

***Notice of OPTN Policy Change***

# **Change Expiration Date of HOPE Act Variance**

<b>Sponsoring Committee:</b>	<b>Ad Hoc Disease Transmission Advisory Committee</b>
<b>Policy Affected:</b>	<b><i>15.7: Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors</i></b>
<b>Board Approved:</b>	<b>December 3, 2019</b>
<b>Effective Date:</b>	<b>December 3, 2019</b>

## **Purpose of Policy Change**

The federal HIV Organ Policy Equity Act (HOPE Act),<sup>1</sup> enacted on November 21, 2013, authorized the OPTN to create a new variance that allows HIV-positive organs to be placed with HIV-positive recipients. The current variance expires on January 1, 2020. The purpose of this policy action is to extend the expiration date.

## **History**

The federal HIV Organ Policy Equity Act (HOPE Act), enacted on November 21, 2013, allows research to be conducted on the transplantation of organs suspected to be HIV-positive through testing collected by the OPTN for allocation purposes into individuals who are infected with HIV before receiving such organ. When the OPTN Board originally approved the HOPE Act variance in June 2015, there was not a defined expiration date. Subsequently, the Executive Committee adopted an expiration date of January 1, 2018, followed by an extension to January 1, 2020.

The transplant community widely supports extending the variance to continue transplantation of organs by programs that meet experience criteria and are approved by the OPTN to participate in the variance. The research results from HOPE Act transplants continue to be actively monitored and evaluated by the National Institute of Health, as described in the accompanying mini-brief.

## **Summary of Changes**

At their meeting on December 3, 2019, the OPTN Board of Directors voted to extend this variance to January 1, 2022, to allow continuation of safe and effective use of HIV-positive organs in HIV-positive recipients for approved programs. Additionally, the Board approved a small clerical change clarifying that participants in the variance are transplant hospitals, not individual patients.

## **Implementation**

There is no member action needed to implement this variance renewal. Program criteria and monitoring will remain unchanged.

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<sup>1</sup> [HIV Organ Policy Equity Act, PL 113-51 \(11/21/2013\)](#).

## Affected Policy Language

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

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

This variance applies to ~~members~~ 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 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.

#### 15.7.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 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~~ transplant hospitals participating in this variance.

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**Mini-Brief**

# **Change Expiration Date of HOPE Act Variance**

*OPTN Ad Hoc Disease Transmission Advisory Committee*

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## **Contents**

Executive Summary	1
Problem the Proposal Will Address	2
Proposed Solution	3
Policy Language	4

# Change Expiration Date of HOPE Act Variance

*Affected Policies:* Policy 15.7: Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors  
*Sponsoring Committee:* Ad Hoc Disease Transmission Advisory Committee  
*Executive Committee Date:* December 2, 2019

## Executive Summary

The federal HIV Organ Policy Equity Act (HOPE Act), enacted on November 21, 2013, allows research to be conducted on the transplantation of organs from donors suspected to be HIV positive through testing collected by the OPTN for allocation purposes into individuals who are infected with HIV before receiving such organ.<sup>1</sup> The legislation required the OPTN to revise its policies “not later than 2 years after the enactment” to allow this research to begin. This statutory requirement was met with OPTN policies being approved in June 2015 and programming implemented in November 2015.

The HOPE Act also 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.” The variance was most recently renewed to extend from January 1, 2018 - January 1, 2020 by the OPTN Executive Committee.<sup>2</sup> The results of the ongoing research continue to be monitored and evaluated but conclusions regarding revisions to the standards of quality have not been reached. The Ad Hoc Disease Transmission Advisory Committee (DTAC) recommends the upcoming January 1, 2020 expiration date for the variance be extended to January 1, 2022.

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<sup>1</sup> HIV Organ Policy Equity Act, PL 113-51 (11/21/2013).

<sup>2</sup> OPTN Board of Directors Meeting, December 4-5, 2017.

## Problem the Proposal Will Address

The federal HIV Organ Policy Equity Act (HOPE Act), enacted on November 21, 2013, allows research to be conducted on the transplantation of organs suspected to be HIV positive through testing collected by the OPTN for allocation purposes into individuals who are infected with HIV before receiving such organ. 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. When the Board originally approved the HOPE Act variance in June 2015 there was not a defined expiration date. Subsequently, the Executive Committee adopted an expiration date of January 1, 2018, followed by another extension until January 1, 2020.

