OPTN APPLICATION GUIDE

Table of Contents

General 3
Application Review Process 4
Primary Surgeon and Physician Checklists 6
Logs 9
Living Donor Recovery Applicants Only 10
“Additional” Transplant Surgeons and Physicians 13
Program Coverage Plan 14
Certificate of Investigation 16

General

1. If you have questions throughout the process, please contact your UNOS Membership Analyst or UNOS Membership Coordinator.

2. This resource provides instructions for every type of application form. Please refer to the initial notification from your UNOS Membership Analyst that outlines which form you must complete.

3. OPTN Bylaws (http://optn.transplant.hrsa.gov/policiesAndBylaws/bylaws.asp) and OPTN Policies (http://optn.transplant.hrsa.gov/policiesAndBylaws/policies.asp) can be found in their entirety on the OPTN website.

   General transplant program requirements can be found in the bylaws under Appendix D, "Membership Requirements for Transplant Hospitals and Transplant Programs". The criteria specific to program staffing, including primary transplant surgeon and physician qualifications for each organ type, can be found in the bylaws under Appendices E-J.

4. Refer to the staffing audit (Center/Individual Report) sent with this application and make all necessary updates [deletions (DEL), edits, and additions] in Table 1: OPTN Staffing Report in the application. If you did not receive a staffing audit (ex. If you are starting a new center/new program), complete Table 1 in its entirety and add additional rows as necessary. For kidney and liver program applications, check "L" and/or "D" to specify each individual's involvement with living donor recoveries and deceased donor transplantation, as applicable.

5. A curriculum vitae (C.V.) must be included for the surgeon and/or physician being proposed as primary and all program directors. If the additional surgeon or physician section has been completed, also provide a C.V. for each additional. Abbreviated C.V.s that do not include publications and presentations are preferred.

6. Supporting documentation such as letters of support, hospital credentialing letters, letters of commitment, and patient logs must be included to document compliance with OPTN requirements. Documentation may be blinded in such a way as to protect patient confidentiality. Checklists for required supporting documentation are available later in this guide.

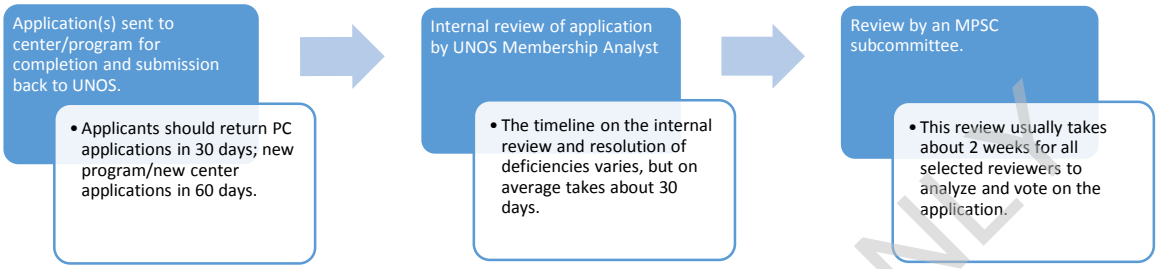
7. The hospital CEO/President or OPTN representative must review the answers and attachments to the application, perform sufficient investigation to determine accuracy and completeness, and sign and date the certification on the cover page. Failure to provide accurate and complete information on application forms and corresponding supplemental information could result in the suspension or denial of OPTN membership.

8. Return the original of all application materials to UNOS at the below address. You may submit materials electronically, in addition to the hard copy original submitted by mail.

   UNOS
   Membership Department
   700 North 4th Street
   Richmond, VA 23219

Application Review Process

1. Appendix A of the bylaws outlines the application process, once a complete application is submitted. http://optn.transplant.hrsa.gov/ContentDocuments/OPTN_Bylaws.pdf#nameddest=Appendix_A



2. New transplant hospitals and new transplant programs should apply approximately 3 months prior to the intended start date. As defined in the bylaws, applications for changes in key personnel should be submitted within 30 days of the effective date of the change.

3. Upon submission of a complete application, the UNOS Membership Coordinator and UNOS Membership Analyst will review the materials for completeness and communicate with the hospital if application deficiencies are identified.

4. The Membership and Professional Standards Committee (MPSC) or a MPSC subcommittee will act on an application and provide a recommendation for interim approval or rejection within 90 days after the OPTN receives an application that has been deemed complete. Applications for membership and designated transplant program approval will be considered in a timely and good faith manner.

5. After the MPSC or a MPSC subcommittee has reviewed an application, the program will be notified of this decision in writing or by the UNOS Membership Analyst if further action on the application is required.

Frequently Asked Questions

- **When is an application needed?**
  An application should be completed for OPTN membership and/or new organ transplant programs, as well as any changes in key personnel (primary surgeon and primary physician) and program reactivations.

- **What is the definition of a primary transplant/donor surgeon?**
  A primary transplant or donor surgeon is one of the required key personnel that designated transplant programs or living donor recovery components must have on site. The primary surgeon must meet the requirements set forth in the bylaws and is responsible for ensuring the operation and compliance of the program according to the OPTN obligations defined in the bylaws.

- **What is the definition of a primary transplant physician?**
  A primary transplant physician is one of the required key personnel that designated transplant programs must have on site. The primary physician must meet the requirements set forth in the bylaws and is responsible for ensuring the operation and compliance of the program according to the OPTN obligations defined in the bylaws.

- **What is the definition of a program director?**
  There is a difference between the definition of a program director and primary. The primaries of a program are described above. The director(s) of a program is designated by the institution and there is not an application for a program director. This role is given by the institution. Changes in program director(s) must be reported to UNOS, as defined in the bylaws and the name(s) and C.V. for the director(s) must be provided to UNOS.

- **How much professional time should the primary spend on site at the hospital?**
  Historically, the MPSC expects the primary surgeon or physician to spend at least 51% of their time on site at the transplant program for which they are being proposed. The MPSC will evaluate lesser amounts of coverage on an application specific basis.

- **How should the summary of transplant training and experience table be completed?**
  A list of the names of the transplant hospital(s), applicable dates, program director name(s), and the number of transplants and procurements performed by the surgeon or the number of transplant patients for which the physician provided substantive patient care (pre-, peri- and post-operatively) must be completed. The number of patients listed during the timeframes here should parallel the logs provided with the application.

- **How should the narratives be completed?**
  Details should be provided to describe the level of involvement in the transplant program and involvement in transplant through prior training/experience in each of the areas listed. These narratives are the opportunity for the proposed surgeon or physician to provide explanation of expertise to the MPSC or MPSC subcommittee for review. We advise that this section be given to the proposed surgeon or physician for completion and autobiographical use.

Application Type Checklist

The following sections of the application must be included for each application type, as indicated below (*x = required*):

Document Required	Application Types			Pre-submission Check List ✓
	New Transplant Hospital	*New Transplant Program at Existing Member Hospital*	*Key Personnel Change*	
Signed cover/certification page	x	x	x	
Organ specific section (primary personnel)	x	x	x	
Signed written program coverage plan	x	x	x	
Documentation of Medicare/Medicaid (if applicable)	x	x	x	
General section	x	x		
OPO section and agreement	x	x Specifying the new organ		
Lab section and agreement	x	x Specifying the new organ		

Primary Surgeon and Physician Checklists

Required Supporting Documentation [Organ Specific Section (Primary Personnel)]
For all new transplant hospitals, new transplant programs in an existing member hospital, and key personnel change applications (primary surgeon and/or physician as applicable), the following supporting documents must also be submitted:

Primary Surgeon **Required Supporting Documentation**	**Pre-submission Checklist ✓**
Current C.V. for the surgical director listed (if different than primary surgeon).	
Current C.V. for the primary surgeon.	
Current C.V. for the living donor recovery surgeon (if applicable). **NOTE:** Reference Living Donor Recovery Applicants section for LD log requirements.	
A letter from the Credentialing Committee of the applicant hospital stating that the surgeon's state license, board certification, training and transplant continuing medical education have been verified. The surgeon must currently also be a member in good standing of the hospital's medical staff. Please provide an explanation of any status other than active/full.	
A copy of the surgeon's current certification by the appropriate American Board(s) or the foreign equivalent.	

Primary Surgeon **Required Supporting Documentation**	**Pre-submission Checklist ✓**
Letter from the surgeon detailing his/her commitment to the program and describing their transplant training/experience.	
Choose one of the pathways listed below:	
If the primary surgeon is being proposed through the "Residency/Fellowship" Pathway:	
A letter of recommendation from the training program's **primary surgeon and transplant program director** outlining the surgeon's overall qualifications to act as a primary transplant surgeon, as well as the surgeon's personal integrity, honesty and familiarity with and experience in adhering to OPTN obligations and compliance protocols, and any other matters judged appropriate. **NOTE:** If the primary surgeon of the training program and the transplant program director are different individuals, a letter from each individual must be submitted. See bylaw requirements for these letters.	
Transplant logs (organized by center, then date) and procurement logs with the procedures (organized by date) from the surgeon's residency/fellowship.	
If the primary surgeon is being proposed through the "Clinical Experience" Pathway:	
A letter of recommendation from **the primary surgeon and transplant program director** at the transplant program last served by the surgeon outlining the surgeon's overall qualifications to act as a primary transplant surgeon, as well as the surgeon's personal integrity, honesty and familiarity with and experience in adhering to OPTN obligations and compliance protocols, and any other matters judged appropriate. **NOTE**: If the primary surgeon of the program and the transplant program director are different individuals, a letter from each individual must be submitted. See bylaw requirements for these letters.	
Transplant logs (organized by center, then date) from the surgeon's post residency/fellowship clinical experience and procurement logs with the procedures (organized by date).	

If the surgeon is unable to meet the requirements for either the residency/fellowship or clinical experience pathways, contact your UNOS Membership Analyst and refer to the bylaws for conditional and pediatric pathways.

Primary Physician **Required Supporting Documentation**	**Pre-submission Checklist ✓**
Current C.V. for the medical director listed (if different than primary physician).	
Current C.V. for the primary physician.	
A letter from the Credentialing Committee of the applicant hospital stating that the physician's state license, board certification, training and transplant continuing medical education have been verified. The physician must currently also be a member in good standing of the hospital's medical staff. Please provide an explanation of any status other than active/full.	

Primary Physician **Required Supporting Documentation**	**Pre-submission Checklist** ✓
A copy of the physician's current certification by the appropriate American Board(s) or the foreign equivalent.	
Letter from the physician detailing his/her commitment to the program and describing their transplant training/experience.	
*Observation log(s) (organized by center/date) as applicable.	
Choose one of the pathways listed below:	
If the primary physician is being proposed through the "Fellowship" Pathway:	
A letter of recommendation from the fellowship training program's **primary physician and transplant program director** outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty and familiarity with and experience in adhering to OPTN obligations and compliance protocols, and any other matters judged appropriate. **NOTE**: If the primary physician of the program and the transplant program director are different individuals, a letter from each individual must be submitted. See bylaw requirements for these letters.	
Transplant recipient logs (organized by center, then date) from the physician's fellowship.	
If the primary physician is being proposed through the "Clinical Experience" Pathway:	
A letter of recommendation from the program's **primary physician and transplant program director** outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty and familiarity with and experience in adhering to OPTN obligations and compliance protocols, and any other matters judged appropriate. **NOTE**: If the primary physician of the program and the transplant program director are different individuals, a letter from each individual must be submitted. See bylaw requirements for these letters.	
Transplant recipient logs (organized by center, then date) from the physician's post fellowship clinical experience.	

*The bylaws do not require that physicians provide observation logs. If the physician has observed organ procurements, transplants, evaluation, the donation process and management of multiple organ donors it is encouraged that these logs be submitted.

If the physician is unable to meet the requirements for either the residency/fellowship or clinical experience pathways, contact your UNOS Membership Analyst and refer to the bylaws for conditional and pediatric pathways.

Logs

Documentation of logs are required to be submitted with applications. All fellowship logs must be signed by the fellowship program director. If submitting logs outside of the sample logs provided, they must at least include the required information noted in the sample logs.

Specifically:

For the primary surgeon

- Date of transplant
- A unique patient identifier; e.g. the Medical Record Number (MRN), UNOS ID
- The unique patient identifier should not be a name or social security number.
- Role of the surgeon, i.e. primary or first assist

For the primary physician

- Date of transplant
- A unique patient identifier; e.g. the Medical Record Number (MRN), UNOS ID
- The unique patient identifier should not be a name or social security number.
- Whether the physician was involved pre-, peri-, and/or post-operatively
- Post-operative care for each recipient is required and defined as 90 days primary follow up care from the date of transplant.

See Living Donor Recovery Applicants section for further requirements of living donor recovery logs.

Living Donor Recovery Applicants Only

A recovery hospital is a designated transplant program that performs the surgery to recover organs from living donors for transplantation. In addition to meeting designated transplant program requirements, recovery hospitals must also meet additional requirements defined in Appendix E (Kidney) and Appendix F (Liver) of the OPTN bylaws. *Only programs who intend to recover organs from living donors need to obtain approval for a designated recovery program.* Transplant hospitals that intend to transplant living donor organs, but not recover them, do not need living donor recovery approval.

For Living Donor Liver Recovery Applicants

Provide documentation (Table 4) that this individual has experience as the primary surgeon or first assistant in 20 major hepatic resection surgeries, including at least 7 living donor hepatectomies.

For the primary living donor recovery surgeon, this log must include

- Date of recovery
- A unique patient identifier; e.g. the Medical Record Number (MRN), UNOS ID
- The unique patient identifier should not be a name or social security number.
- Role of the surgeon, i.e. primary or first assist

- A Current Procedural Terminology (CPT) code for the procedure

  When documenting involvement in living donor hepatectomies, be sure to specify that the procedure was performed on the donor if the corresponding CPT code is not provided. It is recognized that in the case of pediatric living donor transplantation, the living organ donation may occur at a hospital that is distinct from the approved transplant hospital.

  Applicable CPT codes for living donor hepatectomies/major hepatic resections:

  Living Donor

  47140 Living Donor Hepatectomy (segments II, III - left lateral segment)
  47141 Living Donor Hepatectomy (segments II, III, IV -- left lobe)
  47142 Living Donor Hepatectomy (segments V, VI, VII, VIII -- right lobe)

  Major Hepatic Resections

  47120 Hepatectomy (partial lobectomy)
  47122 Trisegmentectomy
  47125 Total left lobectomy
  47130 Total right lobectomy

Please use this checklist to keep track of supporting documents that must be submitted if the surgeon is being proposed as the primary donor surgeon who performs living donor recoveries:

Primary Living Donor Liver Recovery Surgeon **Supporting Documentation**	**Pre-submission Checklist** ✓
Living Donor Liver Experience: A log (organized by date) of major hepatic resection surgeries and living donor hepatectomies performed within the past 5 years.	

For Living Donor Kidney Recovery Applicants:
Provide documentation (Table 4) summarizing this individual's training and experience. Include the number of open nephrectomies and laparoscopic nephrectomies (as applicable) in which the individual participated as the primary surgeon or first assistant.

Open nephrectomy donor surgeon: Provide documentation in the Donor Recovery Log (Table 5) that the donor surgeon has experience as the primary surgeon or first assistant in at least 10 open nephrectomies (living donor nephrectomies, deceased donor nephrectomies, and/or removal of polycystic or diseased kidneys). If the primary open nephrectomy donor surgeon has completed an ASTS fellowship, the certificate can be the alternative to having performed 10 open nephrectomies.

Laparoscopic nephrectomy donor surgeon: Provide documentation in the Donor Recovery Log (Table 5) that the donor surgeon has performed 15 laparoscopic nephrectomies, 7 as primary surgeon, within the last 5 years.

For open and laparoscopic nephrectomy donor surgeons, this log must include

- Date of nephrectomy
- A unique patient identifier; e.g. the Medical Record Number (MRN), UNOS ID
- The unique patient identifier should not be a name or social security number.
- Role of the surgeon, i.e. primary or first assist

- A Current Procedural Terminology (CPT) code for the procedure

When documenting involvement in living donor nephrectomies, be sure to specify that the procedure was performed on the donor if the corresponding CPT code is not provided. It is recognized that in the case of pediatric living donor transplantation, the living organ donation may occur at a hospital that is distinct from the approved transplant hospital.

Applicable CPT Codes for living donor kidney:

Open Donor Nephrectomy

50220 Remove kidney, open
50225 Removal kidney open, complex
50230 Removal kidney open, radical
50234 Removal of kidney & total ureter and bladder cuff, through same incision
50236 Removal of kidney & ureter through separate incision
50300 Removal of donor kidney (Cadaver donor, unilateral or bilateral)
50320 Removal of donor kidney (open)
50340 Removal of recipient kidney

Laparoscopic Nephrectomy

50545 Laparo radical nephrectomy (includes removal of Gerota's fascia and surrounding fatty tissue, removal of regional lymph nodes, and adrenalectomy)
50546 Laparoscopic nephrectomy including partial ureterectomy
50547 Laparo removal donor kidney (including cold preservation), from living donor
50549 Laparo proc, renal

Please use these checklists to keep track of supporting documents that must be submitted if the surgeon is being proposed as the primary donor surgeon who performs living donor recoveries:

***Primary Open Nephrectomy Donor Surgeon* Supporting Documentation**	**Pre-submission Checklist ✓**
Choose one of the pathways listed below:	
ASTS Pathway:	
A copy of the surgeon's certificate designating completion of an accredited kidney American Society of Transplant Surgeons (ASTS) fellowship.	
Open Nephrectomy Pathway:	
A log (organized by date) of completion of at least 10 open nephrectomies.	

***Primary Laparoscopic Nephrectomy Donor Surgeon* Supporting Documentation**	**Pre-submission Checklist ✓**
A log (organized by date) of completion of at least 15 laparoscopic nephrectomies in the last 5 years as primary surgeon or first assistant. At least 7 of these nephrectomies must have been performed as the primary surgeon.	

"Additional" Transplant Surgeons and Physicians

OPTN requirements for transplant program designation include identification of a primary surgeon and primary physician, both of whom must meet minimum requirements as defined in the bylaws. These requirements do not apply to all surgeons and physicians who participate in and support the transplant program. "Additional" transplant surgeons and physicians are defined below. In addition to answering questions in the application form, you must also submit a C.V. for all surgeons and physicians who are listed as "additional."

"Additional" transplant surgeons must be designated by the transplant hospital to provide transplant services and be able to independently manage the care of transplant patients, including performing the transplant operations and organ procurement procedures.

Please use this checklist to keep track of supporting documents that must be submitted for an additional surgeon:

Additional Surgeon **Supporting Documentation**	**Pre-submission Checklist** ✓
Current C.V. for the surgeon.	

"Additional" transplant physicians must be designated by the transplant hospital to provide transplant services and be able to independently manage the care of transplant patients.

Please use this checklist to keep track of documents that must be submitted for an additional physician:

Additional Physician **Supporting Documentation**	**Pre-submission Checklist** ✓
Current C.V. for the physician.	

Program Coverage Plan

In accordance with the bylaws, the program director(s), in conjunction with the primary transplant surgeon and transplant physician, must submit a written Program Coverage Plan, which may include an approved hospital protocol or procedure for handling program coverage. The plan must document how 100% medical and surgical coverage is provided by individuals credentialed by the hospital to provide transplant service for the program and address the following requirements:

1. Transplant programs must have transplant surgeons and transplant physicians available 365 days a year, 24 hours a day, 7 days a week to provide program coverage, unless a written explanation is provided that justifies the current level of coverage to the satisfaction of the MPSC.

