HOPE Act Variance Request Form

CERTIFICATION

The undersigned, a duly authorized representative of the applicant, does hereby certify that the answers and attachments to this application are true, correct and complete, to the best of his or her knowledge after investigation. I understand that the intentional submission of false data to the OPTN may result in action by the Secretary of the Department of Health and Human Services, and/or civil or criminal penalties. By submitting this application to the OPTN, the applicant agrees: (i) to be bound by OPTN Obligations, including amendments thereto, if the applicant is granted membership and (ii) to be bound by the terms, thereof, including amendments thereto, in all matters relating to consideration of the application without regard to whether or not the applicant is granted membership.

If you have any questions, please call the UNOS Membership Team at 833-577-9469 or email MembershipRequests@unos.org.

Principal Investigator

_____	_____	_____
Printed Name	**Signature**	**Email Address**

Part 1: General Information

Name of Transplant Hospital: _____

OPTN Member Code (4 Letters): _____

Transplant Hospital Address (where transplants occur)

Street: _____ Suite: _____

City: _____ State: _____ Zip: _____

Name of Person Completing Form: _____ Title: _____

Email Address of Person Completing Form: _____

Date Form is submitted to OPTN Contractor: _____

Members must submit this form and all required information to the OPTN Contractor at HOPEAct.VarianceRequest@unos.org

Part 2: Instructions and Principal Investigator

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.
2. OPTN Final Rule, 42 CFR Part 121
3. OPTN Bylaws
4. OPTN 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 published by the Secretary of Health and Human and Services under subsection (a) of section 377E of the Public Health Service Act." 42 C.F.R. § 121.6(b)(1)(ii)(A). 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*. Note that for living donation, IRB approved protocols must be developed for both the living donor as well as the transplant recipient.

Principal Investigator: _____

Email Address: _____

Phone: _____

Part 3: Additional Information

The following information is **required** with submission of the variance request:

1. Institutional Review Board letter stating approval to participate in an IRB approved research protocol conforming to 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 15.7 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.

4. 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)."*

Final Human Immunodeficiency Virus (HIV) Organ Policy Equity (HOPE) Act Safeguards and Research Criteria for Transplantation of Organs Infected With HIV, 80 Fed. Reg. 73785-01, 73792 (Nov. 25, 2015).

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)

5. Variance Policy Language - For reference only, no member information required.

PUBLIC BURDEN STATEMENT

The private, non-profit Organ Procurement and Transplantation Network (OPTN) collects this information in order to perform the following OPTN functions: to assess whether applicants meet OPTN Bylaw requirements for membership in the OPTN; and to monitor compliance of member organizations with OPTN Obligations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0915-0184 and it is valid until xx/xx/20xx. This information collection is required to obtain or retain a benefit per 42 CFR §121.11(b)(2). All data collected will be subject to Privacy Act protection (Privacy Act System of Records #09-15-0055). Data collected by the private non-profit OPTN also are well protected by a number of the Contractor's security features. The Contractor's security system meets or exceeds the requirements as prescribed by OMB Circular A-130, Appendix III, Security of Federal Automated Information Systems, and the Departments Automated Information Systems Security Program Handbook. The public reporting burden for this collection of information is estimated to average 1.33 hours per response, including the time for reviewing instructions, searching existing data sources, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to HRSA Reports Clearance Officer, 5600 Fishers Lane, Room 14N136B, Rockville, Maryland, 20857 or paperwork@hrsa.gov.