OMB No. 0915-0184
Expiration Date: xx/xx/20xx

# OPTN Membership Application for Transplant Hospitals and Programs

**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.

**OPTN Representative**

| _____ | _____ | _____ |
|---|---|---|
| **Printed Name** | **Signature** | **Email Address** |

# Part 1: General Information

**Name of Hospital: _____**

**OPTN Member Code: _____** **CMS Provider #: _____**

**This application corresponds with what other organ application? (check all that apply)**

- ☐ **Kidney**
- ☐ **Liver**
- ☐ **Intestine**
- ☐ **Pancreas**
- ☐ **Islet**
- ☐ **Heart**
- ☐ **Lung**
- ☐ **VCA – Head and Neck**
- ☐ **VCA – Upper Limb**
- ☐ **VCA – Lower Limb**
- ☐ **VCA – Abdominal Wall**
- ☐ **VCA – Musculoskeletal Composite Graft Segment**
- ☐ **VCA – Spleen**
- ☐ **VCA – Vascularized Gland**
- ☐ **VCA – Uterus**
- ☐ **VCA – External Male Genitalia**
- ☐ **VCA – Other Genitourinary Organs**

**Transplant Hospital Address (where transplants occur)**

**Street: _____ Suite: _____ Phone #: _____**

**City: _____ State: _____ Zip: _____Fax #: _____**

**Hospital Website Address: _____**

☐ **Is this a standalone pediatric hospital?**

**Name of Person Completing Form: _____ Title: _____**

**Email Address of Person Completing Form: _____**

**Date Form is submitted to OPTN Contractor: _____**

OMB No. 0915-0184
Expiration Date: xx/xx/20xx

# Part 2: Geographic Requirements for Transplant Hospitals

***Check to attest to the following***

☐ *The transplant hospital is entirely within a single donation service area (DSA).*

☐ *All operating room facilities used for organ transplantation are under common executive leadership and governance oversight.*
***Provide documentation displaying common executive leadership and governance oversight.***

☐ *All transplant hospital operating rooms where transplants are performed are within a geographically contiguous campus.*
***Provide a map that displays and identifies the following:***
- *The transplant hospital campus and the location of each operating room facility*
- *Building name(s) and address(es)*
- *Floor number(s)*
- *Unit identifier(s)*

☐ *All the transplant hospital operating rooms where transplants are performed within a one mile walking distance from the main hospital's physical address.*

**Approval of Transplant Hospitals with Operating Rooms Beyond the Established Geographic Boundaries**

As long as the hospital is able to fulfill all other requirements established in these Bylaws, the OPTN may approve transplant hospitals that have operating rooms used for transplantation beyond the geographical boundaries established above. The hospital may submit an application to the OPTN to consider its specific circumstances if all of the conditions in Appendix D.2.A of the OPTN bylaws.

***Check if the above applies to your hospital***

☐ *The hospital has operating rooms beyond the established geographic boundaries.*

***Submit a written explanation detailing the mitigating circumstances that necessitate designation of a single transplant hospital or preclude registration of a second transplant hospital, and a written plan for transplant patient care.***

The hospital will also participate in an informal discussion with the MPSC.

OMB No. 0915-0184
Expiration Date: xx/xx/20xx

# Part 3: Designated Transplant Program Requirement

In order to receive organs for transplantation, a transplant hospital member must have current approval as a designated transplant program for at least one organ. A transplant hospital can only have one designated transplant program for each respective organ. Designated transplant programs must meet *at least one* of the following requirements

***Check all that apply***

☐ *The hospital has approval as a transplant program by the Secretary of the U.S. Department of Health and Human Services (HHS) for reimbursement under Medicare.*

☐ *The hospital has approval as a transplant program in a Department of Veterans Affairs, Department of Defense, or other Federal hospital.*

☐ *The hospital qualifies as a designated transplant program according to the membership requirements of these Bylaws.*

OMB No. 0915-0184
Expiration Date: xx/xx/20xx

# Part 4: Quality Assessment and Performance Improvement (QAPI) Requirement

***By checking the boxes below, the transplant hospital attests to the following for the transplant hospital's Quality Assessment and Performance Improvement (QAPI) program:***

☐ *The transplant hospital has developed, implemented and maintained an ongoing, comprehensive and data-driven QAPI program designed to monitor and evaluate compliance with OPTN requirements and produce measurable process improvement initiatives.* The QAPI plan must incorporate all designated transplant programs at the transplant hospital.

☐ *The hospital has documented implementation of all elements of the QAPI plan.*

***Provide QAPI plan documentation as an attachment to the application.***

OMB No. 0915-0184
Expiration Date: xx/xx/20xx

# Part 5: Facilities and Resources

A successful transplant program requires adequate facilities and resources. Read each section and provide the requested documentation with the application.