   Example: A single surgeon or single physician program will not be able to have 365/24/7 surgical or medical coverage. A written explanation should include that 365/24/7 coverage is not possible and must describe how the program will handle surgical/medical coverage. A transplant program served by a single surgeon or physician shall inform its patients of this fact and potential unavailability of one or both of these individuals, as applicable which could affect patient care, including the ability to accept organ offers, procurement, and transplantation.

2. Transplant programs must provide patients with a written summary of the Program Coverage Plan when placed on the waiting list and when there are any substantial changes in the program or its personnel.

   Note: A substantial change in the program or personnel may be defined as a change in operations that requires an interruption in transplantation, such as periods of short-term inactivity or a key personnel change that has been approved by the MPSC.

3. A transplant surgeon must be readily available in a timely manner to facilitate organ acceptance, procurement, and transplantation.

   Note: Single surgeon programs must notify patients that organ acceptance, procurement, and transplantation will be unavailable at times.

4. A transplant surgeon or transplant physician may not be on call simultaneously for two transplant programs more than 30 miles apart unless the circumstances have been reviewed and approved by the MPSC.

   Note: If review of this type of situation is being requested, please provide an explanation for MPSC approval.

   Example: If a surgeon or physician is on staff (primary or additional) at Center A and Center B and Center A and Center B are 31 miles apart, the surgeon or physician cannot be on call at the same time for both centers.

5. Unless the MPSC provides an exemption for specific reasons, the primary surgeon or primary physician cannot be designated as the primary surgeon or primary physician at more than 1 transplant hospital unless there are additional transplant surgeons or transplant physicians at each of those facilities.

Note: Exemptions will be evaluated by the MPSC. If the primary surgeon or physician will be the primary at more than 1 transplant hospital, the MPSC may request an explanation and evidence of additional transplant surgeons and physicians at each hospital.

6. Additional transplant surgeons must be credentialed by the transplant hospital to provide transplant services and be able to independently manage the care of transplant patients, including performing the transplant operations and organ procurement procedures.

   Note: Those transplant surgeons that cannot independently perform transplants will be defined as “other”.

7. Additional transplant physicians must be credentialed by the transplant hospital to provide transplant services and be able to independently manage the care of transplant patients.

   Note: Those transplant physicians that cannot independently manage the care of patients will be defined as “other”.

Certificate of Investigation

As part of the plan for continuing policy compliance that is required in the membership application, each primary surgeon or primary physician must submit an assessment of all physicians and surgeons in the program. This assessment must include any involvement in prior transgressions of OPTN obligations and plans to ensure compliance. This information is subject to medical peer review confidentiality requirements and must be submitted according to the guidelines provided in the application and to the satisfaction of the MPSC.

The Certificate of Investigation requires certification by the primary transplant surgeon and physician that the transplant hospital has conducted its own review of all the transplant surgeons and physicians in with the transplant program. You can add additional rows as needed to include a listing of all surgeons and physicians.

If prior transgressions were identified, the transplant hospital must submit a copy of the plan developed to ensure that the improper conduct is not continued or repeated.

A transgression is defined as a corroborated act that dangerously or deliberately violates OPTN requirements and has resulted in harm to the integrity of the organ transplant system.

If your application is for a personnel change, the proposed primary surgeon/physician should sign the certificate (not the departing/former primary surgeon or physician).

OMB No. 0915-0184
Expiration Date: 05/31/2017

APPLICATION FOR INSTITUTIONAL MEMBERSHIP

AS A CLINICAL TRANSPLANT HOSPITAL

IN THE ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK (OPTN)

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

Name of Hospital:	
Hospital Address:	
City, State, & Zip Code:	
Contact Person and Title:	
Phone:	**Email:**

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 this collection of information is estimated to average 8 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 10C-03I, 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. 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.

Date:	Signature:
Print Name:	Title:
Applicant #:	

OMB No. 0915-0184
Expiration Date: 05/31/2017

Part 1: Section A – Transplant Hospital

1. The bylaws require that an applicant has in force medical liability insurance with a minimum of $1,000,000 coverage limit per occurrence. Coverage must be provided by an insurer that is either:
   - Licensed
   - Approved by the insurance regulatory agency of the state in which the applicant's principal office is located.

   In lieu of commercial insurance coverage, evidence of equivalent coverage through a funded, self-insurance arrangement will suffice.

   a) Is your hospital insured for the required professional liability with a minimum of $1,000,000 coverage limit per occurrence?

Yes	
No	

   b) If no, and you have a funded self-insurance program; provide the name of the fund administrator, the amount of the self-insurance fund, and a description of the coverage available to your institution.

Fund Administrator	Amount of Self Insurance Fund	Describe Coverage

   c) Will you require transplant surgeons and transplant physicians on your medical staff to carry professional liability insurance or to participate in a funded self-insurance program beyond what is described in “a” or “b” above? If yes, describe the amount of coverage or funded self-insurance that you will require.

	Response Required (check one)	Amount of Self Insurance Coverage
Yes		
No		

OMB No. 0915-0184
Expiration Date: 05/31/2017

Part 1: Section B – Donation after Circulatory Death (DCD) Protocols

Donation after Circulatory Death (DCD). In accordance with the bylaws, transplant hospitals must develop, and once developed must comply with, protocols to facilitate the recovery of organs from DCD donors. Transplant Hospital DCD recovery protocols must address the model requirements set forth in the policies.

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 Circulatory Death (DCD) organ recovery protocol has been developed, adopted and implemented in accordance with OPTN Bylaws; and that the DCD organ recovery protocol addresses the requirements.
Signature:
Date:
Name:

OMB No. 0915-0184
Expiration Date: 05/31/2017

Part 2: Section A – Program Description

Duplicate this section for each organ application that is being submitted

Indicate below all programs and components for which the hospital is applying.

Application (Check)	Program Type	Application (Check)	Program Type
	Kidney		Pancreas
	Living Donor Kidney Recoveries		Pancreas Islet Cell
	Liver		Heart
	Living Donor Liver Recoveries		Lung

1. Indicate below the anticipated start date that the transplant program will become operational.

[Insert detailed response here. Table will expand automatically]

2. Will this program perform transplants in patients under age 18?

Yes	
No	

3. Is this a stand-alone pediatric hospital?

Yes	
No	
No, we are affiliated with:	

4. Is this program certified by Medicare?

   If yes, submit evidence of certification and complete the table below:

CMS provider number:
Certification date:

5. If a Certificate of Need (CON) is required by your state prior to initiation of this transplant program, provide the below information.

Date Application Made	Application (Actual or Anticipated) Approval Date

OMB No. 0915-0184
Expiration Date: 05/31/2017

Part 2: Section B – Facilities

Transplant programs require extensive facilities and commitment of resources. Consequently, transplant hospitals must allocate sufficient operating and recovery room resources, intensive care resources, and surgical beds to the transplant program. Describe below how this hospital satisfies these requirements.

Operating Room(s):	
Recovery Room(s):	
ICU:	
Surgical Intensive Care (SICU):	
Step-Down Unit/Floor:	
Outpatient Transplant Clinic:	
Total # of Days/Hours Available for Outpatient Transplant Clinic:	
Additional information:	

OMB No. 0915-0184
Expiration Date: 05/31/2017

Part 2: Section C – Human Resources

1. **Clinical Nursing:** Describe the nursing support that will be provided to the transplant program.

   a) Patient to nurse ratio:

ICU	NON-ICU

   b) Describe training/orientation for clinical nursing staff caring for transplant patients. Include details regarding competencies required before a nurse is given responsibility for care of transplant patients.

[Insert detailed response here, table will expand automatically.]

   c) Will a transplant nurse specialist be actively involved in the care of patients on the transplant unit? If so, describe responsibilities.

[Insert detailed response here, table will expand automatically.]

2. Transplant Program Personnel: OPTN Bylaws require that transplant programs have support personnel on staff to ensure quality patient care. For details regarding roles and responsibilities for these positions, reference the bylaws. In the table below, indicate if individuals in these positions are designated members of the transplant team or serve as consultants to support the transplant program.

Position	Designated Member of Transplant Team	Consultative, available as needed
Clinical Transplant Coordinator		
Financial Coordinator		
Clinical Transplant Pharmacist		
Mental Health and Social Support		
Radiology		
Infectious Disease		
Pulmonary Medicine		
Pathology		
Immunology		
Physical Therapy		
Rehabilitation Medicine		
Dietary & Nutritional Support		

3. Other Medical Discipline Involvement: Indicate in the table if the transplant program has immediate access to the following services and their location:

Specialty Area	In-House	Offsite
Microbiology		
Clinical Chemistry		
Immunological Monitoring		
Blood Bank		
Hepatology		
Pediatrics		
Nephrology (with dialysis capability)		
Pulmonary Medicine (with respiratory therapy support)		

4. Anesthesiology Commitment: All transplant hospitals must show evidence of collaborative involvement with experts in the field of anesthesiology.

   a) Is there a director of transplant anesthesiology and/or an anesthesiology service chief for the organ transplant program covered in this application?

Yes	
No	

   b) Does the department of anesthesiology or the hospital medical staff have a credentialing process for transplant anesthesiologists?

Yes	
No	

   c) Select the statement that best describes the anesthesiology care.

Care for transplant procedures will be provided exclusively by members of a transplant anesthesiology team	
Care for transplant procedures will be provided by members of a transplant anesthesiology team and other non-team members	
Care for transplant procedures will be distributed among anesthesiology department members	

   d) How many anesthesiologists, including the director, will participate in transplant care?

[Insert detailed response here. Table will expand automatically]

   e) Is there a written protocol for the conduct of anesthesia in transplant cases?

Yes	
No	

   f) In what way do the anesthesiologists participate in transplant patient care?

Phase of Patient Care	**Yes**	**No**	**If Requested**
See patients preoperatively			
Participate on the Selection Committee			
Consultation preoperatively with subspecialists (e.g. cardiologists, pulmonologists) as needed for specific cases			
Participate in M&M Conferences			
Other (describe)			

OMB No. 0915-0184
Expiration Date: 05/31/2017

5. Staffing Resources – Planning:
   Using the chart below, show the expected transplant volume and staffing levels (FTEs) for year 1 through year 3 of the program.

	Year 1	Year 2	Year 3
Workload Volume			
Projected Transplant Volumes			
Projected # of Candidates Waitlisted			
Expected # of New Evaluations Each Year			
Projected # of Patients Followed Post-transplant			
Staffing/Personnel Projections (FTEs)			
Surgeons – Primary/Additional			
Surgeons – Other			
Surgeons – Transplant Fellow			
Physician – Primary/Additional			
Physician – Other (Organ Specific)			
Physician – Fellow (Organ Specific)			
Physician Extenders(s)			
Transplant Pathologists			
Transplant Coordinators			
Dietary/Nutritional Counselors			
Financial Counselors			
Social Workers			
Transplant Program Administrative Management			
Administrative Assistants			
Data Coordinators			
Transplant Pharmacists			
Transplant Psychiatrist/Psychologist			

OMB No. 0915-0184
Expiration Date: 05/31/2017

Part 2: Section D - Program Administration:

1. Describe administrative relationships of the transplant program with the hospital (include an organizational chart).

[Insert detailed response here, table will expand automatically.]

2. Describe the institutional commitment to this program including hospital resources to be dedicated to this program for the next two years.

[Insert detailed response here, table will expand automatically.]

3. Describe oversight and management of the transplant program, including if the program is part of a designed comprehensive transplant center or service line, and how this transplant program fits into the overall hospital structure.

[Insert detailed response here, table will expand automatically.]

4. Describe the role of the transplant administrator and areas of oversight (including non-transplant duties).

[Insert detailed response here, table will expand automatically.]

5. Describe in detail the transplant program's quality assurance/performance improvement protocol or process, and how the transplant program will review its performance. Indicate the method, frequency of reviews, and participants (by title). Expand or duplicate table as needed.

Individuals Involved: (Name and title)
Methods:
Frequency of reviews:
Metrics/Data Tracked:
Detailed response:

6. Will specialty representatives participate with the transplant team in patient specific reviews post-transplant (i.e. morbidity and mortality meetings, etc)?

Individuals Involved: (Name and title)
Methods:
Detailed response:

7. Will hospital administration receive periodic reports for the transplant program? If so, indicate frequency and data reported. Expand table as needed.

Frequency of reports:
Metrics/Data Tracked:
Detailed response:

8. Describe the process for ensuring compliance with OPTN obligations. Include who is responsible (name and title/position) and how this process is integrated with other transplant programs and institution wide.

Name/Title:
[Insert detailed response here, table will expand automatically.]

9. Data Collection and Submission: In accordance with the OPTN policies, members must submit data on candidates, recipients, and donors.

   a) Describe the methods that will to be used to collect, verify, and submit data on a timely basis.

[Insert detailed response here, table will expand automatically.]

   b) Describe the training/orientation for the data coordinator(s) supporting the transplant program. Include details regarding competencies measured as part of the training.

[Insert detailed response here, table will expand automatically.]

OMB No. 0915-0184
Expiration Date: 05/31/2017

Part 2: Section E –Protocols/Methods/Procedures

1. Are there written policies and procedures for transplantation and patient management?

Yes, individual physician/surgeon specific	
Yes, program specific for all team members	
No	

How often will these be reviewed and who participates in the review?

[Insert detailed response here, table will expand automatically.]

2. Describe below how patients (additional explanation for living donors when applicable) will move through the pre-, peri-, and post-transplantation process (from identification and referral, selection committee review process, patient notification, post surgery/post transplant care and plan/policy for transitioning patients back to referring doctors post-transplant) as applicable. The description should include:

   - resources involved with each step (address expected average volume of patients moving through the system at any given time)
   - the process for continuous review of patients currently waitlisted for transplant

[Insert detailed response here, table will expand automatically.]

3. Describe existing or anticipated development of outreach programs for facilitating referrals.

[Insert detailed response here, table will expand automatically.]

4. Describe the approach for responding to patient inquiries and emergencies.

Routine patient calls:
Outpatient emergencies:

5. What provisions are made for patient assistance/funding for temporary housing, medications, etc.?

[Insert detailed response here, table will expand automatically.]

6. Describe types of transplant team meetings and who participates in them. Are rounds conducted with a multi-disciplinary team? Who participates in them? Duplicate or expand table as needed.

Meeting Type:
Attendees (role, not name):
Multi-disciplinary team rounds:
Participants:

7. Who oversees and directs the outpatient transplant clinic? Which physicians and surgeons regularly participate in the transplant clinic?

Transplant Clinic Oversight:
Transplant Clinic Participation:

8. Patient Selection Criteria: Transplant programs must establish procedures for selecting transplant candidates and distributing organs in a fair and equitable manner.

   a) Describe the patient evaluation protocol for this transplant program.

[Insert detailed response here, table will expand automatically.]

   b) Are there formal exclusion criteria for acceptance?

[Insert detailed response here, table will expand automatically.]

   c) Who gives final approval for adding patients to the waiting list?

Single Individual	
Committee of (list titles of participants):	

9. Immunosuppression: Answer the questions below regarding immunosuppression:

   a) Is there a standard immunosuppression protocol?

Yes, individual physician/surgeon specific	
Yes, program specific for all team members	
No	

   b) Indicate who (role/title) manages immunosuppression at various stages of the transplant process:

Initial hospitalization	
First 3 months post-transplant	
Long term (after 3 months)	

Describe the interactions of team members in providing immunosuppression management.

10. Off-site Transplant-related Services: In the space below, summarize plans for any transplant-related services provided outside of the transplant hospital. Provide a letter of support or agreement from each off-site provider.

[Insert detailed response here, table will expand automatically.]

OMB No. 0915-0184
Expiration Date: 05/31/2017

Part 2: Section F – Business/Implementation Plan

The existence of a business/implementation plan is a critical element for any successful transplant program. The OPTN requests verification that such a business/implementation plan exists in support of this application.

Verification of this plan is requested when:

- applying for institutional membership
- establishing a new transplant program
- the MPSC requires it as a condition for reactivating a transplant program

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 Business/Implementation Plan has been developed, adopted and will be consulted regarding the institutional commitments being made and acknowledge in the this transplant program application.
Signature:
Date:
Name:

OMB No. 0915-0184
Expiration Date: 05/31/2017

Part 2: Section G – Organ Procurement Arrangements

As part of the application submission, include a letter of agreement or contract with your OPO that specifically indicates it will provide the organ for which the hospital is applying.

1. Describe the process for organ acceptance, including who (role/title) is involved in taking organ offer calls. Elaborate if you utilize a hired offer screening service.

   [Insert detailed response here, table will expand automatically.]

2. Describe any regional transplant agreements below.

   [Insert detailed response here, table will expand automatically.]

OMB No. 0915-0184
Expiration Date: 05/31/2017

Part 2: Section H – Histocompatibility Testing Arrangements

1. Each transplant program must have a written agreement with a histocompatibility laboratory(ies) that will be providing testing services. Select the statement below that best describes how this transplant program will meet this requirement.

a) This hospital already has an OPTN approved in-house histocompatibility laboratory	
b) This hospital is also submitting a separate OPTN application for histocompatibility testing services to be provided by its in-house laboratory	
c) This hospital will be entering into a contract with an OPTN approved outside histocompatibility laboratory to provide testing services to this program	

2. If the answer to question 1(c) above is "yes," list the names and addresses of the histocompatibility laboratory(ies) and submit each written agreement. The agreement must include all of the elements required in the OPTN Bylaws. Expand rows as needed.

Histocompatibility Laboratory Name	Address	Functions Performed

Department of Health and Human Services
Health Resources and Services Administration

OMB No. 0915-0184
Expiration Date: 05/31/2017

APPLICATION FOR APPROVAL OF A

CLINICAL TRANSPLANT PROGRAM

IN AN EXISTING MEMBER TRANSPLANT HOSPITAL

ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK (OPTN)

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

Name of Hospital:	
Address:	
City, State, & Zip Code:	
Contact Person and Title:	
Phone Number:	**Email:**

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 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 10C-03I, 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. 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.

Date:	Signature:
Print Name:	Title:
Applicant #:	

Department of Health and Human Services
Health Resources and Services Administration

OMB No. 0915-0184
Expiration Date: 05/31/2017

PERSONNEL CHANGE APPLICATION

CLINICAL TRANSPLANT PROGRAM

ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK (OPTN)

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

Name of Hospital:	
Address:	
City, State, & Zip Code:	
Contact Person and Title:	
Phone Number:	**Email:**

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 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 10C-03I, 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. 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.

Date:	Signature:
Print Name:	Title:
Applicant #:	

Part 3: Kidney Transplant Program
Including Programs Performing Living Donor Kidney Recoveries

This application is for (check all that apply):

	Kidney Transplantation	Living Donor Kidney Component	
		Open Nephrectomy	Laparoscopic Nephrectomy
New Program			
Key Personnel Change			
Reactivation			

Table 1: OPTN Staffing Report

Member Code:	**Name of Transplant Hospital:**	
Main Program Phone Number:	**Main Program Fax Number:**	**Hospital URL:** http://www
Toll Free Phone Number for Patients:	**Hospital Number:**	

Refer to the staffing audit sent with this application and complete the table below for staff that are not captured on the staffing audit or to update information for current staff, including deleting (DEL) an individual. If you did not receive an audit with this application, complete the entire staffing report. Make sure to use individuals' full, legal names (middle name/initial also included when possible) to prevent duplicate entries within the UNOS Membership Database and UNet. **Check "L" and/or "D" to specify each individual's involvement with deceased donor kidney transplantation, living donor kidney recoveries, or both, as applicable**. Add additional rows as necessary.

