

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

*Ad Hoc Disease Transmission Advisory Committee  
June 6-7, 2016  
Board of Directors Meeting*



# How does this proposal support the OPTN Strategic Plan?

Promote living donor and transplant recipient safety

- Allows the OPTN to review IRB data safety monitoring reports to identify issues or trends across multiple research studies



# What problem will the proposal solve and how?

- Non-specific data submission requirements for the HOPE Act Variance
  - Require members participating in a HOPE Act research study to provide periodic reports from their data safety monitoring boards (DSMBs) to the OPTN
- Absence of an expiration date for the HOPE Act Variance
  - Executive Committee adopted an expiration date of January 1, 2018



# Was this proposal changed in response to public comment?

- No changes are being proposed
- Unanimously supported by all regions and committees
- Concerns raised by the ASTS
  - Only required for randomized trials
  - Inclusion of DSMB reports is practicing medicine and interfering with IRB judgment
  - Confusingly heterogeneous data collection



# How will members implement this proposal?

- This proposal was implemented on November 21, 2015
- Transplant hospitals participating in a HOPE Act IRB approved research study must provide the OPTN with a schedule of deadlines for DSMB reports and provide them to the OPTN according to the schedule
- To date, all four transplant hospitals that have joined the open variance have met this requirement



# How will the OPTN implement this proposal?

- This proposal was implemented on November 21, 2015
- Ad Hoc Work Group will review DSMB reports and other OPTN data to monitor the safety of the research studies

# Overall Project Impact

**Product**

Policy Change

**Impacted Populations:**

*Transplant hospitals participating in HOPE Act research studies  
HIV Positive Transplant Candidates and Recipients*

**Total IT Implementation Hours**

**0/12,820**

**Total Overall Implementation and Maintenance Hours**

**230/19,560**

# Resolution 10 (page 46)

- RESOLVED, that changes to Policy 15.6 (Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors), as set forth below and implemented on November 21, 2015, are hereby approved, effective September 1, 2016.
- FURTHER RESOLVED, that Policy 15.6 (Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors), will expire on January 1, 2018.