The number of transplants performed as part of the research variance remains low, but continues to grow, particularly in the most recent year. The HOPE Act legislation does not limit HIV positive donor transplants to only kidney and liver. The initial research and policy focus was on these organs because of the substantial experience with transplantation of HIV negative kidneys and livers into HIV positive recipients. The OPTN Board of Directors approved an expansion to the variance in June 2019 to allow additional organs, besides kidney and liver, to be included in this variance. Figure 1 shows the number of transplants performed since the first transplant was performed in March 2016.

**Figure 1: HOPE Act Transplants**

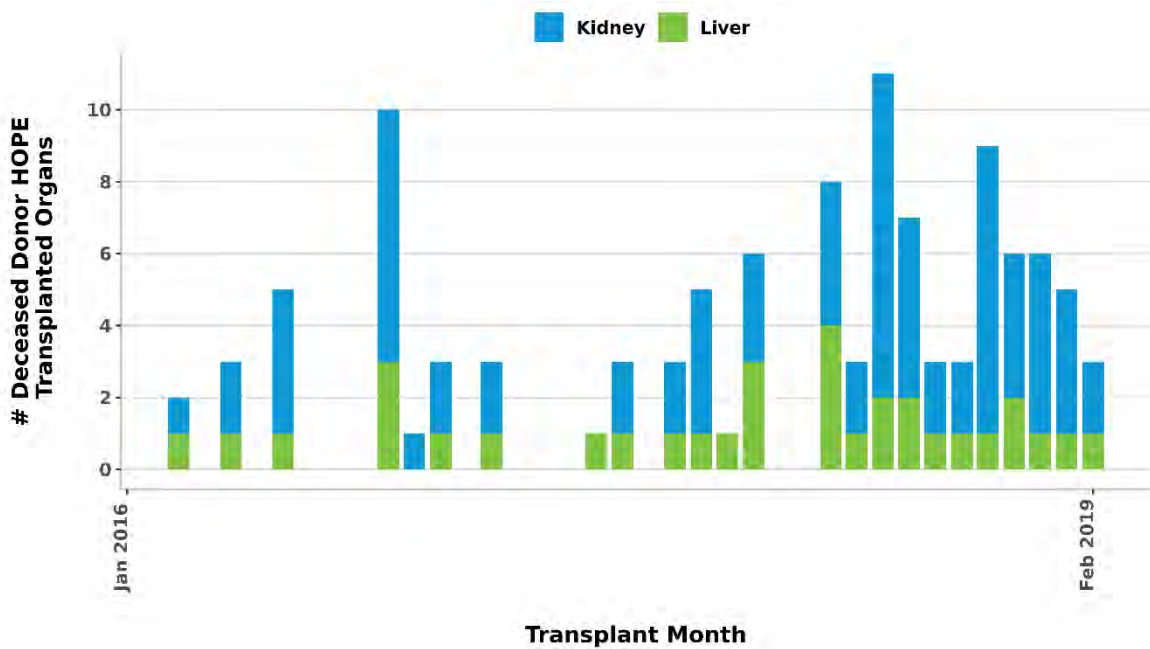
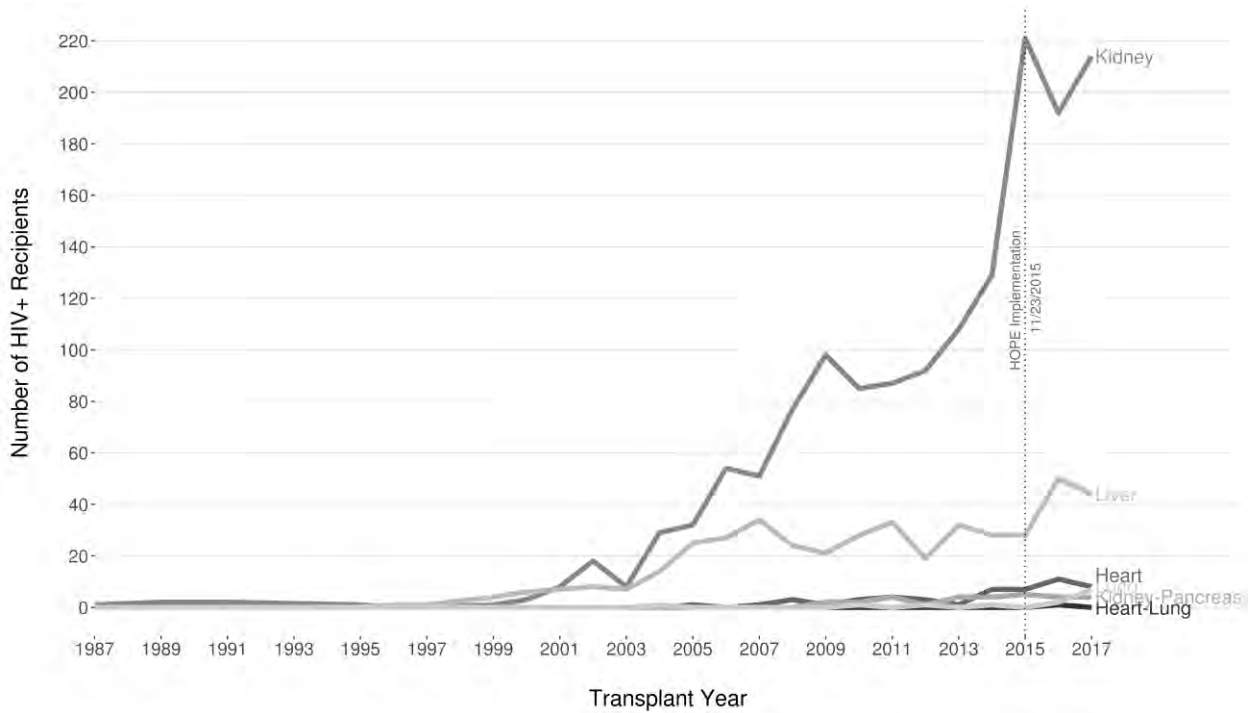