Identify the **transplant program medical and/or surgical director(s)**.

DEL	Name	L	D	Address	Phone	Fax	Email

Identify the **primary surgeon and additional surgeon(s)** who perform transplants for the program and living donor recoveries.

DEL	Name	Open	Lap	D	Address	Phone	Fax	Email

Identify **other surgeon(s)** who perform transplants for the program and living donor recoveries.

DEL	Name	Open	Lap	D	Address	Phone	Fax	Email

Identify the **primary physician and additional physicians** (internists) who participate in this transplant program.

DEL	Name	Open	Lap	D	Address	Phone	Fax	Email

Identify **other physicians** (internists) who participate in this transplant program.

DEL	Name	Open	Lap	D	Address	Phone	Fax	Email

Identify the **transplant program administrator(s)/hospital administrative director(s)/manager(s)** who will be involved with this program. The * denotes the primary transplant administrator.

DEL	Name	L	D	Address	Phone	Fax	Email
	*						

Identify the **clinical transplant coordinator(s)** who will be involved in this transplant program.

DEL	Name	L	D	Address	Phone	Fax	Email

Identify the **data coordinator(s)** who will be involved in this transplant program. The * denotes the primary data coordinator.

DEL	Name	L	D	Address	Phone	Fax	Email
	*						

Identify the **social worker(s)** who will be involved with this program.

DEL	Name	L	D	Address	Phone	Fax	Email

Identify the **Independent Donor Advocate(s) (IDA)** who will be involved in the care of living donors (complete only if the application includes changes to the living donor component).

DEL	Name	Address	Phone	Fax	Email

Identify the **pharmacist(s)** who will be involved with this program.

DEL	Name	L	D	Address	Phone	Fax	Email

Identify the **financial counselor(s)** who will be involved with this program.

DEL	Name	L	D	Address	Phone	Fax	Email

Identify the **anesthesiologists** who will be involved with this program. The * denotes the director of anesthesiology.

DEL	Name	L	D	Address	Phone	Fax	Email
	*						

Identify the **QAPI team members** who will be involved with this program.

DEL	Name	L	D	Address	Phone	Fax	Email

Identify **any other transplant staff** who will be involved with this program.

DEL	Name	Title	L	D	Address	Phone	Fax	Email

OMB No. 0915-0184
Expiration Date: 05/31/2017

Part 3A: Personnel – Transplant Program Director(s)

Identify the surgical and/or medical director(s) of the kidney transplant program and/or the living donor component and submit a CV for each program director. Briefly describe the leadership responsibilities for each individual, including their role in living donor kidney recoveries, if applicable.

Name	Date of Appointment	Primary Areas of Responsibility

OMB No. 0915-0184
Expiration Date: 05/31/2017

Part 3B, Section 1: Personnel – Surgical – Primary Surgeon

1. Identify the primary transplant surgeon:

Name:

a) Provide the following dates (use MM/DD/YY):

Date of employment at this hospital:
Date assumed role of primary surgeon:

b) The surgeon is being proposed as (check all that apply):

Primary Kidney Transplant Surgeon	
Living Donor Recovery Surgeon	

c) Does the surgeon have FULL privileges at this hospital?

Yes	
No	

If the surgeon does **not** currently have full privileges:

Date full privileges to be granted (MM/DD/YY):
Explain the individual's current credentialing status, including any limitations on practice:

d) How much of the surgeon's professional time is spent on site at this hospital?

Percentage of professional time on site:
Number of hours per week:

e) How much of the surgeon's professional time is spent on site at other facilities (hospitals, health care facilities, and medical group practices)?

Facility Name	Type	Location (City, State)	% Professional Time on Site

f) List the surgeon's current board certification(s) below. If board certification is pending, indicate the date the exam has been scheduled. If individual has been recertified, use that date, also provide a copy of certification(s).

Certification Type	**Certificate Effective Date** (MM/DD/YY)	**Certificate Valid Through Date** (MM/DD/YY)	**Certification Number**

g) Check the applicable pathway(s) through which the surgeon will be proposed. Refer to the bylaws for the necessary qualifications and more specific descriptions of the required supporting documents.

Membership Criteria	
2-Year Kidney Transplant Fellowship	
Clinical Experience (Post Fellowship)	
Pediatric Pathway	

h) Transplant Experience (Post Fellowship) and Training (Fellowship): List the name(s) of the transplant hospital(s), applicable dates, program director name(s), and the number of kidney transplants and procurements performed by the surgeon at each transplant hospital.

Training and Experience	ASTS Approved Program? Y/N	Date (MM/DD/YY) Start	Date (MM/DD/YY) End	Transplant Hospital	Program Director	# KI Transplants as Primary	# KI Transplants as 1st Assistant	# of KI Procurements as Primary or 1st Assistant
Fellowship Training								
Experience Post Fellowship								

i) Describe in detail the proposed primary surgeon's level of involvement in **this** transplant program as well as **prior** training and experience.

	Describe Level of Involvement in this Transplant Program	**Describe Prior Training/Experience**
Pre-Operative Patient Management		
Recipient Selection		
Donor Selection		
Transplant Surgery		
Post-Operative Care		
Histocompatibility and Tissue Typing		
Post-Operative Immunosuppressive Therapy		
Outpatient Follow-Up		
Coverage of Multiple Transplant Hospitals (if applicable)		
Living Donor Transplantation (if applicable)		
Additional Information:		

Table 2: Primary Surgeon - Transplant Log (Sample)

Complete a separate form for each transplant hospital.

Organ:	
Name of proposed primary surgeon:	
Name of hospital where transplants were performed:	
Date range of surgeon's appointment/training: MM/DD/YY to MM/DD/YY	

List cases in date order. Extend lines on log as needed. Patient ID should not be name or Social Security Number.

#	Date of Transplant	Medical Record/ OPTN ID #	Primary Surgeon	1st Assistant
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				
21				
22				
23				
24				
25				
26				
27				
28				
29				
30				

Director's Signature	**Date**
Print Name	

Table 3: Primary Surgeon - Procurement Log (Sample)

Organ:	
Name of proposed primary surgeon:	

List cases in date order. Extend lines on log as needed. Patient ID should not be name or Social Security Number.

#	Date of Procurement	Donor ID Number	Location of Donor (Hospital)	Comments (LD/CAD/Multi-Organ)
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				
21				
22				
23				
24				
25				
26				
27				
28				
29				
30				

Director's Signature	**Date**
Print Name	

Part 3B: Section 2 – Personnel, Additional Surgeon(s)

Complete this section to describe surgeons involved in the program that are not designated as primary. For each surgeon, they should be designated as additional as described below. Duplicate this section as needed.

Additional transplant surgeons must be credentialed by the transplant hospital to provide transplant services and be able to independently manage the care of transplant patients, including performing the transplant operations and organ procurement procedures.

1. Identify the additional transplant surgeon**:**

Name:

a) Provide the following dates (use MM/DD/YY):

Date of employment at this hospital:

b) The surgeon is involved as a (check all that apply):

Kidney Transplant Surgeon	
Living Donor Kidney Recovery Surgeon	

c) Does the surgeon have FULL privileges at this hospital?

Yes	
No	

If the surgeon does **not** currently have full privileges:

Date full privileges to be granted (MM/DD/YY):
Explain the individual's current credentialing status, including any limitations on practice:

d) How much of the surgeon's professional time is spent on site at this hospital?

Percentage of professional time on site:
Number of hours per week:

e) How much of the surgeon's professional time is spent on site at other facilities (hospitals, health care facilities, and medical group practices)?

Facility Name	Type	Location (City, State)	% Professional Time On Site

f) List the surgeon's current board certification(s) below. If board certification is pending, indicate the date the exam has been scheduled. If the surgeon has been recertified, use that date.

Board Certification Type	**Certification Effective Date/ Recertification Date** (MM/DD/YY)	**Certification Valid Through Date** (MM/DD/YY)	**Certificate Number**

Part 3C: Section 1 - Living Donor Kidney Recoveries Personnel
Primary Open and Laparoscopic Nephrectomy Donor Surgeon

The laparoscopic and open donor nephrectomy expertise may reside within the same or different individuals. Duplicate pages as needed.

1. Identify the primary living donor kidney recovery surgeon:

Name:

a) This donor surgeon is being proposed as (check all that apply):

Primary Open Nephrectomy Donor Surgeon	
Primary Laparoscopic Nephrectomy Donor Surgeon	

b) Provide the following dates (use MM/DD/YY):

Date of employment at this hospital:
Date assumed role of primary surgeon:

c) Does the donor surgeon have FULL privileges at this hospital? (check one)

Yes	
No	

If the donor surgeon does **not** currently have full privileges:

Date full privileges to be granted (MM/DD/YY):
Explain the donor surgeon's current credentialing status, including any limitations on practice:

d) How much of the donor surgeon's professional time is spent on site at this hospital?

Percentage of professional time on site:
Number of hours per week:

e) Experience/Training:

	Yes	No
Did the donor surgeon complete an accredited ASTS fellowship with a certificate in kidney?		
If "Yes," complete the questions below and provide a copy of the certificate.		
Transplant hospital:		
Fellowship program director:		
Training start date: (MM/DD/YY)	Training end date**:** (MM/DD/YY)	

f) Describe the proposed primary donor surgeon's level of involvement in the program and if applicable, describe the donor surgeon's plan for coverage of transplant programs located in multiple transplant centers.

[Insert response here, table will expand automatically.]

g) Conversion Coverage Plan: If the open and laparoscopic expertise resides within different individuals, then the program must document how both individuals will be available to the surgical team. Describe how the center will handle surgical decisions and coverage for the laparoscopic to open conversion.

[Insert response here, table will expand automatically.]

Table 4: Primary Donor Surgeon(s) - Open and Laparoscopic Nephrectomies *(Duplicate as needed)*

Summary of Experience and Training for:	[Insert Name]

The numbers entered should be validated on the donor recovery log on the next page. Insert additional rows as needed.

Training and Experience	ASTS Approved Program? Y/N	Date (MM/DD/YY) Start	Date (MM/DD/YY) End	Transplant Hospital	Program Director	# Open Nephrectomies as Primary	# Open Nephrectomies as 1st Assistant	# Laparoscopic Nephrectomies as Primary	# Laparoscopic Nephrectomies as 1st Assistant
Fellowship Training									
Experience Post Fellowship									

OMB No. 0915-0184
Expiration Date: 05/31/2017

Table 5: Primary Donor Surgeon – Donor Recovery Log

Application Type: (Check all that apply)	
Open Nephrectomy	
Laparoscopic Nephrectomy	

Name of proposed primary donor surgeon:	
Name of transplant center where nephrectomies were performed:	

Cases should be listed by type then date order. Insert additional rows as needed.

#	Date of Nephrectomy	Donor ID #	Nephrectomy Site (Hospital)	Procedure (Check Type)		Role in Procedure (Check Type)		CPT Code
				Open	Lap	Primary	1st Assistant	
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
13								
14								
15								
16								
17								
18								
19								
20								

Part 3C: Section 2 - Living Donor Kidney Recoveries Personnel
Additional Open and Laparoscopic Nephrectomy Donor Surgeon(s)

Complete this section to describe additional donor surgeons involved in the program that are not designated as primary. For each surgeon, they should be designated as additional as described below. Duplicate this section as needed.

Additional transplant surgeons must be credentialed by the transplant hospital to provide transplant services and be able to independently manage the care of transplant patients, including performing the transplant operations and organ procurement procedures.

1. Identify the additional donor recovery surgeon.

Name:

a) This donor surgeon is being proposed as (check all that apply):

Open Nephrectomy Donor Surgeon	
Laparoscopic Nephrectomy Donor Surgeon	

b) Provide the following dates (use MM/DD/YY):

Date of employment at this hospital:
Date assumed role of primary surgeon:

c) Does the donor surgeon have FULL privileges at this hospital? (check one)

Yes	
No	

If the donor surgeon does **not** currently have full privileges:

Date full privileges to be granted (MM/DD/YY):
Explain the donor surgeon's current credentialing status, including any limitations on practice:

d) How much of the donor surgeon's professional time is spent on site at this hospital?

Percentage of professional time on site:
Number of hours per week:

e) Experience/Training:

		Yes	No
Did the donor surgeon complete an accredited ASTS fellowship with a certificate in kidney?			
If "Yes," complete the questions below and provide a copy of the certificate.			
Transplant hospital:			
Fellowship program director:			
Training start date: (MM/DD/YY)	Training end date**:** (MM/DD/YY)		

f) Describe the proposed donor surgeon's level of involvement in the program and if applicable, describe the donor surgeon's plan for coverage of transplant programs located in multiple transplant centers.

[Insert response here, table will expand automatically.]

Part 3D: Section 1 - Medical Personnel, Primary Physician

1. Identify the Primary transplant physician.

Name:

a) Provide the following dates (use MM/DD/YY):

Date of employment at this hospital:
Date assumed role of primary physician:

b) Does the physician have FULL privileges at this hospital? (check one)

Yes	
No	

If the physician does **not** currently have full privileges:

Date full privileges to be granted (MM/DD/YY):
Explain the physician's current credentialing status, including any limitations on practice:

c) How much of the physician's professional time is spent on site at this hospital?

Percentage of professional time on site:
Number of hours per week:

d) How much of the physician's professional time is spent on site at other facilities (hospitals, health care facilities, and medical group practices)?

Facility Name	**Type**	**Location (City, State)**	**% Professional Time On Site**

e) List the physician's current board certification(s) below. If board certification is pending, indicate the date the exam has been scheduled. If the physician has been recertified, use that date, also provide a copy of the certifications(s).

Board Certification Type	**Certification Effective Date/ Recertification Date** (MM/DD/YY)	**Certification Valid Through Date** (MM/DD/YY)	**Certificate Number**

f) Check the applicable pathway(s) through which the physician will be proposed. Refer to the bylaws for the necessary qualifications and more specific descriptions of the required supporting documents.

Membership Criteria	
12-month Transplant Nephrology Fellowship	
Clinical Experience (Post Fellowship)	
Pediatric Gastroenterology Fellowship (3 years)	
3-Year Pediatric Nephrology Fellowship ***for Board-Certified or Eligible Pediatric Nephrologists***	
12-month Pediatric Transplant Nephrology Fellowship ***for Board-Certified or Eligible Pediatric Nephrologists***	
Combined Pediatric Nephrology Training and Experience ***for Board-Certified or Eligible Pediatric Nephrologists***	
Pediatric Pathway	
Conditional Pathway – ***Only available to Existing Programs***	

g) Transplant Experience (Post Fellowship)/Transplant Training (Fellowship): List the name(s) of the transplant hospital(s), applicable dates, program director name(s), and the number of transplant patients for which the physician provided substantive patient care (pre-, peri- and post-operatively from the time of transplant).

Training and Experience	AST Approved Program? Y/N	Date (MM/DD/YY)		Transplant Hospital	Program Director	#KI Patients Followed		
		Start	End			Pre	Peri	Post
Fellowship Training								
Experience Post Fellowship								

h) Training/Experience. If applicable, list how the physician fulfills the criteria for participating as an observer of kidney transplants, kidney procurements, the evaluation of the donor and donor process, and the management of at least 3 multiple organ donors.

Date From - To (MM/DD/YY)	**Transplant Hospital**	**# of KI Procurements Observed**	**# of KI Transplants Observed**	**# of KI Donors/ Donor Process**	**# of Multi-Organ Donors Observed Management**

i) Describe in detail the proposed primary physician's level of involvement in **this** transplant program as well as **prior** training and experience.

	Describe Level of Involvement in this Transplant Program	**Describe Prior Training/Experience** Individuals certified in pediatric nephrology should address these areas as they pertain to the pediatric kidney candidate/recipient.
Candidate Evaluation Process		
Pre- and Post-Operative Care		
Post-Operative Immunosuppressive Therapy		
Long-term Outpatient Follow-Up		
Care of Acute and Chronic Kidney Failure		
Donor Selection		
Recipient Selection		
Histologic Interpretation of Allograft Biopsies and Interpretation of Ancillary Tests for Renal Dysfunction		
Care of Living Donors (if applicable)		
Coverage of Multiple Transplant Hospitals (if applicable)		
Fluid and Electrolyte Management (Peds Only)		
Effects of Transplantation and Immunosuppressive Agents on Growth and Development (Peds Only)		
Manifestation of Rejection in the Pediatric Patient (Peds Only)		
Additional Information:		

Table 6: Primary Physician – Recipient Log (Sample)

Organ:	
Name of proposed primary physician:	
Name of transplant hospital where transplants were performed:	
Date range of physician's appointment/training: MM/DD/YY to MM/DD/YY	

List cases in date order. Patient ID should not be name or Social Security Number. Extend lines on log as needed.

#	Date of Transplant	Medical Record/ OPTN ID #	Pre-Operative	Peri-Operative	Post-Operative	Comments
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
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28						
29						
30						

Director's Signature	**Date**
Print Name	

OMB No. 0915-0184
Expiration Date: 05/31/2017

Table 7: Primary Physician – Observation Log (Sample)

Organ:	
Name of proposed primary physician:	

In the tables below, document the physician's participation as an observer in organ transplants and procurements, as well as observing the selection and management of multiple organ donors that include the organ for which application is being submitted.

List cases in date order. Patient ID should not be name or Social Security Number. Add rows as needed.

Transplants Observed

#	Date of Transplant	Medical Record/ OPTN ID #	Hospital
1			
2			
3			
4			
5			

Procurements Observed

#	Date of Procurement	Medical Record/ OPTN ID #	Donor Hospital
1			
2			
3			
4			
5			

Donor Selection and Management

#	Date of Procurement	Medical Record/ OPTN ID #	Donor Hospital	Kidney or Multi-Organ
1				
2				
3				
4				
5				

Part 3D: Section 2 – Personnel, Additional Physician(s)

Complete this section to describe physicians involved in the program that are not designated as primary. For each physician, they should be designated as additional as described below. Duplicate this section as needed.

Additional transplant physicians must be credentialed by the transplant hospital to provide transplant services and be able to independently manage the care of transplant patients.

1. Identify the additional transplant physician.

Name:

a) Provide the following dates (use MM/DD/YY):

Date of employment at this hospital:

b) Does the physician have FULL privileges at this hospital? (check one)

Yes	
No	

If the physician does **not** currently have full privileges:

Date full privileges to be granted (MM/DD/YY):
Explain the physician's current credentialing status, including any limitations on practice:

c) How much of the physician's professional time is spent on site at this hospital?

Percentage of professional time on site:
Number of hours per week:

d) How much of the physician's professional time is spent on site at other facilities (hospitals, health care facilities, and medical group practices)?

Facility Name	Type	Location (City, State)	% Professional Time On Site

e) List the physician's current board certification(s) below. If board certification is pending, indicate the date the exam has been scheduled. If the physician has been recertified, use that date, also provide a copy of the certifications(s).

