**HOPE ACT**

Request to Join the Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors

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| **For UNOS Use Only** |
| Date Submitted to UNOS: |
| Date of Activation: |
| Expiration Date: |
| Organization Code: |

An open variance allows any OPTN member to join by submitting an application as dictated by the specific variance. *OPTN Members participating in this open variance must comply with all applicable provisions of the:*

1. [National Organ Transplant Act, as amended, 42 U.S.C. 273 et seq.](http://optn.transplant.hrsa.gov/governance/about-the-optn/history-nota/)

2. [OPTN Final Rule, 42 CFR Part 121](http://optn.transplant.hrsa.gov/governance/about-the-optn/final-rule/)

3. [OPTN Bylaws](http://optn.transplant.hrsa.gov/governance/bylaws/)

4. [OPTN Policies](http://optn.transplant.hrsa.gov/governance/policies/)

Members participating in this open variance must also be “participating in clinical research approved by an institutional review board, as defined in 45 CFR part 46, under the [research criteria](https://www.federalregister.gov/articles/2015/11/25/2015-30172/final-human-immunodeficiency-virus-hiv-organ-policy-equity-hope-act-safeguards-and-research-criteria) published by the Secretary under subsection (a) of section 377E of the Public Health Service Act.” *An application must be submitted for each individual IRB approved protocol.*

1. **Participant Information**
   1. **Submitting Transplant Hospital:**
   2. **Principal Investigator’s Contact Information:**

*(Please include email address)*

1. **Required Information**
   1. Institutional Review Board letter stating approval to participate in an IRB approved research protocol conforming with the research criteria.
   2. IRB approval expiration date. A new IRB approval letter must be submitted prior to the expiration date in order for HIV positive candidates participating in the research study to receive organ offers from HIV positive donors.
   3. A detailed schedule of required deadlines for IRB data safety monitoring reports that addresses the requirements in the HHS research criteria. *(Policy 15.6 requires members to submit the reports to the OPTN Contractor at each deadline in the schedule)*
   4. Participating Programs:

\_\_\_ Kidney (Deceased Donor)

\_\_\_ Liver (Deceased Donor)

\_\_\_ Kidney (Living Donor)

\_\_\_ Liver (Living Donor)

1. **[Variance](http://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf" \l "nameddest=Policy_15)****[Policy Language](http://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf" \l "nameddest=Policy_15)**

**Members must submit this form and all required information to the OPTN Contractor at** [HOPEAct.VarianceRequest@unos.org](mailto:HOPEAct.VarianceRequest@unos.org)