Figure 2: HOPE Act Transplants



## Proposed Solution

The goal of HOPE Act research is to study the feasibility and safety of performing transplants from donors suspected to be HIV positive through testing collected by the OPTN for allocation purposes into HIV positive candidates. Based on the initial experience with kidney and liver transplantation, the transplant community supports expanding the variance to include transplantation of other organs by programs that meet National Institutes of Health (NIH) experience criteria. The results of the research continue to be actively monitored and evaluated. The DTAC recommended that the variance should be extended. The current expiration date is set for January 1, 2020. During its October 21, 2019 meeting, the DTAC unanimously voted to extend the expiration date to January 1, 2022.

Additionally, the policy language in *Policy 15.7: Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors*, includes clarification that the variance specifically refers to transplant hospitals and not all members.

## Policy Language

1 **RESOLVED**, that the changes in Policy 15.7: Open Variance for the Recovery and Transplantation of  
2 **Organs from HIV Positive Donors**, as set forth below, are approved, effective December 4, 2019.

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4 **FURTHER RESOLVED**, the expiration date for Policy 15.7: Open Variance for the Recovery and  
5 **Transplantation of Organs from HIV Positive Donors**, scheduled for January 1, 2020, is extended to  
6 **January 1, 2022**.

### 7 8 **15.7 Open Variance for the Recovery and Transplantation of Organs** 9 **from HIV Positive Donors**

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

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

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

#### 22 23 **15.7.A Requirements for Allocating HIV Positive Deceased Donor Organs**

24 In addition to the requirements of the OPTN Final Rule, the OPO may allocate HIV positive  
25 organs only after determining the potential deceased donor is HIV positive and the HIV positive  
26 candidate is willing to accept an HIV positive organ as part of a research protocol. The OPO must  
27 only allocate HIV positive organs to HIV positive candidates appearing on the match run, except  
28 in cases of directed donation. The OPO must verify that the potential recipient is registered as a  
29 HIV positive candidate at a transplant hospital that meets the requirements in *Policy 15.7.C:*  
30 *Transplant Hospital Requirements for Transplantation of HIV Positive Organs*.

#### 31 32 **15.7.B Requirements for Allocating HIV Positive Living Donor Organs**

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

#### 36 37 **15.7.C Transplant Hospital Requirements for Transplantation of HIV Positive Organs**

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39 positive organs only if *all* of the following conditions are true:

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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*.

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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~~ transplant hospitals participating in this variance.

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