Board Certification Type	Certification Effective Date/ Recertification Date (MM/DD/YY)	Certification Valid Through Date (MM/DD/YY)	Certificate Number

OMB No. 0915-0184
Expiration Date: 05/31/2017

Table 8: Certificate of Investigation

1. List all transplant surgeons and physicians currently involved in the program.

   a) This hospital has conducted its own peer review of all surgeons and physicians listed below to ensure compliance with applicable OPTN/UNOS bylaws. Expand rows as needed.

Names of Surgeons

Names of Physicians

   b) If prior transgressions were identified, has the hospital developed a plan to ensure that the improper conduct is not continued?

Yes	
No	
Not Applicable	

   c) If yes, what steps are being taken to correct the prior improper conduct or to ensure the improper conduct is not repeated in this program? Provide a copy of the plan.

I certify that this review was performed for each named surgeon and physician according to the hospital's peer review procedures.

Signature of Primary Surgeon	**Date**
Print Name	
Signature of Primary Physician	**Date**
Print Name	

Table 9: Program Coverage Plan

Provide a copy of the current Program Coverage Plan and answer the questions below. The program coverage plan must be signed by either the:

a. OPTN/UNOS Representative
b. Program Director(s)
c. Primary Surgeon and Primary Physician

	Yes	**No**
Is this a single surgeon program?		
Is this a single physician program?		
If single surgeon or single physician, submit a copy of the patient notice or the protocol for providing patient notification.		
Does this transplant program have transplant surgeon(s) and physician(s) available 365 days a year, 24 hours a day, 7 days a week to provide program coverage?		
If the answer to the above question is "No," an explanation must be provided that justifies why the current level of coverage should be acceptable to the MPSC.		
Transplant programs shall provide patients with a written summary of the Program Coverage Plan at the time of listing and when there are any substantial changes in program or personnel. Has this program developed a plan for notification?		
Is a surgeon/physician available and able to be on the hospital premises to address urgent patient issues?		
A transplant surgeon or transplant physician may not be on call simultaneously for two transplant programs more than 30 miles apart unless circumstances have been reviewed and approved by the MPSC.		
Is a transplant surgeon readily available in a timely manner to facilitate organ acceptance, procurement, and implantation?		
Unless exempted by the MPSC for specific causal reasons, the primary transplant surgeon/primary transplant physician cannot be designated as the primary surgeon/primary transplant physician at more than one transplant hospital unless there are additional transplant surgeons/transplant physicians at each of those facilities. Is this program requesting an exemption? If yes, provide explanation below.		
Additional information:		

Part 3: Liver Transplant Program
Including Programs Performing Living Donor Recoveries

This application is for (check all that applies):

	Liver Transplantation	Living Donor Recoveries/Component
New Program		
Key Personnel Change		
Reactivation		

Table 1: OPTN Staffing Report

Member Code:	**Name of Hospital:**	
Main Program Phone Number:	**Main Program Fax Number:**	**Hospital URL:** http://www
Toll Free Phone Number for Patients:		**Hospital Number#:**

Refer to the staffing audit sent with this application and complete the table below for staff that are not captured on the staffing audit or to update information for current staff, including deleting (DEL) an individual. If you did not receive an audit with this application, complete the entire staffing report. Make sure to use individuals' full, legal names (middle name/initial also included when possible) to prevent duplicate entries within the UNOS Membership Database and UNet. **Check "L" and/or "D" to specify each individual's involvement with deceased donor liver transplantation, living donor liver recoveries, or both, as applicable.** Add additional rows as necessary.

Identify the **transplant program medical and surgical director(s)**.

DEL	Name	L	D	Address	Phone	Fax	Email

Identify the **primary and additional surgeons** who perform transplants for the program and living donor recoveries.

DEL	Name	L	D	Address	Phone	Fax	Email

Identify **other surgeons** who perform transplants for the program and living donor recoveries.

DEL	Name	L	D	Address	Phone	Fax	Email

Identify **the primary and additional physicians** (internists) who participate in this transplant program.

DEL	Name	L	D	Address	Phone	Fax	Email

Identify **other physicians** (internists) who participate in this transplant program.

DEL	Name	L	D	Address	Phone	Fax	Email

Identify the **transplant program administrator(s)/hospital administrative director(s)/manager(s)** who will be involved with this program. The * denotes the primary transplant administrator.

DEL	Name	L	D	Address	Phone	Fax	Email
	*						

Identify the **clinical transplant coordinator(s)** who will be involved with this program.

DEL	Name	L	D	Address	Phone	Fax	Email

Identify the **data coordinator(s)** who will be involved in this transplant program. The * denotes the primary data coordinator.

DEL	Name	L	D	Address	Phone	Fax	Email
	*						

Identify the **social worker(s)** who will be involved with this program.

DEL	Name	L	D	Address	Phone	Fax	Email

Identify the **Independent Donor Advocate(s) (IDA)** who will be involved in the care of living donors (complete only if the application includes changes to the living donor component).

DEL	Name	Address	Phone	Fax	Email

Identify the **pharmacist(s)** who will be involved with this program.

DEL	Name	L	D	Address	Phone	Fax	Email

Identify the **financial counselor(s)** who will be involved with this program.

DEL	Name	L	D	Address	Phone	Fax	Email

Identify the **director of anesthesiology** who will be involved with this program.

DEL	Name	L	D	Address	Phone	Fax	Email

Identify the **anesthesiologist(s)** who will be involved with this program.

DEL	Name	L	D	Address	Phone	Fax	Email

Identify the **QAPI team member(s)** who will be involved with this program.

DEL	Name	L	D	Address	Phone	Fax	Email

Identify **any other transplant staff** who will be involved with this program.

DEL	Name	Title	L	D	Address	Phone	Fax	Email

OMB No. 0915-0184
Expiration Date: 05/31/2017

Part 3A: Personnel – Transplant Program Director(s)

Identify the surgical and/or medical director(s) of the liver transplant program and/or the living donor component and submit a C.V. for each program director. Briefly describe the leadership responsibilities for each individual, including their role in living donor liver recoveries, if applicable.

Name	Date of Appointment	Primary Areas of Responsibility

Part 3B, Sections 1 & 2: Personnel – Surgical – Primary Surgeon(s)

1. **Identify the primary liver transplant surgeon and/or living donor surgeon #1.**

Name:

a) Provide the following dates (use MM/DD/YY):

Date of employment at this hospital:
Date assumed role of primary surgeon:

b) This surgeon is being proposed as (check all that apply):

Primary Liver Transplant Surgeon and/or	
Primary Living Donor Recovery Surgeon #1	

If the proposed individual is already designated as the approved OPTN primary liver surgeon and the application is for a personnel change as one of the primary living donor surgeons only, complete c) through g) only.

c) Does the surgeon have FULL privileges at this hospital?

Yes	
No	

If the surgeon does **not** currently have full privileges:

Date full privileges to be granted (MM/DD/YY):
Explain the individual's current credentialing status, including any limitations on practice:

d) How much of the surgeon's professional time is spent on site at this hospital?

Percentage of professional time on site:
Number of hours per week:

e) How much of the surgeon's professional time is spent on site at other facilities (hospitals, health care facilities, and medical group practices)?

Facility Name	Type	Location (City, State)	% Professional Time On Site

f) List the surgeon's current board certification(s) below. If board certification is pending, indicate the date the exam has been scheduled. If the surgeon has been recertified, use that date. Provide a copy of certification(s).

Certification Type	Certificate Effective Date	Certificate Valid Through Date	Certification Number

OMB No. 0915-0184
Expiration Date: 05/31/2017

	(MM/DD/YY)	(MM/DD/YY)	

OMB No. 0915-0184
Expiration Date: 05/31/2017

g) Check the applicable pathway through which the surgeon will be proposed.
Refer to the bylaws for the necessary qualifications and more specific descriptions of the required supporting documents.

Membership Criteria	
Two Year Transplant Fellowship	
Clinical Experience (Post Fellowship)	
Pediatric Pathway	
Living Donor Liver Experience – Criteria for Full Approval	
Living Donor Liver Experience – Criteria for Conditional Approval	

h) Transplant Experience (Post Fellowship)/Training (Fellowship):
List the name(s) of the transplant hospital(s), applicable dates, program director name(s), and the number of transplants and procurements performed by the surgeon at each transplant hospital.

Training and Experience	ASTS Approved Programs? Y/N	Date (MM/DD/YY)		Transplant Hospital	Program Director	# LI Transplants as Primary	# LI Transplants as 1st Assistant	# of LI Procurements as Primary or 1st Assistant
		Start	End					
Fellowship Training								
Experience Post - Fellowship								

OMB No. 0915-0184
Expiration Date: 05/31/2017

i) Describe in detail the proposed primary surgeon's level of involvement in **this** transplant program as well as **prior** training and experience.

	Describe Level of Involvement in This Transplant Program	**Describe Prior Training/Experience**
Pre-Operative Patient Management (Patients With End Stage Liver Disease)		
Recipient Selection		
Donor Selection		
Histocompatibility and Tissue Typing		
Transplant Surgery		
Post-Operative Care and Continuing Inpatient Care		
Use of Immunosuppressive Therapy		
Differential Diagnosis of Liver Dysfunction in the Allograft Recipient		
Histologic Interpretation of Allograft Biopsies		
Interpretation of Ancillary Tests for Liver Dysfunction		
Long Term Outpatient Care		
Living Donor Transplantation (if applicable)		

Pediatric (if applicable)		
Coverage of Multiple Transplant Hospitals (if applicable)		
Additional Information:		

2. **Primary Living Donor Recovery Surgeon #2.** Complete this section ONLY if applying for initial approval to perform living donor recoveries or if making a change in key personnel for both of the primary living donor surgeons (one of the surgeons, use Section 1; both of the surgeons, use Sections 1 and 2).

Name:

a) Provide the following dates (use MM/DD/YY):

Date of employment at this hospital:
Date assumed role of primary surgeon:

b) Does the surgeon have FULL privileges at this hospital? (check one)

Yes	
No	

If the surgeon does **not** currently have full privileges:

Date full privileges to be granted (MM/DD/YY):
Explain the individual's current credentialing status, including any limitations on practice:

c) How much of the surgeon's professional time is spent on site at this hospital?

Percentage of professional time on site:
Number of hours per week:

d) How much of the surgeon's professional time is spent on site at other facilities (hospitals, health care facilities, and medical group practices)?

Facility Name	**Type**	**Location (City, State)**	**% Professional Time On Site**

e) List the surgeon's current board certification(s) below. If board certification is pending, indicate the date the exam has been scheduled. If the surgeon has been recertified, use that date. Provide a copy of certification(s).

Board Certification Type	**Certification Effective Date/ Recertification Date** (MM/DD/YY)	**Certification Valid Through Date** (MM/DD/YY)	**Certificate Number**

OMB No. 0915-0184
Expiration Date: 05/31/2017

f) Summarize how the surgeon's experience fulfills the membership criteria.
Check the applicable pathway through which the surgeon will be proposed.
Refer to the bylaws for the necessary qualifications and more specific descriptions of the required supporting documents.

Membership Criteria	
Two Year Liver Transplant Fellowship	
Experience (Post Fellowship)	
Pediatric Pathway	
Living Donor Liver Experience – Criteria for Full Approval	
Living Donor Liver Experience – Criteria for Conditional Approval	

g) Transplant Experience (Post Fellowship)/Training (Fellowship):
List the name(s) of the transplant hospital(s), applicable dates, program director name(s), and the number of transplants and procurements performed by the surgeon at each transplant hospital.

Training and Experience	ASTS Approved Programs? Y/N	Date (MM/DD/YY)		Transplant Hospital	Program Director	# LI Transplants as Primary	# LI Transplants as 1st Assistant	# of LI Procurements as Primary or 1st Assistant
		Start	End					
Fellowship Training								
Experience Post Fellowship								

OMB No. 0915-0184
Expiration Date: 05/31/2017

h) Describe in detail the proposed primary surgeon's level of involvement in **this** transplant program as well as **prior** training and experience.

	Describe Level of Involvement in This Transplant Program	**Describe Prior Training/Experience**
Pre-Operative Patient Management (Patients With End Stage Liver Disease)		
Recipient Selection		
Donor Selection		
Histocompatibility and Tissue Typing		
Transplant Surgery		
Post-Operative Care and Continuing Inpatient Care		
Use of Immunosuppressive Therapy		
Differential Diagnosis of Liver Dysfunction in the Allograft Recipient		
Histologic Interpretation of Allograft Biopsies		
Interpretation of Ancillary Tests for Liver Dysfunction		
Long Term Outpatient Care		
Living Donor Transplantation (if applicable)		
Pediatric (if applicable)		

Coverage of Multiple Transplant Hospitals (if applicable)		
Additional Information:		

OMB No. 0915-0184
Expiration Date: 05/31/2017

Table 2: Primary Surgeon - Transplant Log (Sample)

Complete a separate form for each transplant hospital.

Organ:	
Name of proposed primary surgeon:	
Name of hospital where transplants were performed:	
Date range of surgeon's appointment/training: MM/DD/YY to MM/DD/YY	

List cases in date order. Extend lines on log as needed. Patient ID should not be name or Social Security Number.

#	Date of Transplant	Medical Record/ OPTN Patient ID #	Primary Surgeon	1st Assistant
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
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26				
27				
28				
29				
30				

Director's Signature	**Date**
Print Name	

OMB No. 0915-0184
Expiration Date: 05/31/2017

Table 3: Primary Surgeon - Procurement Log (Sample)

Organ:	
Name of proposed primary surgeon:	
Name of hospital where surgeon was employed when procurements were performed:	
Date range of surgeon's appointment/training: MM/DD/YY to MM/DD/YY	

List cases in date order. Patient ID should not be name or Social Security Number. Insert additional rows as needed.#

	Date of Procurement	Donor ID Number	Location of Donor (hospital)	Comments (LD/CAD/Multi-organ)
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
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27				
28				
29				
30				

Director's Signature	**Date**
Print Name	

OMB No. 0915-0184
Expiration Date: 05/31/2017

Table 4: Primary Living Donor Surgeon – Log for Living Donor Hepatectomies and other Hepatic Resection Surgeries (Sample) (For Living Donor Applicants Only)

Organ:	
Name of proposed primary living donor surgeon:	
Date range of surgeon's appointment/training: MM/DD/YY to MM/DD/YY	

This log will provide documentation that demonstrates that this individual has experience as the primary surgeon or first assistant in major hepatic resection surgeries, including living donor hepatectomies.

Documentation should include the date of the surgery, medical records identification and/or OPTN/UNOS identification number, the role of the surgeon in the operative procedure, and the Current Procedural Terminology (CPT) code for the procedure. When documenting involvement in living donor hepatectomies, be sure to specify that the procedure was performed on the donor if the corresponding CPT code is not provided. It is recognized that in the case of pediatric living donor transplantation, the living organ donation may occur at a hospital that is distinct from the approved transplant hospital.

List cases in date order. Patient ID should not be name or Social Security Number. Insert additional rows as needed.

#	Date of Surgery	Medical Records/ UNOS ID #	Surgeon Role: Primary/ 1st Assistant	Recovery Hospital	CPT Code
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					

Part 3B: Section 3- Personnel, Additional Surgeon(s)

Complete this section of the application to describe surgeons involved in the program that are not designated as primary. For each surgeon, they should be designated as additional as described below. Duplicate this section as needed.

Additional transplant surgeons must be credentialed by the transplant hospital to provide transplant services and be able to independently manage the care of transplant patients, including performing the transplant operations and organ procurement procedures.

1. Identify the additional transplant surgeon:

Name:

a) Provide the following dates (use MM/DD/YY):

Date of employment at this hospital:

b) This surgeon is involved as a (check all that apply):

Liver Transplant Surgeon and/or	
Living Donor Liver Recovery Surgeon	

c) Does the surgeon have FULL privileges at this hospital? (check one)

Yes	
No	

If the surgeon does **not** currently have full privileges:

Date full privileges to be granted (MM/DD/YY):
Explain the individual's current credentialing status, including any limitations on practice:

d) How much of the surgeon's professional time is spent on site at this hospital?

Percentage of professional time on site:
Number of hours per week:

e) How much of the surgeon's professional time is spent on site at other facilities (hospitals, health care facilities, and medical group practices)?

Facility Name	Type	Location (City, State)	% Professional Time On Site

f) List the surgeon's current board certification(s) below. If board certification is pending, indicate the date the exam has been scheduled. If the surgeon has been recertified, use that date. Provide a copy of the certifications(s).

Board Certification Type	**Certification Effective Date/ Recertification Date** (MM/DD/YY)	**Certification Valid Through Date** (MM/DD/YY)	**Certificate Number**

Part 3C: Section 1 – Medical Personnel, Primary Physician

1. Identify the primary transplant physician:

Name:

a) Provide the following dates (use MM/DD/YY):

Date of employment at this hospital:
Date assumed role of primary physician:

b) Does the physician have FULL privileges at this hospital? (check one)

Yes	
No	

If the physician does **not** currently have full privileges:

Date full privileges to be granted (MM/DD/YY):
Explain the individual's current credentialing status, including any limitations on practice:

c) How much of the physician's professional time is spent on site at this hospital?

Percentage of professional time on site:
Number of hours per week:

d) How much of the physician's professional time is spent on site at other facilities (hospitals, health care facilities, and medical group practices)?

Facility Name	**Type**	**Location** (City, State)	**% Professional Time On Site**

e) List the physician's current board certification(s) below. If board certification is pending, indicate the date the exam has been scheduled. If the physician has been recertified, use that date. Provide a copy of the certifications(s)

Board Certification Type	**Certification Effective Date/ Recertification Date** (MM/DD/YY)	**Certification Valid Through Date** (MM/DD/YY)	**Certificate Number**

f) Summarize how the physician's experience fulfills the membership criteria. Check the applicable pathway through which the physician will be proposed.

Refer to the bylaws for the necessary qualifications and more specific descriptions of the required supporting documents.

Membership Criteria	
12 Month Transplant Hepatology Fellowship	
Clinical Experience (Post Fellowship)	
3 Year Pediatric Gastroenterology Fellowship	
Pediatric Transplant Hepatology Fellowship ***for Board-Certified or Eligible Pediatric Gastroenterologists***	
Combined Training/Experience ***for Board-Certified or Eligible Pediatric Gastroenterologists***	
Pediatric Pathway	
12 Month Conditional Pathway – ***Only available to Existing Programs***	

OMB No. 0915-0184
Expiration Date: 05/31/2017

g) Transplant Experience (Post Fellowship)/Transplant Training (Fellowship):
List the name(s) of the transplant hospital(s), applicable dates, program director name(s), and the number of transplant patients for which the physician provided substantive patient care (pre-, peri- and post-operatively from the time of transplant).

Training and Experience	**Date** (MM/DD/YY)		**Transplant Hospital**	**Program Director**	**#LI Patients Followed**		
	Start	**End**			**Pre**	**Peri**	**Post**
Experience Post Fellowship							
Fellowship Training							

OMB No. 0915-0184
Expiration Date: 05/31/2017

h) Transplant Training/Experience:
If applicable, list how the physician fulfills the criteria for participating as an observer of liver transplants, liver procurements, the evaluation of the donor and donor process, and the management of at least 3 multiple organ donors.

