods:</b>	<b>September 29 – December 5, 2014 January 27- March 27, 2015 January 22- March 22, 2019</b>
<b>Variance Approval Dates:</b>	<b>June 2, 2015 June 6, 2016 December 4, 2017 June 10, 2019</b>
<b>Extension Approval Date:</b>	<b>December 6, 2021</b>
<b>Expiration Date:</b>	<b>January 15, 2026</b>

### **Purpose of Change**

The variance extension allows HIV positive donor organs to continue to be allocated to HIV positive patients, supporting utilization of HIV positive organs and access to transplant for HIV positive candidates. After five years of HOPE Act transplants, over 300 HIV positive candidates have received organ transplants under the OPTN HOPE Act policy variance.<sup>1</sup> There are currently 36 participating hospitals in the research variance, and between them there are 35 approved programs for deceased donor kidney, 26 programs for deceased donor liver, five programs for living donor kidney, four programs for living donor liver, and one program for heart transplantation.

### **Variance History**

Since 2013, the OPTN Board has approved the initial HOPE Act research variance, an expansion of the HOPE Act research variance from kidney and liver to all other organs, and two extensions of the variance expiration. The initial variance, as well as the substantive change to the variance expanding the variance to all organs, were adopted following periods of overwhelmingly supportive public comment.

### **Summary of Changes**

This proposal does not change the OPTN variance or policy related to the HOPE Act but extends the existing variance to apply until January 15, 2026.

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<sup>1</sup>Amber Wilk, *One Year Evaluation of the Modification of OPTN HOPE Act Variance to Include Other Organs*, Report to the OPTN Ad Hoc Disease Transmission Advisory Committee. July 28, 2021.

## Implementation

### Operations affecting Transplant Hospitals

This proposal does not change any of the previously approved variance requirements for transplant hospitals participating in a HOPE Act IRB approved research study to provide the OPTN with a schedule of deadlines for data safety monitoring reports and provide reports to the OPTN according to the schedule.

Transplant hospitals will continue to apply and submit reports to participate in the variance as they have done in the past. This proposal does not impact the previous compliance requirements for members. Before a transplant hospital can have HIV positive organs allocated to their candidates, the hospital must submit a request for an open variance that includes required documents such as the detailed schedule of required deadlines for IRB data safety monitoring board reports and a copy of the IRB approval letter. The process and requirements for being approved to perform transplants as allowed under the HOPE act and OPTN policy have not changed.

### Affected Variance Language

#### ***15.7 Open Variance for the Recovery and Transplantation of Organs from HIV-positive Donors***

*This variance applies to transplant hospitals 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 transplantation of organs from HIV-positive donors, as applicable.*

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

- 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.*

#### **15.7.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. The OPO must 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.*

### **15.7.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.*

### **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 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, 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 that the candidate is willing to accept an HIV-positive organ as part of a research protocol.*

*Transplant hospitals must notify the OPTN 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 may release to the public the names of transplant hospitals participating in this variance.*