**1. Facilities**

***Provide an executive summary of your transplant program's physical space. Include operating and recovery room resources, intensive care resources, and surgical beds.***

**2. OPO Affiliation**

***Provide all letters of agreement or contracts with OPO members per OPTN Bylaws.***

**3. Histocompatibility Laboratory Affiliation**

***Provide a copy of the written agreement with an OPTN approved histocompatibility laboratory to perform the tissue typing of recipients and donors. Each lab agreement must include all of the following:***

- ***The sample requirements for typing and crossmatching.***
- ***The loci and level of resolution typed.***
- ***A process for requesting extended HLA typing.***
- ***A process for reporting and verifying HLA and unacceptable antigen data at the time of registration on the waiting list and any time there are changes.***
- ***A process for reporting HLA typing results to the OPTN Contractor.***
- ***A process for resolving HLA typing discrepancies and errors.***
- ***The maximum turnaround time from receipt of sample to reporting of results to the transplant program.***
- ***A process to obtain sensitization history for each patient.***
- ***The frequency of periodic sample collection.***
- ***The frequency of antibody screenings.***
- ***The criteria for crossmatching.***
- ***The assay format that will be used for antibody screening and for crossmatching.***
- ***The criteria for determining unacceptable antigens used during organ allocation.***
- ***The duration for which specimens need to be stored for repeat or future testing.***
- ***If desensitization is performed, then a protocol for monitoring antibody levels.***
- ***If the laboratory registers candidates for the transplant program, then a process for blood type verification according to Policy 3.3: Candidate Blood Type Determination before Waiting List Registration.***
- ***If post-transplant monitoring is performed, then a protocol for monitoring antibody levels.***

**4. Blood Bank Services**

Transplant programs must have access to large quantities of blood and provide proof of extensive blood bank support.

***Provide a list of all local blood banks with whom the transplant hospital interacts.***

_____
_____
_____

**5. Additional Laboratory Services**

Transplant programs must have immediate access to microbiology, clinical chemistry, histocompatibility testing, and radiology services, as well as the necessary resources to monitor immunosuppressive medications.

***Provide a list of laboratories with whom the transplant hospital interacts.***

OMB No. 0915-0184
Expiration Date: xx/xx/20xx

# Part 6: Additional Transplant Program Personnel

Transplant programs must have other support personnel on staff to ensure quality patient care. The sections below provide details of support staff that a transplant program is required to have on staff.

**1. Clinical Transplant Coordinator**

Each transplant program will have on staff at least one Clinical Transplant Coordinator. The Clinical Transplant Coordinator will be a designated member of the transplant team, working with patients and their families to coordinate care, beginning with the evaluation for transplantation and continuing through and after transplantation.

The Coordinator should be a registered nurse or other licensed clinician who oversees a team of other healthcare personnel and support staff.

***List at least one clinical transplant coordinator for the program below:***

**Name: _____**

**Email address: _____ Phone Number: _____**

**2. Financial Coordinator**

Each transplant hospital should have on staff a Financial Coordinator who will be responsible for coordinating and clarifying the available financial resources for patient care. The Financial Coordinator will be a designated member of the transplant team, working with patients and their families to coordinate the financial resources required for care, beginning with the transplantation evaluation and continuing after transplantation to ensure continuity of care.

The Coordinator will also work with other members of the transplant team, insurers and administrative personnel at the transplant hospital.

***List at least one financial coordinator for the program below:***

**Name: _____**

**Email address: _____ Phone Number: _____**

**3. Clinical Transplant Pharmacist**

Each transplant program should identify at least one Clinical Transplant Pharmacist on staff who will provide pharmaceutical expertise to transplant recipients. The Clinical Transplant Pharmacist should be a member of the transplant team, providing comprehensive pharmaceutical care to transplant recipients.

The Transplant Pharmacist will work with patients and their families, and members of the transplant team, including physicians, surgeons, nurses, clinical coordinators, social workers, financial coordinators and administrative personnel. The Transplant Pharmacist should be a licensed pharmacist with experience in transplant pharmacotherapy.

***List at least one transplant pharmacist for the program below:***

**Name: _____**

**Email address: _____ Phone Number: _____**

**4. Medical Expert Support**

The proper care and management of transplant recipients require both physicians and ancillary health professionals.

***Provide proof of collaboration with experts in these fields, i.e. a list of the transplant program collaborators from the following disciplines:***

- *Anesthesiology*
- *Hepatology*
- *Histocompatibility and immunogenetics*
- *Immunology*
- *Infectious disease*
- *Nephrology, including dialysis capability*
- *Pathology*
- *Pediatrics*
- *Physical therapy and rehabilitation medicine*
- *Pulmonary medicine, including respiratory therapy support*
- *Radiology*

**5. Mental Health and Social Support**

Each transplant program must have on staff professionals who are designated members of the transplant team and whose primary responsibility is coordinating the psychosocial needs of transplant

candidates, recipients, living donors, and their families. These professionals will work with patients and families in a compassionate, culturally sensitive, and thoughtful way to facilitate continuity of care.

Responsibilities will include, but are not limited to:

- The psychosocial evaluation of potential living donors and recipients.
- Substance abuse evaluation, treatment, referral, and monitoring.
- Individual counseling.
- Crisis intervention.
- Support groups and newsletters.
- Patient care conferences.
- Patient advocacy.
- Patient and family education.
- Referral to community services such as vocational rehabilitation and housing.
- Death, dying, and bereavement counseling.
- Transplant team building.
- Department meetings, including staff and process improvement meetings.
- Participation in organ donation awareness initiatives.
- Participation with community advocacy groups such as the National Kidney Foundation and the Coalition for Donation.

***Check to attest to the following:***

☐ The transplant program employs mental health and social support staff that have the responsibilities indicated above.

# Part 7: Transplant Hospital Compliance

***Check to attest to the following:***

☐ By accepting membership in the OPTN, transplant hospitals agree to comply with all OPTN Obligations according to *Article 1.1.E: Member Compliance*.

If any regulatory agency takes a final adverse action against a transplant hospital, the transplant hospital must notify the OPTN Contractor in writing within 10 business days. The transplant hospital must also provide all documents relating to the final adverse action to the OPTN Contractor.

**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 4 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.