Date From - To MM/DD/YY	**Transplant Hospital**	**# of LI Transplants Observed**	**# of LI Procurements Observed**	**# of LI Donors/ Donor Process**	**# of Multi-Organ Donors Observed Management**

i) Describe in detail the proposed primary physician's level of involvement in **this** transplant program as well as **prior** training and experience.

	Describe Level of Involvement in This Transplant Program	**Describe Prior Training/Experience**
Pre-Operative Patient Management (Patients With End Stage Liver Disease)		
Recipient Selection		
Donor Selection		
Histocompatibility and Tissue Typing		
Immediate Post-Operative and Continuing Inpatient Care		
Use of Immunosuppressive Therapy		
Differential Diagnosis of Liver Dysfunction in the Allograft Recipient		
Histologic Interpretation of Allograft Biopsies		
Interpretation of Ancillary Tests for Liver Dysfunction		
Long Term Outpatient Care		
Living Donor Transplantation (if applicable)		
Pediatric (if applicable)		

Coverage of Multiple Transplant Hospitals (if applicable)		
Additional Information:		

OMB No. 0915-0184
Expiration Date: 05/31/2017

Table 5: Primary Physician – Recipient Log (Sample)

Complete a separate form for each transplant hospital.

Organ:	
Name of proposed primary physician:	
Name of hospital where transplants were performed:	
Date range of physician's appointment/training: MM/DD/YY to MM/DD/YY	

List cases in date order. Patient ID should not be name or Social Security Number. Extend lines on log as needed.

#	Date of Transplant	Medical Record/OPTN ID #	Pre-Operative	Peri-Operative	Post-Operative	Comments
1						
2						
3						
4						
5						
6						
7						
8						
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21						
22						
23						
24						
25						

Director's Signature	**Date**
Print Name	

OMB No. 0915-0184
Expiration Date: 05/31/2017

Table 6: Primary Physician – Observation Log (Sample)

Organ:	
Name of proposed primary physician:	

In the tables below, document the physician's participation as an observer in organ transplants and procurements, as well as observing the selection and management of multiple organ donors that include the organ for which application is being submitted.

List cases in date order. Patient ID should not be name or Social Security Number. Extend lines on log as needed.

Transplants Observed

#	Date of Transplant	Medical Record/ OPTN ID #	Hospital
1			
2			
3			

Procurements Observed

#	Date of Procurement	Medical Record/ OPTN ID #	Donor Hospital
1			
2			
3			

Donor Selection and Management/Multi-Organ Donation

#	Date of Procurement	Medical Record/ OPTN ID #	Donor Hospital	Liver or Multi-organ?
1				
2				
3				

Part 3C: Section 2 – Personnel, Additional Physician(s) Instructions

Complete this section of the application to describe physicians involved in the program that are not designated as primary. For each physician, they should be designated as Additional as described below. Duplicate this section as needed.

Additional transplant physicians must be credentialed by the transplant hospital to provide transplant services and be able to independently manage the care of transplant patients.

1. Identify the additional transplant physician:

Name:

a) Provide the following dates (use MM/DD/YY):

Date of employment at this hospital:

b) Does the physician have FULL privileges at this hospital? (check one)

Yes	
No	

If the physician does **not** currently have full privileges:

Date full privileges to be granted (MM/DD/YY):
Explain the individual's current credentialing status, including any limitations on practice:

c) How much of the physician's professional time is spent on site at this hospital?

Percentage of professional time on site:
Number of hours per week:

d) How much of the physician's professional time is spent on site at other facilities (hospitals, health care facilities, and medical group practices)?

Facility Name	**Type**	**Location** (City, State)	**% Professional Time On Site**

e) List the physician's current board certification(s) below. If board certification is pending, indicate the date the exam has been scheduled. If the physician has been recertified, use that date. Provide a copy of the certification(s).

Board Certification Type	**Certification Effective Date/ Recertification Date** (MM/DD/YY)	**Certification Valid Through Date** (MM/DD/YY)	**Certificate Number**

Part 3D: Personnel - Director of Liver Transplant Anesthesia

Liver transplant programs must designate a director of liver transplant anesthesia who has expertise in the area of peri-operative care of liver transplant patients and can serve as an advisor to other members of the team.

Refer to the bylaws for necessary qualifications and requirements.

Designated Director: _____	**Y**	**N**
Has expertise in the area of peri-operative care of liver transplant patients and can serve as an advisor to other members of the team?		
Is a Diplomate of the American Board of Anesthesiology? (required)		
If no, foreign equivalent: _____ (required)		
Experienced in liver transplant anesthesia by one of the following ways:		
• Peri-operative care of at least 10 liver transplant recipients in combination with fellowship training in critical care medicine, cardiac anesthesiology or liver transplant fellowship **OR** • Within the last five years, experience in the peri-operative care of at least 20 liver transplant recipients in the operating room **NOTE:** *Experience acquired during postgraduate (residency) training does not count for this purpose.*		
Clinical Responsibilities		
Pre-operative assessment of transplant candidates		
Participation in candidate selection		
Intra operative management		
Post operative visits		
Participation on candidate selection committee		
Consultation preoperatively with subspecialists as needed		
Participate in M & M conferences and quality improvement initiatives		
Administrative Responsibilities		
Designated member of liver transplant team		
Responsible for establishing internal policies for anesthesiology participation in peri-operative care of liver transplant recipients		
Ensures policies developed in the context of institutional needs, liver transplant volume and quality initiatives		
Ensures policies establish a clear communication channel between the liver transplant anesthesiology service and services from other disciplines (for example, peri-operative consults, candidate selection, M & M conferences, quality improvement and intra-operative guidelines based on existing and published knowledge)		
Expectation: The Director of Liver Transplant Anesthesia should earn a minimum of 8 hours of credit in transplant related educational activities from the Council for Continuing Medical Education (ACCME®) Category I Continuing Medical Education (CME) within the most recent 3 year period.		

Director's Signature	**Date**
Print Name	

OMB No. 0915-0184
Expiration Date: 05/31/2017

Table 6: Certificate of Investigation

1. List all transplant surgeons and physicians currently involved in the program.

   a) This hospital has conducted its own peer review of all surgeons and physicians listed below to ensure compliance with applicable OPTN Bylaws Insert rows as needed.

Names of Surgeons*

Names of Physicians*

   b) If prior transgressions were identified has the hospital developed a plan to ensure that the improper conduct is not continued?

Yes	
No	
Not Applicable	

   c) If yes, what steps are being taken to correct the prior improper conduct or to ensure the improper conduct is not repeated in this program? Provide a copy of the plan.

I certify that this review was performed for each named surgeon and physician according to the hospital's peer review procedures.

Signature of Primary Surgeon	**Date**
Print Name	
Signature of Primary Physician	**Date**
Print Name	

OMB No. 0915-0184
Expiration Date: 05/31/2017

Table 7: Program Coverage Plan

Provide a copy of the current Program Coverage Plan and answer the questions below. The program coverage plan must be signed by either the:

a. OPTN/UNOS Representative;
b. Program Director(s); or
c. Primary Surgeon and the Primary Physician.

	Yes	**No**
Is this a single surgeon program?		
Is this a single physician program?		
If single surgeon or single physician, submit a copy of the patient notice or the protocol for providing patient notification.		
Does this transplant program have transplant surgeon(s) and physician(s) available 365 days a year, 24 hours a day, 7 days a week to provide program coverage?		
If the answer to the above question is "No," an explanation must be provided that justifies why the current level of coverage should be acceptable to the MPSC.		
Transplant programs shall provide patients with a written summary of the Program Coverage Plan at the time of listing and when there are any substantial changes in program or personnel. Has this program developed a plan for notification?		
Is a surgeon/physician available and able to be on the hospital premises to address urgent patient issues?		
A transplant surgeon or transplant physician may not be on call simultaneously for 2 transplant programs more than 30 miles apart unless circumstances have been reviewed and approved by the MPSC.		
Is a transplant surgeon readily available in a timely manner to facilitate organ acceptance, procurement, and implantation?		
Unless exempted by the MPSC for specific causal reasons, the primary transplant surgeon/primary transplant physician cannot be designated as the primary surgeon/primary transplant physician at more than one transplant hospital unless there are additional transplant surgeons/transplant physicians at each of those facilities. Is this program requesting an exemption? If yes, provide explanation below.		
Additional Information:		

Part 3: Pancreas Transplant Program

This application is for (check all that apply):

Pancreas Transplantation	
New Program	
Key Personnel Change	
Reactivation	

Table 1: OPTN Staffing Report

Member Code:	**Name of Hospital:**	
Main Program Phone Number:	**Main Program Fax Number:**	**Hospital URL:** http://www
Toll Free Phone Numbers for Patients:		**Hospital #:**

Refer to the staffing audit sent with this application and complete the table below for staff that are not captured on the staffing audit or to update information for current staff, including deleting (DEL) an individual. If you did not receive an audit with this application, complete the entire staffing report. Make sure to use individuals' full, legal names (middle name/initial also included when possible) to prevent duplicate entries within the UNOS Membership Database and UNet.

Identify the **transplant program medical and surgical director(s)**:

DEL	Name	Address	Phone	Fax	Email

Identify **primary surgeon and additional surgeons** who perform transplants for the program.

DEL	Name	Address	Phone	Fax	Email

Identify **other surgeons** who perform transplants for the program.

DEL	Name	Address	Phone	Fax	Email

Identify **primary physicians and additional physicians** who perform transplants for the program.

DEL	Name	Address	Phone	Fax	Email

Identify **other physicians** who perform transplants for the program.

DEL	Name	Address	Phone	Fax	Email

Identify the **transplant program administrator(s)/hospital administrative director(s)/manager(s)** who will be involved with this program. The * denotes the primary transplant administrator.

DEL	Name	Address	Phone	Fax	Email
	*				

Identify the **clinical transplant coordinator(s)** who will be involved with this program.

DEL	Name	Address	Phone	Fax	Email

Identify the **data coordinator(s)** who will be involved in this transplant program. The * denotes the primary data coordinator.

DEL	Name	Address	Phone	Fax	Email
	*				

Identify the **social worker(s)** who will be involved with this program.

DEL	Name	Address	Phone	Fax	Email

Identify the **pharmacist(s)** who will be involved with this program.

DEL	Name	Address	Phone	Fax	Email

Identify the **anesthesiologist(s)** who will be involved with this program. The * denotes the director of anesthesiology.

DEL	Name	Address	Phone	Fax	Email
	*				

Identify the **financial counselor(s)** who will be involved with this program.

DEL	Name	Address	Phone	Fax	Email

Identify the **QAPI team member(s)** who will be involved with this program.

DEL	Name	Address	Phone	Fax	Email

Identify **any other transplant staff** who will be involved with this program.

DEL	Name	Title	Address	Phone	Fax	Email

OMB No. 0915-0184
Expiration Date: 05/31/2017

Part 3A: Personnel – Transplant Program Director(s)

Identify the surgical and/or medical director(s) of the pancreas transplant program (submit a C.V. for the program director). Briefly describe the leadership responsibilities for each individual.

Name	Date of Appointment	Primary Areas of Responsibility

Part 3B, Section 1: Personnel – Surgical – Primary Surgeon

1. Identify the primary transplant surgeon:

Name:

a) Provide the following dates (use MM/DD/YY):

Date of employment at this hospital:
Date assumed role of primary surgeon:

b) Does the surgeon have FULL privileges at this hospital? (Check one)

Yes	
No	

If the surgeon does **not** currently have full privileges:

Date full privileges to be granted (MM/DD/YY):
Explain the individual's current credentialing status, including any limitations on practice:

c) How much of the surgeon's professional time is spent on site at this hospital?

Percentage of professional time on site:
Number of hours per week:

d) How much of the surgeon's professional time is spent on site at other facilities (hospitals, health care facilities, and medical group practices)?

Facility Name	**Type**	**Location** (City, State)	**% Professional Time On Site**

e) List the surgeon's current board certification(s) below. If board certification is pending, indicate the date the exam has been scheduled. If the surgeon has been recertified, use that date. Provide a copy of certification(s).

Board Certification Type	**Certification Effective Date / Recertification Date** (MM/DD/YY)	**Certification Valid Through Date** (MM/DD/YY)	**Certificate Number**

OMB No. 0915-0184
Expiration Date: 05/31/2017

f) Check the applicable pathway through which the surgeon will be proposed. Refer to the bylaws for the necessary qualifications and more specific descriptions of the required supporting documents.

Membership Criteria	
2-Year Transplant Fellowship	
Clinical Experience (Post Fellowship)	
Pediatric Pathway	

OMB No. 0915-0184
Expiration Date: 05/31/2017

g) Transplant Experience (Post Fellowship)/Training (Fellowship):
List the name(s) of the transplant hospital(s), applicable dates, program director name(s), and the number of transplants and procurements performed by the surgeon at each transplant hospital.

Training and Experience	ASTS Approved Program? Y/N	Date (MM/DD/YY)		Transplant Hospital	Program Director	# PA Transplants as Primary	# PA Transplants as First Assistant	# of PA Procurements as Primary or 1st Assistant
		Start	End					
Fellowship Training								
Experience Post Fellowship								

h) Describe in detail the proposed primary surgeon's level of involvement in **this** transplant program as well as **prior** training and experience.

	Describe Level of Involvement in This Transplant Program	**Describe Prior Training/Experience**
Pre-Operative Patient Management (Patients with Diabetes Mellitus)		
Recipient Selection		
Donor Selection		
Histocompatibility and Tissue Typing		
Transplant Surgery		
Immediate Post-Operative and Continuing Inpatient Care		
Post-Operative Immunosuppressive Therapy		
Differential Diagnosis of Pancreatic Dysfunction in the Allograft Recipient		
Histologic Interpretation of Allograft Biopsies		
Interpretation of Ancillary Tests for Pancreatic Dysfunction		
Long-Term Outpatient Follow-Up		
Pediatric (if applicable)		
Coverage of Multiple Transplant Hospitals (if applicable)		
Additional Information:		

OMB No. 0915-0184
Expiration Date: 05/31/2017

Table 2: Primary Surgeon - Transplant Log (Sample)

Complete a separate form for each transplant hospital.

Organ:	
Name of proposed primary surgeon:	
Name of hospital where transplants were performed:	
Date range of surgeon's appointment/training: MM/DD/YY to MM/DD/YY	

List cases in date order. Patient ID should not be name or Social Security Number. Extend lines on log as needed.

#	Date of Transplant	Medical Record/ OPTN Patient ID #	Primary Surgeon	1st Assistant
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				
21				
22				
23				
24				
25				
26				
27				
28				
29				
30				

Director's Signature	**Date**
Print Name	

OMB No. 0915-0184
Expiration Date: 05/31/2017

Table 3: Primary Surgeon - Procurement Log (Sample)

Organ:	
Name of proposed primary surgeon:	
Name of hospital where surgeon was employed when procurements were performed:	
Date range of surgeon's appointment/training: MM/DD/YY to MM/DD/YY	

List cases in date order. Patient ID should not be name or Social Security Number. Extend lines on log as needed.

#	Date of Procurement	Donor ID Number	Location of Donor (hospital)	Comments (LD/CAD/Multi-organ)
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				
21				
22				
23				
24				
25				
26				
27				
28				
29				
30				

Director's Signature	**Date**
Print Name	

OMB No. 0915-0184
Expiration Date: 05/31/2017

Part 3B, Section 3: Personnel – Additional Surgeon(s)

Complete this section of the application to describe surgeons involved in the program that are not designated as primary. For each surgeon, they should be designated as additional as described below. Duplicate this section as needed.

Additional transplant surgeons must be credentialed by the transplant hospital to provide transplant services and be able to independently manage the care of transplant patients, including performing the transplant operations and organ procurement procedures.

1. Identify the additional transplant surgeon:

Name:

a) Provide the following dates (use MM/DD/YY):

Date of employment at this hospital:

b) Does the surgeon have FULL privileges at this hospital? (Check one)

Yes	
No	

If the surgeon does **not** currently have full privileges:

Date full privileges to be granted (MM/DD/YY):
Explain the individual's current credentialing status, including any limitations on practice:

c) How much of the surgeon's professional time is spent on site at this hospital?

Percentage of professional time on site:
Number of hours per week:

d) How much of the surgeon's professional time is spent on site at other facilities (hospitals, health care facilities, and medical group practices)?

Facility Name	**Type**	**Location** (City, State)	**% Professional Time On Site**

OMB No. 0915-0184
Expiration Date: 05/31/2017

e) List the surgeon's current board certification below. If board certification is pending, indicate the date the exam has been scheduled. If the surgeon has been recertified, use that date. Provide a copy of the certifications(s).

Board Certification Type	**Certification Effective Date / Recertification Date** (MM/DD/YY)	**Certification Valid Through Date** (MM/DD/YY)	**Certificate Number**

OMB No. 0915-0184
Expiration Date: 05/31/2017

Part 3C: Section 1 - Medical Personnel, Primary Physician

1. Identify the primary transplant physician:

Name:

a) Provide the following dates (use MM/DD/YY):

Date of employment at this hospital:
Date assumed role of primary physician:

b) Does the physician have FULL privileges at this hospital? (Check one)

Yes	
No	

If the physician does **not** currently have full privileges:

Date full privileges to be granted (MM/DD/YY):
Explain the individual's current credentialing status, including any limitations on practice:

c) How much of the physician's professional time is spent on site at this hospital?

Percentage of professional time on site:
Number of hours per week:

d) How much of the physician's professional time is spent on site at other facilities (hospitals, health care facilities, and medical group practices)?

Facility Name	**Type**	**Location** (City, State)	**% Professional Time On Site**

e) List the physician's current board certification(s) below. If board certification is pending, indicate the date the exam has been scheduled. If the physician has been recertified, use that date. Provide a copy of the certifications(s)

Board Certification Type	**Certification Effective Date / Recertification Date** (MM/DD/YY)	**Certification Valid Through Date** (MM/DD/YY)	**Certificate Number**

f) Summarize how the physician's experience fulfills the membership criteria. Check the applicable pathway

through which the physician will be proposed. Refer to the bylaws for the necessary qualifications and more specific descriptions of the required supporting documents.

Membership Criteria	
12-Month Transplant Fellowship	
Clinical Experience Pathway (Post Fellowship)	
Pediatric Pathway	

OMB No. 0915-0184
Expiration Date: 05/31/2017

g) Transplant Experience (Post Fellowship)/Transplant Training (Fellowship):
List the name(s) of the transplant hospital(s), applicable dates, program director name(s), and the number of transplant patients for which the physician provided substantive patient care (pre-, peri- and post-operatively from the time of transplant).

Training and Experience	AST Approved Program? Y/N	Date (MM/DD/YY)		Transplant Hospital	Program Director	# PA Patients Followed		
		Start	End			Pre	Peri	Post
Fellowship Training								
Experience Post Fellowship								

OMB No. 0915-0184
Expiration Date: 05/31/2017

h) Transplant Training/Experience:
If applicable, list how the physician fulfills the criteria for participating as an observer of pancreas transplants, pancreas procurements, the evaluation of the donor and donor process, and the management of at least 3 multiple organ donors.

Date From - To MM/DD/YY	**Transplant Hospital**	**# of PA Transplants Observed**	**# of PA Procurements Observed**	**# of PA Donors/ Donor Process**	**# of Multi-Organ Donors Observed Management**

OMB No. 0915-0184
Expiration Date: 05/31/2017

i) Describe in detail the proposed primary physician's level of involvement in **this** transplant program as well as **prior** training and experience.

