

**APPLICATION FOR APPROVAL FOR INSTITUTIONAL MEMBERSHIP
AS AN INDEPENDENT ORGAN PROCUREMENT ORGANIZATION
(IOPO)
IN THE ORGAN PROCUREMENT AND TRANSPLANTATION
NETWORK (OPTN)**

UNOS
700 North 4th Street
Richmond, VA 23219
Main Phone: 804-782-4800

Name of OPO: _____
Address: _____
City, State, and Zip Code: _____
Contact Person: _____
Phone Number: (____) _____

PUBLIC BURDEN STATEMENT: 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 project is 0915-0184. Public reporting burden for the applicant for this collection of information is estimated to average 40 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, 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 10-33, Rockville, Maryland 20857.

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. By submitting this application to the OPTN, the applicant agrees: (i) to be bound by the Organ Procurement and Transplantation Network's rules and regulations, 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.

Signature: _____ Date: _____

Print Name: _____ Title: _____

Applicant Code: _____

Independent Organ Procurement Organization

Organ Procurement Organizations: An organization designated as an organ procurement organization by the Secretary of the Department of Health and Human Services (HHS) under Section 1138(b) of the Social Security Act or an organization that meets all requirements for such designation other than OPTN membership (OPO) is eligible for membership in the OPTN.

OPOs shall abide by applicable provisions of the National Organ Transplant Act, as amended, 42 U.S.C. 273 *et seq.*; the requirements set forth in the OPTN Final Rule, 42 CFR Part 121; the Bylaws; and OPTN policies.

OPOs shall also submit to reviews (including on-site reviews) and requests for information as may be necessary to determine compliance with the OPTN Final Rule, 42 CFR Part 121; the Bylaws; and OPTN policies. Failure to conform with such requirements shall be cause for corrective action described in Appendix A of the Bylaws.

Instructions

1. An independent organ procurement organization (IOPO) must complete this application for institutional membership. "Independent" is defined as the demonstration of distinct governing body that is separate and not under the direct or indirect control of the governing body of any of the transplant hospitals or of the governing body of a commonly controlled group of OPOs or hospitals. The Criteria for Institutional Membership are found in the Bylaws which can be accessed on the OPTN website at www.optn.transplant.hrsa.gov.
2. An IOPO is eligible for a voting institutional membership.
3. By submitting this application to the OPTN, the applicant acknowledges that its duly authorized representatives have received and read the current Charter and Bylaws of OPTN and the applicant agrees: (i) to be bound by the terms thereof, 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.
4. A duly authorized representative of the applicant must review the answers and attachments to the application, perform sufficient investigation to determine accuracy and completeness, and sign and date the certification on the cover page of the application. Failure to furnish accurate and complete information in connection with the application and subsequent site visits and requests for supplemental information constitute grounds for denial or suspension of OPTN membership.
5. Application responses must be typed and complete. Do not omit pages that were not used. Electronic versions (MS Word) of this application are available upon request.
6. Attach additional pages as necessary and reference the question and page number on each attachment. **Table rows should be expanded as needed to fully respond to questions.**
7. The original application should be loose bound with tabs and returned to the address listed below.

Express Mail
UNOS
Membership Services
700 North 4th Street
Richmond, VA 23219
Main Phone: 804-782-4800

US Mail
UNOS
Membership Services
P.O. Box 2484
Richmond, VA 23218

Application for Independent Organ Procurement Organization

1. Provide the full name of OPO and the CMS provider identification number.

- a) IOPO Name: _____
Address: _____

- b) CMS Provider Number: _____

2. Identify the CEO, Executive Director, Medical Director(s). Provide names, addresses, and CVs.

Name	Mailing Address, Phone Number and Email Address
CEO:	
Executive Director:	
Medical Director(s):	

3. Provide documentation that demonstrates that this organization has been:

- 1) designated as an organ procurement organization by the Secretary of the Department of Health and Human Services (HHS) under Section 1138(b) of the Social Security Act; or
- 2) that this organization that meets all requirements for such designation other than OPTN membership (OPO) and is eligible for membership in the OPTN.

4. List below the names and addresses of clinical transplant hospitals that this OPO will serve and the type of programs that it will serve for each transplant hospital (i.e. kidney, heart, heart/lung, lung, liver, pancreas, pancreas islet cell)

- Describe the regional transplant agreements.
- Attach the written contracts/agreements with each organization.

Name & Address	Type of Programs	Regional Transplant Agreements

Expand rows as needed.

5. Outline the purposes and the goals of this organization as stipulated in the charter and bylaws.
- Attach copies of charter and bylaws.
6. Attach list of names and positions of the Board of Directors and/or Advisory Board.
7. Attach a copy of non-profit status notification from federal and state offices.
8. Attach a copy of the organization's most recent annual report.
9. Is the IOPO insured for professional liability? Yes ____ No ____
- If "yes", name the insurer and give the policy limits per person and per occurrence and the expiration date of the current insurance coverage.
 - If "no", and it has a funded self-insurance program, give the name of the fund administrator and the amount of the self-insurance fund, and describe the coverage available to the institution from the fund.
10. Name below and provide a copy of an agreement that documents arrangements with a CLIA certified laboratory(ies) in the appropriate specialty or subspecialty or service, to provide donor infectious disease screening including acquired immune deficiency virus, consistent with OPTN standards.

11. Provide the name of OPTN approved histocompatibility laboratory(ies) with which the OPO will be affiliated.
- Attach copies of any agreements.
12. Describe your defined service area in terms of geographic region (counties served), population base and hospital allocation catchment area.
- Indicate to what extent your defined service area is exclusive and for any non-exclusive service areas served, what other OPOs are involved.
 - Include a map diagramming the area.
13. Attach a list of donor hospitals served and provide a current copy of each agreement.
14. Communication of Information for Organ Distribution: The OPO is responsible for equitable organ allocation within its service area according to OPTN policies and must be able to communicate in a timely manner appropriate information necessary to facilitate equitable organ distribution as well as perform other functions necessary to discharge this responsibility.
- Describe how this OPO will fulfill this requirement including the arrangements for recovery and distribution of renal and non-renal organs and tissues, and the arrangement for recovery and distribution of tissue (eye, bone, skin, etc.).
 - Attach agreements with tissue and eye banks within area.

15. Describe the anticipated procedures for complying with the data submission requirements of OPTN membership.

16. List the personnel who will be responsible for data collection and submission. Indicate their background in this area and the percentage of their time that will be dedicated to data collection and submission.

Name	Background	% of Time Dedicated to Data Collection & Submission

17. List all personnel (by position) employed by this OPO. (Expand table rows as necessary)

Name	Position

18. Plan for Public Education on Organ Donation. Provide a description of activities that the OPO will be involved with regarding public education about organ donation, including how donor families, transplant patients, and transplant recipients participate.

- Attach a copy of the plan for addressing multi-cultural issues related to organ donation.

19. Donation after Cardiac Death (DCD). OPOs must develop, and once developed must comply with, protocols to facilitate the recovery of organs from DCD donors. OPO DCD recovery protocols must address the required model elements set forth in the OPTN Bylaws.

Certification Statement

The undersigned, as the duly authorized Chief Executive Officer, hereby certifies after investigation that to the best of his or her knowledge a Donation after Cardiac Death (DCD) organ recovery protocol has been developed, adopted and will be implemented in accordance with OPTN Bylaws and that the DCD organ recovery protocol addresses the required model elements.

Chief Executive Officer

Date
