**HOPE ACT**

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

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| **For OPTN Contractor Use Only** |
| Date Submitted: |
| 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 of Health and Human and Services under subsection (a) of section 377E of the Public Health Service Act.” Members must meet the study team experience requirements outlined in the research criteria and protocols must address the clinical criteria and safety monitoring requirements of the research criteria.

The OPTN does not develop specific research protocols for use in the HOPE Act open variance. Transplant centers must develop their own protocol meeting the HHS research guidelines reference above, or if joining an on-going multi-center clinical trial, must utilize a protocol associated with the corresponding trial.

All transplant recipients and living donors are research subjects defined by the HHS research criteria and must be covered under an IRB approved protocol. *An application must be submitted for each individual IRB approved protocol.*

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

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

*(Please include name, phone number, and email address)*

1. **Application Type**

\_\_\_ New

\_\_\_ Renewal

1. **Required Information (in addition to this request)**
   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 *(OPTN Policy 15.6 requires members to submit the reports to the OPTN Contractor at each deadline in the schedule).* This must include the actual dates when Data and Safety Monitoring Board (DSMB) reports will be submitted to OPTN Contractor. If a central DSMB is used as part of a multi-center trial, this must be indicated in the request.

Additionally, for submission to the OPTN Contractor, each DSMB report must contain a list of OPTN transplant recipient identification numbers for all recipients included in the report.

* 1. By submitting this application, for each of the organ types checked below, we attest that the proposed HOPE Act transplant team at our center meets the minimum experience criteria laid out by the HHS research criteria (below) and further that we have advised our IRB of this experience requirement for participation in the HOPE research program.

*“The transplant physician and HIV physician collectively must have experience with at least 5 HIV-negative to HIV-positive transplants with the designated organ(s) over the last 4 years. This constitutes the minimal experience necessary, and the IRB must evaluate key personnel (i.e., transplant surgeon, transplant physician, and HIV physician) in the context of total expertise and experience with respect to HIV and/or organ transplantation (confirm and document HIV-negative to HIV-positive transplant experience of the team).” - HOPE Act, Safeguards and Research Criteria for Transplantation of Organs Infected With HIV*

* 1. Desired organ transplant types to perform under the HOPE Act:

\_\_\_ Kidney (Deceased Donor)

\_\_\_ Kidney (Living Donor)

\_\_\_ Pancreas (Deceased Donor)

\_\_\_ Heart (Deceased Donor)

\_\_\_ Lung (Deceased Donor)

\_\_\_ Liver (Deceased Donor)

\_\_\_ Liver (Living Donor)

\_\_\_ Intestine (Deceased Donor)

\_\_\_ VCA (Living Donor)

\_\_\_ VCA (Deceased 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)  -** For reference only, no member information required.