	Describe Level of Involvement in This Transplant Program	**Describe Prior Training/Experience**
Pre-Operative Patient Management (Patients with Diabetes Mellitus)		
Recipient Selection		
Donor Selection		
Histocompatibility and Tissue Typing		
Immediate Post-Operative and Continuing Inpatient Care		
Post-Operative Immunosuppressive Therapy		
Differential Diagnosis of Pancreatic Dysfunction in the Allograft Recipient		
Histologic Interpretation of Allograft Biopsies		
Interpretation of Ancillary Tests for Pancreatic Dysfunction		
Long-Term Outpatient Follow-up		
Pediatric (if applicable)		
Coverage of Multiple Transplant Hospitals (if applicable)		
Additional Information:		

OMB No. 0915-0184
Expiration Date: 05/31/2017

Table 5: Primary Physician – Recipient Log (Sample)

Complete a separate form for each transplant hospital.

Organ:	
Name of proposed primary physician:	
Name of hospital where transplants were performed:	
Date range of physician's appointment/training: MM/DD/YY to MM/DD/YY	

List cases in date order. Patient ID should not be name or Social Security Number. Extend lines on log as needed.

#	Date of Transplant	Medical Record/OPTN ID #	Pre-Operative	Peri-Operative	Post-Operative	Comments
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						
18						
19						
20						
21						
22						
23						
24						
25						

Director's Signature	**Date**
Print Name	

OMB No. 0915-0184
Expiration Date: 05/31/2017

Table 6: Primary Physician – Observation Log (Sample)

Organ:	
Name of proposed primary physician:	

In the tables below, document the physician's participation as an observer in organ transplants and procurements, as well as observing the selection and management of multiple organ donors that include the organ for which application is being submitted.

List cases in date order. Patient ID should not be name or Social Security Number. Extend lines on log as needed.

Transplants Observed

#	Date of Transplant	Medical Record / OPTN ID #	Hospital
1			
2			
3			

Procurements Observed

#	Date of Procurement	Medical Record / OPTN ID #	Donor Hospital
1			
2			
3			

Donor Selection and Management / Multi-Organ Donation

#	Date of Procurement	Medical Record / OPTN ID #	Donor Hospital	Multi-organ?
1				
2				
3				

OMB No. 0915-0184
Expiration Date: 05/31/2017

Part 3C: Section 2 – Personnel, Additional Physician(s)

Complete this section of the application to describe physicians involved in the program that are not designated as primary. For each physician, they should be designated as Additional as described below. Duplicate this section as needed.

Additional transplant physicians must be credentialed by the transplant hospital to provide transplant services and be able to independently manage the care of transplant patients.

1. Identify the additional transplant physician:

Name:

a) Provide the following dates (use MM/DD/YY):

Date of employment at this hospital:

b) Does physician have FULL privileges at this hospital? (Check one)

Yes	
No	

If the physician does **not** currently have full privileges:

Date full privileges to be granted (MM/DD/YY):
Explain the individual's current credentialing status, including any limitations on practice:

c) How much of the physician's professional time is spent on site at this hospital?

Percentage of professional time on site:
Number of hours per week:

d) How much of the physician's professional time is spent on site at other facilities (hospitals, health care facilities, and medical group practices)?

Facility Name	**Type**	**Location** (City, State)	**% Professional Time On Site**

e) List the physician's current board certification(s) below. If board certification is pending, indicate the date the exam has been scheduled. If the physician has been recertified, use that date. Provide a copy of the certifications(s)

Board Certification Type	**Certification Effective Date / Recertification Date** (MM/DD/YY)	**Certification Valid Through Date** (MM/DD/YY)	**Certificate Number**

OMB No. 0915-0184
Expiration Date: 05/31/2017

Table 7: Certificate of Investigation

1. List all transplant surgeons and physicians currently involved in the program.

   a) This hospital has conducted its own peer review of all surgeons and physicians listed below to ensure compliance with applicable OPTN Bylaws. Insert rows as needed.

Names of Surgeons

Names of Physicians

   b) If prior transgressions were identified has the hospital developed a plan to ensure that the improper conduct is not continued?

Yes	
No	
Not Applicable	

   c) If yes, what steps are being taken to correct the prior improper conduct or to ensure the improper conduct is not repeated in this program? Provide a copy of the plan.

I certify that this review was performed for each named surgeon and physician according to the hospital's peer review procedures.

Signature of Primary Surgeon	**Date**
Print Name	
Signature of Primary Physician	**Date**
Print Name	

OMB No. 0915-0184
Expiration Date: 05/31/2017

Table 8: Program Coverage Plan

Provide a copy of the current Program Coverage Plan and answer the questions below. The program coverage plan must be signed by either the:

a. OPTN/UNOS Representative;
b. Program Director(s); or
c. Primary Surgeon and the Primary Physician.

	Yes	No
Is this a single surgeon program?		
Is this a single physician program?		
If single surgeon or single physician, submit a copy of the patient notice or the protocol for providing patient notification		
Does this transplant program have transplant surgeon(s) and physician(s) available 365 days a year, 24 hours a day, 7 days a week to provide program coverage?		
If the answer to the above question is "No," an explanation must be provided that justifies why the current level of coverage should be acceptable to the MPSC.		
Transplant programs shall provide patients with a written summary of the Program Coverage Plan at the time of listing and when there are any substantial changes in program or personnel. Has this program developed a plan for notification?		
Is a surgeon/physician available and able to be on the hospital premises to address urgent patient issues?		
A transplant surgeon or transplant physician may not be on call simultaneously for 2 transplant programs more than 30 miles apart unless circumstances have been reviewed and approved by the MPSC.		
Is a transplant surgeon readily available in a timely manner to facilitate organ acceptance, procurement, and implantation?		
Unless exempted by the MPSC for specific causal reasons, the primary transplant surgeon/primary transplant physician cannot be designated as the primary surgeon/primary transplant physician at more than one transplant hospital unless there are additional transplant surgeons/transplant physicians at each of those facilities. Is this program requesting an exemption? If yes, provide explanation below.		
Additional Information:		

Part 3: Heart Transplant Program

This application is for (check all that apply):

Heart Transplantation	
New Program	
Key Personnel Change	
Reactivation	

Table 1: OPTN Staffing Report

Member Code:	**Name of Transplant Hospital:**	
Main Program Phone Number:	**Main Program Fax Number:**	**Hospital URL:** http://www
Toll Free Phone Number for Patients:	**Hospital Number:**	

Refer to the staffing audit sent with this application and complete the table below for staff that are not captured on the staffing audit or to update information for current staff, including deleting (DEL) an individual. If you did not receive an audit with this application, complete the entire staffing report. Add additional rows as necessary. Make sure to use individuals' full, legal names (middle name/initial also included when possible) to prevent duplicate entries within the UNOS Membership Database and UNet.

Identify the **transplant program medical and/or surgical director(s)**.

DEL	Name	Address	Phone	Fax	Email

Identify the **primary surgeon and additional surgeon(s)** who perform transplants for the program.

DEL	Name	Address	Phone	Fax	Email

Identify **other surgeon(s)** who perform transplants for the program.

DEL	Name	Address	Phone	Fax	Email

Identify the **primary physician and additional physicians** (internists) who participate in this transplant program.

DEL	Name	Address	Phone	Fax	Email

Identify **other physicians** (internists) who participate in this transplant program.

DEL	Name	Address	Phone	Fax	Email

Identify the **transplant program administrator(s) / hospital administrative director(s) / manager(s)** who will be involved with this program. The * denotes the primary transplant administrator.

DEL	Name	Address	Phone	Fax	Email
	*				

Identify the **clinical transplant coordinator(s)** who will be involved in this transplant program.

DEL	Name	Address	Phone	Fax	Email

Identify the **data coordinator(s)** who will be involved in this transplant program. The * denotes the primary data coordinator.

DEL	Name	Address	Phone	Fax	Email
	*				

Identify the **social worker(s)** who will be involved with this program.

DEL	Name	Address	Phone	Fax	Email

Identify the **pharmacist(s)** who will be involved with this program.

DEL	Name	Address	Phone	Fax	Email

Identify the **financial counselor(s)** who will be involved with this program.

DEL	Name	Address	Phone	Fax	Email

Identify the **anesthesiologists** who will be involved with this program. The * denotes the director of anesthesiology.

DEL	Name	Address	Phone	Fax	Email
	*				

Identify the **QAPI team members** who will be involved with this program.

DEL	Name	Address	Phone	Fax	Email

Identify **any other transplant staff** who will be involved with this program.

DEL	Name	Title	Address	Phone	Fax	Email

OMB No. 0915-0184
Expiration Date: 05/31/2017

Part 3A: Personnel – Transplant Program Director(s)

1. Identify the transplant program surgical and/or medical director(s) of the heart transplant program and submit a C.V. for each program director. Briefly describe the leadership responsibilities for each individual.

Name	Date of Appointment	Primary Areas of Responsibility

Part 3B, Section 1: Personnel – Surgical – Primary Surgeon

1. Identify the primary transplant surgeon:

Name:

a) Provide the following dates (use MM/DD/YY):

Date of employment at this hospital:
Date assumed role of primary surgeon:

b) Does the surgeon have FULL privileges at this hospital?

Yes	
No	

If the surgeon does **not** currently have full privileges:

Date full privileges to be granted (MM/DD/YY):
Explain the individual's current credentialing status, including any limitations on practice:

c) How much of the surgeon's professional time is spent on site at this hospital?

Percentage of professional time on site:
Number of hours per week:

d) How much of the surgeon's professional time is spent on site at other facilities (hospitals, health care facilities, and medical group practices)?

Facility Name	Type	Location (City, State)	% Professional Time On Site

e) List the surgeon's current board certification(s) below. If board certification is pending, indicate the date the exam has been scheduled. If individual has been recertified, use that date. Provide a copy of certification(s).

Certification Type	Certificate Effective Date (MM/DD/YY)	Certificate Valid Through Date (MM/DD/YY)	Certification Number

f) Check the applicable pathway(s) through which the surgeon will be proposed. Refer to the bylaws for the necessary qualifications and more specific descriptions of the required supporting documents.

Membership Criteria	
Cardiothoracic Surgery Residency Pathway	
Twelve-Month Heart Transplant Fellowship Pathway	
Clinical Experience Pathway	
Alternative Pathway for Predominately Pediatric Programs	

g) Transplant Experience (Post Fellowship) and Training (Fellowship): List the name(s) of the transplant hospital(s), applicable dates, program director name(s), and the number of transplants and procurements performed by the surgeon at each transplant hospital.

Training and Experience	**ABTS Approved Program? Y/N**	**Date** (MM/DD/YY)		**Transplant Hospital**	**Program Director**	**# of Transplants as Primary**		**# of Transplants as 1st Assistant**		**# of Procurements as Primary or 1st Assistant**	
		Start	**End**			**HR**	**HL**	**HR**	**HL**	**HR**	**HL**
Residency Training											
Fellowship Training											
Experience Post Fellowship											

h) Describe in detail the proposed primary surgeon's level of involvement in this transplant program as well as prior training and experience.

	Describe Level of Involvement in This Transplant Program	**Describe Prior Training/Experience**
Pre-Operative Patient Management		
Recipient Selection		
Donor Selection		
Transplant Surgery		
Post-Operative Hemodynamic Care		
Use of Mechanical Assist Devices		
Post-Operative Immunosuppressive Therapy		
Outpatient Follow-Up		
Coverage of Multiple Transplant Hospitals (if applicable)		
Additional Information		

Table 2: Primary Surgeon - Transplant Log (Sample)

Complete a separate form for each transplant hospital.

Organ:	
Name of proposed primary surgeon:	
Name of hospital where transplants were performed:	
Date range of surgeon's appointment/training: MM/DD/YY to MM/DD/YY	

List cases in date order. Extend lines on log as needed. Patient ID should not be name or Social Security Number.

#	Date of Transplant	Medical Record / OPTN ID #	Primary Surgeon	1st Assistant
1				
2				
3				
4				
5				
6				
7				
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Director's Signature	**Date**
Print Name	

OMB No. 0915-0184
Expiration Date: 05/31/2017

Table 3: Primary Surgeon - Procurement Log (Sample)

Organ:	
Name of proposed primary surgeon:	

List cases in date order. Extend lines on log as needed. Patient ID should not be name or Social Security Number.

#	Date of Procurement	Donor ID Number	Location of Donor (Hospital)	Comments (LD/CAD/Multi-Organ)
1				
2				
3				
4				
5				
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Director's Signature	**Date**
Print Name	

OMB No. 0915-0184
Expiration Date: 05/31/2017

Part 3B, Section 2: Personnel – Additional Surgeon(s)

Complete this section to describe surgeons involved in the program that are not designated as primary. For each surgeon, they should be designated as additional as described below. Duplicate this section as needed.

Additional transplant surgeons must be credentialed by the transplant hospital to provide transplant services and be able to independently manage the care of transplant patients, including performing the transplant operations and organ procurement procedures.

1. Identify the additional transplant surgeon:

Name:

a) Provide the following dates (use MM/DD/YY):

Date of employment at this hospital:

b) Does the surgeon have FULL privileges at this hospital?

Yes	
No	

If the surgeon does **not** currently have full privileges:

Date full privileges to be granted (MM/DD/YY):
Explain the individual's current credentialing status, including any limitations on practice:

c) How much of the surgeon's professional time is spent on site at this hospital?

Percentage of professional time on site:
Number of hours per week:

d) How much of the surgeon's professional time is spent on site at other facilities (hospitals, health care facilities, and medical group practices)?

Facility Name	Type	Location (City, State)	% Professional Time On Site

e) List the surgeon's current board certification(s) below. If board certification is pending, indicate the date the exam has been scheduled. If the surgeon has been recertified, use that date.

Board Certification Type	**Certification Effective Date / Recertification Date** (MM/DD/YY)	**Certification Valid Through Date** (MM/DD/YY)	**Certificate Number**

Part 3C, Section 1: Personnel – Medical – Primary Physician

1. Identify the primary transplant physician:

Name:

a) Provide the following dates (use MM/DD/YY):

Date of employment at this hospital:
Date assumed role of primary physician:

b) Does the physician have FULL privileges at this hospital? (check one)

Yes	
No	

If the physician does **not** currently have full privileges:

Date full privileges to be granted (MM/DD/YY):
Explain the physician's current credentialing status, including any limitations on practice:

c) How much of the physician's professional time is spent on site at this hospital?

Percentage of professional time on site:
Number of hours per week:

d) How much of the physician's professional time is spent on site at other facilities (hospitals, health care facilities, and medical group practices)?

Facility Name	Type	Location (City, State)	% Professional Time On Site

e) List the physician's current board certification(s) below. If board certification is pending, indicate the date the exam has been scheduled. If the physician has been recertified, use that date. Also provide a copy of the certification(s).

Board Certification Type	Certification Effective Date / Recertification Date (MM/DD/YY)	Certification Valid Through Date (MM/DD/YY)	Certificate Number

f) Check the applicable pathway(s) through which the physician will be proposed. Refer to the bylaws for the necessary qualifications and more specific descriptions of the required supporting documents.

Membership Criteria	
Twelve-Month Transplant Cardiology Fellowship Pathway	
Clinical Experience	
Alternate Pathway for Predominately Pediatric Programs	
Conditional Approval	

g) Transplant Experience (Post Fellowship) and Training (Fellowship): List the name(s) of the transplant hospital(s), applicable dates, program director name(s), and the number of transplant patients for which the physician provided substantive patient care (pre-, peri- and post-operatively from the time of transplant).

Training and Experience	**Date** (MM/DD/YY)		**Transplant Hospital**	**Program Director**	**# Heart Patients Followed**			**# Heart/Lung Patients Followed**		
	Start	**End**			**Pre**	**Peri**	**Post**	**Pre**	**Peri**	**Post**
Fellowship Training										
Experience Post Fellowship										

h) Training/Experience: If applicable, list how the physician fulfills the criteria for participating as an observer of heart procurements, heart transplants, the evaluation of the donor and donor process, and management of at least 3 multiple organ donors which include the heart and/or heart/lung.

Date From - To (MM/DD/YY)	**Transplant Hospital**	**# of HR Procurements Observed**	**# of HR Transplants Observed**	**# of HR Donors/ Donor Process**	**# of Multi-Organ Donors Observed Management**

i) Describe in detail the proposed primary physician's level of involvement in **this** transplant program as well as **prior** training and experience.

	Describe Level of Involvement in This Transplant Program	**Describe Prior Training/Experience**
Candidate Evaluation Process		
Pre- and Post-Operative Hemodynamic Care		
Post-Operative Immunosuppressive Therapy		
Long-Term Outpatient Follow-Up		
Care of Acute and Chronic Heart Failure		
Use of Mechanical Assist Devices		
Donor Selection		
Recipient Selection		
Histologic Interpretation and Grading of Myocardial Biopsies for Rejection		
Coverage of Multiple Transplant Hospitals (if		

applicable)		
Additional Information		

OMB No. 0915-0184
Expiration Date: 05/31/2017

Table 6: Primary Physician – Recipient Log (Sample)

Organ:	
Name of proposed primary physician:	
Name of transplant hospital where transplants were performed:	
Date range of physician's appointment/training: MM/DD/YY to MM/DD/YY	

List cases in date order. Patient ID should not be name or Social Security Number. Extend lines on log as needed.

#	Date of Transplant	Medical Record/ OPTN ID #	Pre-Operative	Peri-Operative	Post-Operative	Comments
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
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Director's Signature	**Date**
Print Name	

OMB No. 0915-0184
Expiration Date: 05/31/2017

Table 7: Primary Physician – Observation Log (Sample)

Organ:	
Name of proposed primary physician:	

In the tables below, document the physician's participation as an observer in organ transplants and procurements, as well as observing the selection and management of multiple organ donors that include the organ for which application is being submitted. *List cases in date order*. *Patient ID should not be name or Social Security Number. Extend lines on log as needed.*

Transplants Observed

#	Date of Transplant	Medical Record / OPTN ID #	Hospital
1			
2			
3			
4			
5			

Procurements Observed

#	Date of Procurement	Medical Record / OPTN ID #	Donor Hospital
1			
2			
3			
4			
5			

Donor Selection and Management

#	Date of Procurement	Medical Record / OPTN ID #	Donor Hospital	Heart or Multi-Organ
1				
2				
3				
4				
5				

Part 3C, Section 2: Personnel – Additional Physician(s)

Complete this section to describe physicians involved in the program that are not designated as primary. For each physician, they should be designated as additional as described below. Duplicate this section as needed.

Additional transplant physicians must be credentialed by the transplant hospital to provide transplant services and be able to independently manage the care of transplant patients.

1. Identify the additional physician:

Name:

a) Provide the following dates (use MM/DD/YY):

Date of employment at this hospital:

b) Does the physician have FULL privileges at this hospital? (check one)

Yes	
No	

If the physician does **not** currently have full privileges:

Date full privileges to be granted (MM/DD/YY):
Explain the physician's current credentialing status, including any limitations on practice:

c) How much of the physician's professional time is spent on site at this hospital?

Percentage of professional time on site:
Number of hours per week:

d) How much of the physician's professional time is spent on site at other facilities (hospitals, health care facilities, and medical group practices)?

