

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

**Sponsoring Committee:** Ad Hoc Disease Transmission Advisory Committee

**Policy/Bylaws Affected:** Policy 15.6 (Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors)

**Public Comment:** January 25, 2016 – March 25, 2016

**Effective Date:** September 1, 2016

## **Problem Statement**

This proposal solves two distinct problems:

1. Non-specific data submission requirements for the HOPE Act Variance  
*Policy 1.3.D: Reporting Requirements for Variances* states, “members participating in a variance must submit data and status reports to the sponsoring Committee at least annually.” The HOPE Act variance in Policy 15.6, however, does not explicitly state what data must be submitted.
2. Absence of an expiration date for the HOPE Act Variance  
*Policy 1.3.B: Application for a Variance* states that variances must have “a defined expiration date or period of time when the variance will end.” The OPTN Final Rule also states that variances “shall be time limited.” When the Board adopted the HOPE Act variance, it did not contain a defined expiration date.

## **Summary of Changes**

This proposal adds a requirement for transplant hospitals participating in HOPE Act research to provide a detailed schedule of institutional review board (IRB) data safety monitoring report deadlines. Additionally they must submit copies of the reports according to the schedule. This requirement went into effect on November 21, 2015 under an Executive Committee action. This proposal made that requirement permanent until the variance expires. This proposal also establishes a January 1, 2018 expiration date for the variance (Policy 15.6).

## **What Members Need to Do**

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

## **Affected Policy/Bylaw Language:**

### **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.

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.