Facility Name	Type	Location (City, State)	% Professional Time On Site

e) List the physician's current board certification(s) below. If board certification is pending, indicate the date the exam has been scheduled. If the physician has been recertified, use that date. Also provide a copy of the certification(s).

Board Certification Type	Certification Effective Date / Recertification Date (MM/DD/YY)	Certification Valid Through Date (MM/DD/YY)	Certificate Number

OMB No. 0915-0184
Expiration Date: 05/31/2017

Table 8: Certificate of Investigation

1. List all transplant surgeons and physicians currently involved in the program.

   a) This hospital has conducted its own peer review of all surgeons and physicians listed below to ensure compliance with applicable OPTN/UNOS bylaws. Expand rows as needed.

Names of Surgeons

Names of Physicians

   b) If prior transgressions were identified, has the hospital developed a plan to ensure that the improper conduct is not continued?

Yes	
No	
Not Applicable	

   If yes, what steps are being taken to correct the prior improper conduct or to ensure the improper conduct is not repeated in this program? Provide a copy of the plan.

I certify that this review was performed for each named surgeon and physician according to the hospital's peer review procedures.

Signature of Primary Surgeon	**Date**
Print Name	
Signature of Primary Physician	**Date**
Print Name	

OMB No. 0915-0184
Expiration Date: 05/31/2017

Table 9: Program Coverage Plan

1. **Provide a copy of the current Program Coverage Plan** and answer the questions below. The program coverage plan must be signed by either the:

   a. OPTN/UNOS Representative
   b. Program Director(s)
   c. Primary Surgeon and Primary Physician

	Yes	No
Is this a single surgeon program?		
Is this a single physician program?		
If single surgeon or single physician, submit a copy of the patient notice or the protocol for providing patient notification.		
Does this transplant program have transplant surgeon(s) and physician(s) available 365 days a year, 24 hours a day, 7 days a week to provide program coverage?		
If the answer to the above question is "No," an explanation must be provided that justifies why the current level of coverage should be acceptable to the MPSC.		
Transplant programs shall provide patients with a written summary of the Program Coverage Plan at the time of listing and when there are any substantial changes in program or personnel. Has this program developed a plan for notification?		
Is a surgeon/physician available and able to be on the hospital premises to address urgent patient issues?		
A transplant surgeon or transplant physician may not be on call simultaneously for two transplant programs more than 30 miles apart unless circumstances have been reviewed and approved by the MPSC.		
Is a transplant surgeon readily available in a timely manner to facilitate organ acceptance, procurement, and implantation?		
Unless exempted by the MPSC for specific causal reasons, the primary transplant surgeon/primary transplant physician cannot be designated as the primary surgeon/primary transplant physician at more than one transplant hospital unless there are additional transplant surgeons/transplant physicians at each of those facilities. Is this program requesting an exemption? If yes, provide explanation below.		
Additional information:		

Part 3: Lung Transplant Program

This application is for (check all that apply):

Lung Transplantation	
New Program	
Key Personnel Change	
Reactivation	

Table 1: OPTN Staffing Report

Member Code:	**Name of Transplant Hospital:**	
Main Program Phone Number:	**Main Program Fax Number:**	**Hospital URL:** http://www
Toll Free Phone Number for Patients:	**Hospital Number:**	

Refer to the staffing audit sent with this application and complete the table below for staff that are not captured on the staffing audit or to update information for current staff, including deleting (DEL) an individual. If you did not receive an audit with this application, complete the entire staffing report. Add additional rows as necessary. Make sure to use individuals' full, legal names (middle name/initial also included when possible) to prevent duplicate entries within the UNOS Membership Database and UNet.

Identify the **transplant program medical and/or surgical director(s)**.

DEL	Name	Address	Phone	Fax	Email

Identify the **primary surgeon and additional surgeon(s)** who perform transplants for the program.

DEL	Name	Address	Phone	Fax	Email

Identify **other surgeon(s)** who perform transplants for the program.

DEL	Name	Address	Phone	Fax	Email

Identify the **primary physician and additional physicians** (internists) who participate in this transplant program.

DEL	Name	Address	Phone	Fax	Email

Identify **other physicians** (internists) who participate in this transplant program.

DEL	Name	Address	Phone	Fax	Email

Identify the **transplant program administrator(s)/hospital administrative director(s)/manager(s)** who will be involved with this program. The * denotes the primary transplant administrator.

DEL	Name	Address	Phone	Fax	Email
	*				

Identify the **clinical transplant coordinator(s)** who will be involved in this transplant program.

DEL	Name	Address	Phone	Fax	Email

Identify the **data coordinator(s)** who will be involved in this transplant program. The * denotes the primary data coordinator.

DEL	Name	Address	Phone	Fax	Email
	*				

Identify the **social worker(s)** who will be involved with this program.

DEL	Name	Address	Phone	Fax	Email

Identify the **pharmacist(s)** who will be involved with this program.

DEL	Name	Address	Phone	Fax	Email

Identify the **financial counselor(s)** who will be involved with this program.

DEL	Name	Address	Phone	Fax	Email

Identify the **anesthesiologists** who will be involved with this program. The * denotes the director of anesthesiology.

DEL	Name	Address	Phone	Fax	Email
	*				

Identify the **QAPI team members** who will be involved with this program

DEL	Name	Address	Phone	Fax	Email

Identify **any other transplant staff** who will be involved with this program.

DEL	Name	Title	Address	Phone	Fax	Email

OMB No. 0915-0184
Expiration Date: 05/31/2017

Part 3A: Personnel – Transplant Program Director(s)

Identify the surgical and/or medical director(s) of the lung transplant program and submit a CV for each program director. Briefly describe the leadership responsibilities for each individual.

Name	Date of Appointment	Primary Areas of Responsibility

Part 3B: Section 1 - Surgical Personnel, Primary Surgeon

1. Identify the primary transplant surgeon:

Name:

a) Provide the following dates (use MM/DD/YY):

Date of employment at this hospital:
Date assumed role of primary surgeon:

b) Does the surgeon have FULL privileges at this hospital?

Yes	
No	

If the surgeon does **not** currently have full privileges:

Date full privileges to be granted (MM/DD/YY):
Explain the individual's current credentialing status, including any limitations on practice:

c) How much of the surgeon's professional time is spent on site at this hospital?

Percentage of professional time on site:
Number of hours per week:

d) How much of the surgeon's professional time is spent on site at other facilities (hospitals, health care facilities, and medical group practices)?

Facility Name	Type	Location (City, State)	% Professional Time On Site

e) List the surgeon's current board certification(s) below. If board certification is pending, indicate the date the exam has been scheduled. If individual has been recertified, use that date. Also provide a copy of certification(s).

Certification Type	Certificate Effective Date (MM/DD/YY)	Certificate Valid Through Date (MM/DD/YY)	Certification Number

f) Check the applicable pathway(s) through which the surgeon will be proposed. Refer to the bylaws for the necessary qualifications and more specific descriptions of the required supporting documents.

Membership Criteria	
Cardiothoracic Surgery Residency Pathway	
Twelve-Month Lung Transplant Fellowship Pathway	
Clinical Experience Pathway	
Alternative Pathway for Predominately Pediatric Programs	

g) Transplant Experience (Post Fellowship) and Training (Fellowship): List the name(s) of the transplant hospital(s), applicable dates, program director name(s), and the number of transplants and procurements performed by the surgeon at each transplant hospital.

Training and Experience	**ABTS Approved Program? Y/N**	**Date** (MM/DD/YY)		**Transplant Hospital**	**Program Director**	**# of Transplants as Primary**		**# of Transplants as 1st Assistant**		**# of Procurements as Primary or 1st Assistant**	
		Start	**End**			**LU**	**HL**	**LU**	**HL**	**LU**	**HL**
Residency											
Fellowship Training											
Experience Post Fellowship											

OMB No. 0915-0184
Expiration Date: 05/31/2017

h) Describe in detail the proposed primary surgeon's level of involvement in this transplant program as well as prior training and experience.

	Describe Level of Involvement in This Transplant Program	**Describe Prior Training/Experience**
Care of Acute and Chronic Lung Failure		
Cardiopulmonary Bypass		
Donor Selection		
Recipient Selection		
Pre- and Postoperative Ventilator Care		
Transplant Surgery		
Postoperative Immunosuppressive Therapy		
Histologic Interpretation and Grading of Lung Biopsies for Rejection		
Long-Term Outpatient follow-Up		
Coverage of Multiple Transplant Hospitals (if applicable)		
Additional Information		

Table 2: Primary Surgeon - Transplant Log (Sample)

Complete a separate form for each transplant hospital.

Organ:	
Name of proposed primary surgeon:	
Name of hospital where transplants were performed:	
Date range of surgeon's appointment/training: MM/DD/YY to MM/DD/YY	

List cases in date order. Extend lines on log as needed. Patient ID should not be name or Social Security Number.

#	Date of Transplant	Medical Record/ OPTN ID #	Primary Surgeon	1st Assistant
1				
2				
3				
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Director's Signature	**Date**
Print Name	

Table 3: Primary Surgeon - Procurement Log (Sample)

Organ:	
Name of proposed primary surgeon:	

List cases in date order. Extend lines on log as needed. Patient ID should not be name or Social Security Number.

#	Date of Procurement	Donor ID Number	Location of Donor (Hospital)	Comments (LD/CAD/Multi-Organ)
1				
2				
3				
4				
5				
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Director's Signature	**Date**
Print Name	

OMB No. 0915-0184
Expiration Date: 05/31/2017

Part 3B: Section 2 – Personnel, Additional Surgeon(s)

Complete this section to describe surgeons involved in the program that are not designated as primary. For each surgeon, they should be designated as additional as described below. Duplicate this section as needed.

Additional transplant surgeons must be credentialed by the transplant hospital to provide transplant services and be able to independently manage the care of transplant patients, including performing the transplant operations and organ procurement procedures.

1. Identify the additional transplant surgeon:

Name:

a) Provide the following dates (use MM/DD/YY):

Date of employment at this hospital:

b) Does the surgeon have FULL privileges at this hospital?

Yes	
No	

If the surgeon does **not** currently have full privileges:

Date full privileges to be granted (MM/DD/YY):
Explain the individual's current credentialing status, including any limitations on practice:

c) How much of the surgeon's professional time is spent on site at this hospital?

Percentage of professional time on site:
Number of hours per week:

d) How much of the surgeon's professional time is spent on site at other facilities (hospitals, health care facilities, and medical group practices)?

Facility Name	Type	Location (City, State)	% Professional Time On Site

e) List the surgeon's current board certification(s) below. If board certification is pending, indicate the date the exam has been scheduled. If the surgeon has been recertified, use that date.

Board Certification Type	**Certification Effective Date / Recertification Date** (MM/DD/YY)	**Certification Valid Through Date** (MM/DD/YY)	**Certificate Number**

Part 3C: Section 1 – Medical Personnel, Primary Physician

1. Identify the primary transplant physician:

Name:

a) Provide the following dates (use MM/DD/YY):

Date of employment at this hospital:
Date assumed role of primary physician:

b) Does the physician have FULL privileges at this hospital? (check one)

Yes	
No	

If the physician does **not** currently have full privileges:

Date full privileges to be granted (MM/DD/YY):
Explain the physician's current credentialing status, including any limitations on practice:

c) How much of the physician's professional time is spent on site at this hospital?

Percentage of professional time on site:
Number of hours per week:

d) How much of the physician's professional time is spent on site at other facilities (hospitals, health care facilities, and medical group practices)?

Facility Name	Type	Location (City, State)	% Professional Time On Site

e) List the physician's current board certification(s) below. If board certification is pending, indicate the date the exam has been scheduled. If the physician has been recertified, use that date. Also provide a copy of the certification(s).

Board Certification Type	Certification Effective Date / Recertification Date (MM/DD/YY)	Certification Valid Through Date (MM/DD/YY)	Certificate Number

f) Check the applicable pathway(s) through which the physician will be proposed. Refer to the bylaws for the necessary qualifications and more specific descriptions of the required supporting documents.

Membership Criteria	
Twelve-Month Transplant Cardiology Fellowship Pathway	
Clinical Experience	
Alternate Pathway for Predominately Pediatric Programs	
Conditional Approval	

g) Transplant Experience (Post Fellowship) and Training (Fellowship): List the name(s) of the transplant hospital(s), applicable dates, program director name(s), and the number of transplant patients for which the physician provided substantive patient care (pre-, peri- and post-operatively from the time of transplant).

Training and Experience	**Date** (MM/DD/YY)		**Transplant Hospital**	**Program Director**	**# Lung Patients Followed**			**# Heart/Lung Patients Followed**		
	Start	**End**			**Pre**	**Peri**	**Post**	**Pre**	**Peri**	**Post**
Experience Post Fellowship										
Fellowship Training										

h) Training/Experience: If applicable, list how the physician fulfills the criteria for participating as an observer of lung procurements, lung transplants, the evaluation of the donor and donor process, and management of at least 3 multiple organ donors which include the lung and/or heart/lung.

Date From - To (MM/DD/YY)	**Transplant Hospital**	**# of LU Procurements Observed**	**# of LU Transplants Observed**	**# of LU Donors / Donor Process**	**# of Multi-Organ Donors Observed Management**

OMB No. 0915-0184
Expiration Date: 05/31/2017

i) Describe in detail the proposed primary physician's level of involvement in **this** transplant program as well as **prior** training and experience.

	Describe Level of Involvement in This Transplant Program	**Describe Prior Training/Experience**
Candidate Evaluation Process		
Care of Acute and Chronic Lung Failure		
Cardiopulmonary Bypass		
Donor Selection		
Recipient Selection		
Pre- and Postoperative Ventilator Care		
Postoperative Immunosuppressive Therapy		
Histologic Interpretation and Grading of Lung Biopsies for Rejection		
Long-Term Outpatient Follow-Up		
Coverage of Multiple Transplant Hospitals (if applicable)		
Additional Information		

OMB No. 0915-0184
Expiration Date: 05/31/2017

Table 6: Primary Physician – Recipient Log (Sample)

Organ:	
Name of proposed primary physician:	
Name of transplant hospital where transplants were performed:	
Date range of physician's appointment/training: MM/DD/YY to MM/DD/YY	

List cases in date order. Patient ID should not be name or Social Security Number. Extend lines on log as needed.

#	Date of Transplant	Medical Record/ OPTN ID #	Pre-Operative	Peri-Operative	Post-Operative	Comments
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
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29						
30						

Director's Signature	**Date**
Print Name	

OMB No. 0915-0184
Expiration Date: 05/31/2017

Table 7: Primary Physician – Observation Log (Sample)

Organ:	
Name of proposed primary physician:	

In the tables below, document the physician's participation as an observer in organ transplants and procurements, as well as observing the selection and management of multiple organ donors that include the organ for which application is being submitted. *List cases in date order. Patient ID should not be name or Social Security Number. Extend lines on log as needed.*

Transplants Observed

#	Date of Transplant	Medical Record / OPTN ID #	Hospital
1			
2			
3			
4			
5			

Procurements Observed

#	Date of Procurement	Medical Record / OPTN ID #	Donor Hospital
1			
2			
3			
4			
5			

Donor Selection and Management

#	Date of Procurement	Medical Record / OPTN ID #	Donor Hospital	Lung, Heart/Lung, or Multi-Organ
1				
2				
3				
4				
5				

Part 3C: Section 2 – Personnel, Additional Physician(s)

Complete this section to describe physicians involved in the program that are not designated as primary. For each physician, they should be designated as additional as described below. Duplicate this section as needed.

Additional transplant physicians must be credentialed by the transplant hospital to provide transplant services and be able to independently manage the care of transplant patients.

1. Identify the additional transplant physician:

Name:

a) Provide the following dates (use MM/DD/YY):

Date of employment at this hospital:

b) Does the physician have FULL privileges at this hospital? (check one)

Yes	
No	

If the physician does **not** currently have full privileges:

Date full privileges to be granted (MM/DD/YY):
Explain the physician's current credentialing status, including any limitations on practice:

c) How much of the physician's professional time is spent on site at this hospital?

Percentage of professional time on site:
Number of hours per week:

d) How much of the physician's professional time is spent on site at other facilities (hospitals, health care facilities, and medical group practices)?

Facility Name	Type	Location (City, State)	% Professional Time On Site

e) List the physician's current board certification(s) below. If board certification is pending, indicate the date the exam has been scheduled. If the physician has been recertified, use that date. Also provide a copy of the certification(s).

Board Certification Type	Certification Effective Date/ Recertification Date (MM/DD/YY)	Certification Valid Through Date (MM/DD/YY)	Certificate Number

OMB No. 0915-0184
Expiration Date: 05/31/2017

Table 8: Certificate of Investigation

1. List all transplant surgeons and physicians currently involved in the program.

   a) This hospital has conducted its own peer review of all surgeons and physicians listed below to ensure compliance with applicable OPTN/UNOS bylaws. Insert rows as needed.

Names of Surgeons

Names of Physicians

   b) If prior transgressions were identified, has the hospital developed a plan to ensure that the improper conduct is not continued?

Yes	
No	
Not Applicable	

   c) If yes, what steps are being taken to correct the prior improper conduct or to ensure the improper conduct is not repeated in this program? Provide a copy of the plan.

I certify that this review was performed for each named surgeon and physician according to the hospital's peer review procedures.

Signature of Primary Surgeon	**Date**
Print Name	
Signature of Primary Physician	**Date**
Print Name	

OMB No. 0915-0184
Expiration Date: 05/31/2017

Table 9: Program Coverage Plan

Provide a copy of the current Program Coverage Plan and answer the questions below. The program coverage plan must be signed by either the:

a. OPTN/UNOS Representative
b. Program Director(s)
c. Primary Surgeon and Primary Physician

	Yes	No
Is this a single surgeon program?		
Is this a single physician program?		
If single surgeon or single physician, submit a copy of the patient notice or the protocol for providing patient notification.		
Does this transplant program have transplant surgeon(s) and physician(s) available 365 days a year, 24 hours a day, 7 days a week to provide program coverage?		
If the answer to the above question is "No," an explanation must be provided that justifies why the current level of coverage should be acceptable to the MPSC.		
Transplant programs shall provide patients with a written summary of the Program Coverage Plan at the time of listing and when there are any substantial changes in program or personnel. Has this program developed a plan for notification?		
Is a surgeon/physician available and able to be on the hospital premises to address urgent patient issues?		
A transplant surgeon or transplant physician may not be on call simultaneously for two transplant programs more than 30 miles apart unless circumstances have been reviewed and approved by the MPSC.		
Is a transplant surgeon readily available in a timely manner to facilitate organ acceptance, procurement, and implantation?		
Unless exempted by the MPSC for specific causal reasons, the primary transplant surgeon/primary transplant physician cannot be designated as the primary surgeon/primary transplant physician at more than one transplant hospital unless there are additional transplant surgeons/transplant physicians at each of those facilities. Is this program requesting an exemption? If yes, provide explanation below.		
Additional information:		

OMB No. 0915-0184
Expiration Date: 05/31/2017

Part 4: Facilities- Pancreas Islet Transplant Program

This section must be completed when applying for a new program or reactivating an existing program.

1. Indicate below the anticipated start date that the transplant program will become operational.

[Insert detailed response here. Table will expand automatically]

2. Does this hospital presently have an OPTN approved pancreas transplant program?

Yes	
No	

The program must document adequate clinical and laboratory facilities for pancreatic islet transplantation as defined by current Food and Drug Administration (FDA) regulations. The program must also document that the required Investigational New Drug (IND) application is in effect as required by the FDA.

Provide the following:

- Documentation that verifies that the program has adequate clinical and laboratory facilities for pancreatic islet transplantation as defined by the current regulations provided by the Food and Drug Administration (FDA).
- Copy of the transplant hospital's IND application form and a copy of the letter from the FDA that verifies receipt of the application.
- Copy of written documentation provided by the FDA that confirms the active status of the IND (if received by transplant hospital at the time of OPTN application submission).
- Letter of agreement or contract with the transplant hospital's OPO that specifically indicates it will provide the pancreas for islet cell transplantation.
- If islet cells are isolated and processed at a location other than the transplant facility, provide the name(s) of the processor(s) and any available arrangement documentation.

OMB No. 0915-0184
Expiration Date: 05/31/2017

Part 5: Supporting Personnel

1. Provide a CV for the physician qualified to cannulate the portal system under direction of the transplant surgeon.

Name of designated physician:

2. Verify that the program has access to the personnel listed below.

	Yes	No
A board-certified endocrinologist		
A physician, administrator, or technician with experience in compliance with FDA regulations.		
A laboratory-based researcher with experience in pancreatic islet isolation and transplantation		

OMB No. 0915-0184
Expiration Date: 05/31/2017

Part 6: Programs Not Located at an Approved Pancreas Transplant Hospital

Refer to the bylaws for the requirements regarding a designated pancreas islet transplant program that is not located in a hospital with an approved pancreas transplant program.

1. There must be an affiliation with an OPTN approved pancreas transplant program, including on site admitting privileges at this applicant hospital for the affiliated hospital's primary pancreas transplant surgeon and physician. Provide a hospital credentialing letter for the primary pancreas transplant surgeon and physician at the applicant hospital.

Name of affiliated transplant hospital:

a) Designated primary pancreas transplant surgeon

Name:
Percentage of time on site:

b) Designated primary pancreas transplant physician.

Name:
Percentage of time on site:

2. Describe the availability of the above qualified personnel to address pre, peri-, and post-operative care issues regardless of the treatment option ultimately selected.

[Insert response here, table will expand automatically.]

3. Provide a copy of the written protocols that demonstrate the program's commitment and ability to counsel patients regarding all their options for appropriate medical treatment for diabetes.

OMB No. 0915-0184
Expiration Date: 05/31/2017

Part 4: Living Donor Recoveries

Complete this section if applying for initial approval for living donor recoveries.

It is recognized that in the case of pediatric living donor recoveries, the living organ donation may occur at a hospital that is distinct from the approved transplant hospital. If this program performs pediatric transplants, list any other hospitals where the donor evaluation and surgery may routinely occur.

Hospital Name	Location

PART 4: Section 1 - Other Staff and Resources

1. How does the hospital assess that the short and long term risks for the potential living donor are acceptable to the medical staff at the transplant hospital and the donor? The response needs to address the following: evaluation, consent, surgical risk, and long-term donor considerations.

[Insert response here, table will expand automatically.]

2. Mental Health and Social Support Services: Identify the designated members of the transplant team who have primary responsibility for coordinating the psychosocial needs of living donors. Describe their role in this process. (Insert rows as needed.)

Name	Role in Providing Support to Living Donors

3. Does the program have the ability to perform a psychosocial assessment of the donor to:

	Yes	No
Make an informed decision?		
Affirm voluntary nature of proceeding with the evaluation and donation?		

4. Describe how the program meets the requirement for having an Independent Donor Advocate (IDA) who is not involved with the potential recipient evaluation and who is independent of the decision to transplant the potential recipient.

[Insert response here, table will expand automatically.]

OMB No. 0915-0184
Expiration Date: 05/31/2017

Part 4, Section 2: Living Donor Recoveries – Protocols

Transplant programs that perform living donor recoveries must demonstrate that they have written protocols as listed below. Submission of actual protocol is not required as a part of this application.

Written protocols must address at a minimum the areas listed below:	**Included in Protocol?**	
	Yes	**No**
Protocols addressing all phases of living donation process: • Evaluation • Pre-Operative • Operative • Post-Operative care • Submission of follow up forms		
IDA – descriptions of duties and responsibilities: • Promotes the best interests of the potential living donor • Advocates the rights of the potential living donor • Assists the potential donor in obtaining and understanding information regarding the consent process, evaluation process, surgical procedure, and benefit and need for follow-up		
Medical evaluation by a physician and/or surgeon experienced in living donation to: • Assess and minimize risks to the potential donor post-donation, which shall include a screen for any evidence of occult renal and infectious disease and medical co-morbidities, which may cause renal disease		
Psychosocial Evaluation of the potential living donor by a psychiatrist, psychologist, or social worker with experience in transplantation to: • Determine decision making capacity • Screen for any pre-existing psychiatric illness • Evaluate any potential coercion		
Screening for evidence of transmissible diseases such as cancers and infections		
Anatomic assessment of the suitability of the organ for transplant purposes		
Informed Consent for Donor Evaluation Process: • Discussion of the potential risks of the procedure including the medical, psychological, and financial risks associated with being a living donor • Assurance that all communication between the potential donor and the transplant center will remain confidential • Discussion of the potential donor's right to opt out at any time during the donation process • Discussion that the medical evaluation or donation may impact the potential donor's ability to obtain health, life, and disability insurance • Disclosure by the transplant center that it is required, at a minimum, to submit living donor follow-up forms addressing the health information of each living donor at 6 months, one-year, and two-year post donation. The protocol must include a plan to collect the information about each donor • Documentation of disclosure to donor candidate by the hospital that it is unlawful to sell or purchase human organs		
Describe how the hospital will assess compliance with each protocol listed above:		

OMB No. 0915-0184
Expiration Date: 05/31/2017

Part 4, Section 3: Kidney Paired Donation (KPD)

1. Will this program participate in the Kidney Paired Donation (KPD) program? If yes, please indicate which matching service will be used.

Yes	No
[Insert detailed response here. Table will expand automatically]	

OPTN APPLICATION GUIDE

Organ Procurement Organizations (OPO)

Table of Contents

General Instructions 2

Application Review Process 3

Check List: 3

General Instructions

1. Please read these instructions carefully. If you have questions throughout the process, please contact your designated Membership Services Department Contact. Though these instructions reference all types of application forms, please refer to the initial notification from your Membership contact that outlines which form must be completed.

2. The OPTN Bylaws and Policies are found in their entirety on the OPTN website:
   a. http://optn.transplant.hrsa.gov/policiesAndBylaws/bylaws.asp and
   b. http://optn.transplant.hrsa.gov/policiesAndBylaws/policies.asp.

3. General membership requirements for Organ Procurement Organizations can be found in the Bylaws under Appendix B, "Membership Requirements for Organ Procurement Organizations (OPOs)". The criteria specific to staffing, including primary key personnel qualifications, can be found in Section B.4 OPO Personnel.

4. The organizations CEO/President or OPTN representative 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. Failure to furnish accurate and complete information, in connection with the form and for supplemental information, constitutes grounds for denial or suspension of OPTN membership.

5. Supporting documentation must be included to substantiate compliance with OPTN requirements. Documentation may be blinded in such a way as to protect patient confidentiality. **Return the original of <u>all</u> application materials to UNOS at the below address. You may submit materials electronically, in addition to the hard copy original submitted by mail.**

Sally Aungier
Sr. Membership Standards Advisor
UNOS
700 N 4th Street
Richmond, VA 23219
Main Phone: 804-782-4800

Application Review Process

1. Upon submission of an application, the Membership staff will review the materials for completeness and communicate with the OPO if deficiencies are identified. The OPO is expected to satisfy the deficiencies within 14 days or as specified at the time of contact.

2. A complete application includes answering questions in detail and providing all supporting documents that are required. The application is only considered complete once all documentation, has been received.

3. Applications for changes in key personnel should be submitted no fewer than 30-days prior to the change.

4. Changes in OPO key personnel will be reported to the Membership and Professional Standards Committee (MPSC).

Check List:

The following items must be included with each type of application (new OPO or personnel change application):

Check List	Required Documents	New OPO	Personnel Change
	Signed cover/certification page	X	X
	CV's for Administrative leadership	X	X
	CV(s) for Medical Directors(s)	X	X
	Organizational Charg	X	
	List of names and positions of the Board of Directors and/or Advisory Board	X	
	Proof OPO is insured for professional liability	X	
	Copy of the plan for conducting or participating in professional education about organ and tissue procurement	X	
	Written agreements with each transplant program served	X	
	Written agreements with each histocompatibility laboratory providing service to the OPO	X	
	Written agreements with tissue & eye banks within area	X	
	List of donor hospitals and copy of service agreements	X	
	Plan for addressing multi-cultural & diversity issues	X	
	Proof of HHS designation or application submission to Medicare	X	
	Personnel list	X	

Department of Health and Human Services
Health Resources and Services Administration

OMB No. 0915-0184
Expiration Date: 05/31/2017

APPLICATION FOR ORGAN PROCUREMENT ORGANIZATION (OPO) MEMBERSHIP

IN THE ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK (OPTN)

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

Name of OPO:	
OPO Address:	
City, State, & Zip Code:	
Contact Person/Title:	
Phone Number:	**Email:**

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 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 10C-03I, 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. 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.

Date:	Signature:
Print Name:	Title:
Applicant #	

OMB No. 0915-0184
Expiration Date: 5/31/2017

ORGAN PROCUREMENT ORGANIZATION (OPO) APPLICATION

OPTN Membership Application Type

Check One	Yes	No
Independent Organ Procurement Organization		
Hospital Based Organ Procurement Organization		
Name of member/applicant hospital if OPO will be hospital-based:		

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

OPO Name:	
CMS Provider Number and Date Approved:	

Part 1: Section A - Personnel, Administrative Director

1. Identify the Administrative Director (Executive Director/CEO/President) who is responsible for organization operations, including effective organ recovery and placement. Attach curriculum vitae (CV)/resume.

Name	Mailing Address, Phone Number, & Email Address	Effective date of appointment

2. If this appointment is for an interim period, when will a permanent director be hired? Describe recruitment plan.

[Insert detailed response here. Table will expand automatically]

Part 1: Section B – Personnel, Medical Director(s)

1. Identify the Medical Director who is ultimately responsible for the medical and clinical activities of the OPO. Attach curriculum vitae (CV).

Name	Mailing Address, Phone Number, & Email Address	Effective date of appointment

2. Is this appointment for an interim period, a specific term, or not term limited?
If the appointment is interim or for a specific term, indicate term beginning and end dates (mm/dd/yy) and explain the recruitment plan, including timeline.

[Insert detailed response here. Table will expand automatically]

3. Medical Directors must be licensed in at least one of the states in the OPO's DSA. Indicate the state(s) in which the medical director is licensed.

[Insert detailed response here. Table will expand automatically]

4. Is more than one person named as a medical director? If yes, please provide the following information for each additional director.

Name	Mailing Address, Phone Number, & Email Address	Term of appointment MM/DD/YY	State(s) where licensed

OMB No. 0915-0184
Expiration Date: 5/31/2017

Part 1: Section C – Personnel, Other Staff

1. 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

2. In Table 1, list all personnel (by position) employed by this OPO.

Part 2: ORGANIZATIONAL INFORMATION

1. Describe the role of each medical or advisory board if a description is not included in the OPO's charter and bylaws.

   Attach a copy of charter and bylaws.

   [Insert detailed response here. Table will expand automatically]

2. Attach organizational chart for the OPO staff and for all Boards.

3. Attach list of names and positions of the Board of Directors and/or Advisory Board.

4. Attach a copy of non-profit status notification documenting that the OPO has nonprofit status as an organization exempt from federal income taxation under section 501 of the Internal Revenue Code of 1986.

5. If available, attach a copy of the organization's most recent annual report.

6. Provide evidence that the OPO is currently insured for professional liability for at least one million dollars with an insurer that is licensed for approval by the insurance regulatory agency of the state where the OPO's principal office is located.
   If the OPO has a funded self-insurance program, provide proof of coverage and documentation that the fund provides equivalent coverage.

7. Describe the OPO's defined Donation Service Area (DSA) in terms of geographic region.

   a) Names of counties or parishes served or the state if an entire state is served.

      [Insert detailed response here or reference attachment. Table will expand automatically]

   b) Total population in the DSA base (most recent official census as well as the latest data estimate of the US Census Bureau performed between censuses.

      [Insert detailed response here. Table will expand automatically]

   c) The number and name of acute care hospitals in the DSA that have operating rooms, equipment and personnel to retrieve organs.

      [Insert detailed response here or reference attachment. Table will expand automatically]

   d) Indicate to what extent your defined service area is exclusive. For any non-exclusive service areas served, what other OPOs are involved.

      [Insert detailed response here or reference attachment. Table will expand automatically]

Part 3: PROCESS AND PROCEDURES

1. Data Collection and Submission: In accordance with the OPTN policies, members must submit data on candidates, recipients, and donors.

   a) Describe the methods that will to be used to collect, verify, and submit data on a timely basis.

   [Insert detailed response here; table will expand automatically.]

   b) Describe the training/orientation for the data coordinator(s). Include details regarding competencies measured as part of the training.

   [Insert detailed response here; table will expand automatically.]

2. Describe the procedures that will be in place to ensure the confidentiality of all organ donors.

   <Type here or reference attachment>

3. Describe in detail the OPOs quality assurance/performance improvement protocol or process and how it will review its performance. Please indicate the method, frequency of reviews, and participants (by title). Expand or duplicate table as needed.

Individuals Involved: (name & title)	
Methods:	
Frequency of reviews:	
Metrics/Data Tracked:	
Detailed response:	

4. Public Education Plan: Provide summary of education plans that includes activities for public education about organ donation, including how donor families, transplant candidates, and recipients will participate.

   [Insert detailed response here. Table will expand automatically]

   Attach a copy of the plan for conducting or participating in professional education about organ and tissue procurement.

5. Organ Allocation Plans: The OPO must have procedures and technology to communicate information to distribute organs to transplant candidates at transplant hospitals within and beyond its service area. Describe how this OPO will meet or exceed 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.

   [Insert detailed response here. Table will expand automatically]

6. Describe the process for ensuring compliance with OPTN obligations. Include who is responsible (name and

title/position)

Name/Title:
[Insert detailed response here; table will expand automatically.]

7. Attach a copy of the OPO's plan for addressing multi-cultural and diversity issues.

8. Patient Safety Contact: Describe process for identifying a patient safety contact for receiving potential disease transmission notifications and related communications as described in OPTN Policies. List contacts in Table 1.

[Insert detailed response here. Table will expand automatically]

9. Donation after Circulatory Death (DCD) Protocols. 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 requirements set forth in the OPTN Policies.

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 Circulatory Death (DCD) organ recovery protocol has been developed, adopted and implemented in accordance with OPTN Bylaws; and that the DCD organ recovery protocol addresses the requirements. This OPO has written agreements with all donor hospitals regarding participation in DCD recovery.
Signature:
Date:
Name:

OMB No. 0915-0184
Expiration Date: 5/31/2017

Part 4: Contracts and Agreements

1. Attach documentation that demonstrates that this organization has been either:

   a) designated as an organ procurement organization by the Secretary of the U.S. Department of Health and Human Services (HHS) under Section 1138(b) of the Social Security Act; or
   b) is an organization that meets all requirements under Section 1138(b), except for OPTN membership.

   If the OPO does not have current Medicare approval for reimbursement, submit evidence that an application has been submitted to Medicare.

2. List below the names and addresses of clinical transplant hospitals that this OPO will serve within its Donation Service Area (DSA). Include the type of transplant programs that it will serve for each transplant hospital (i.e. kidney, heart, lung, liver, pancreas, pancreas islet cell).

   Attach copies of the written contracts/agreements with each transplant hospital.

Transplant Hospital Name & Address	Type of Programs

Expand rows as needed.

3. Describe any regional transplant agreements below.

[Insert detailed response here. Table will expand automatically]

4. Name below and provide a copy of an agreement with a Clinical Laboratory Improvement Amendment (CLIA) certified laboratory(ies) that meets OPTN standards to provide donor screening for transmissible disease, including Human Immunodeficiency Virus (HIV).

[Insert detailed response here. Table will expand automatically]

5. Name below and attach a copy of the agreement with OPTN approved histocompatibility laboratory(ies) to perform the necessary tissue typing of donated organs. The agreement must include all of the elements required in the OPTN Bylaws.

[Insert detailed response here. Table will expand automatically]

6. Attach a list of donor hospitals served and provide a current copy of each agreement**.**

7. List below tissue banks with which the OPO has written agreements for referral, recovery, processing, preservation, storage, and distribution of tissue from donors.
   Attach copies of the agreements.

[Insert detailed response here. Table will expand automatically]

Table 1: OPTN Staffing Report

Organ Procurement Organization

Member Code:	**Name of OPO:**	
Main OPO Phone Number:	**Main OPO Fax Number:**	**OPO website URL:** http://www
Toll Free Phone number:		

List all staff affiliated with the OPO (Insert additional rows as needed).

Name	Title	Mailing Address	Phone	Email

OMB No. 0915-0184
Expiration Date: 5/31/2017

APPLICATION FOR APPROVAL FOR CHANGE IN KEY PERSONNEL

ORGAN PROCUREMENT ORGANIZATION (OPO)

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, & Zip Code:	
Contact Person/Title:	
Phone Number:	**Email:**

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.

Date:	Signature:
Print Name:	Title:
Applicant #	

Organ Procurement Organization

Change in Key Personnel

Check all applicable changes	Primary Personnel	
	Administrative Director	Complete Part 1 below
	Medical Director	Complete Part 2 below

Part 1: Administrative Director

1. Identify the Administrative Director (Executive Director/CEO/President) who is responsible for organization operations, including effective organ recovery and placement. Attach curriculum vitae (CV)/resume.

Name	Mailing Address, Phone Number, & Email Address	Effective Date of appointment

2. If this appointment is for an interim period, when will a permanent director be hired? Describe recruitment plan.

[Insert detailed response here. Table will expand automatically]

Part 2: Medical Director

1. Identify the Medical Director who is ultimately responsible for the medical and clinical activities of the OPO. Attach curriculum vitae (CV).

Name	Mailing Address, Phone Number, & Email Address	Effective Date of appointment

Expand rows as needed

2. Is this appointment for an interim period, a specific term, or not term limited?
If the appointment is interim or for a specific term, indicate term beginning and end dates (mm/dd/yy) and explain the recruitment plan, including timeline.

[Insert detailed response here. Table will expand automatically]

3. Medical Directors must be licensed in at least one of the states in the OPO's DSA. Indicate the states in which the medical director is licensed.

[Insert detailed response here. Table will expand automatically]

4. Is more than one person named as a medical director? If yes, provide the following information for each additional director.

Name	Mailing Address, Phone Number, & Email Address	Term of appointment MM/DD/YY	State(s) where licensed

OPTN APPLICATION GUIDE

Histocompatibility Laboratories

Table of Contents

General Instructions 2

Application Review Process 3

Check Lists: 4

Helpful Information 5

General Instructions

1. Please read these instructions carefully. If you have questions throughout the process, please contact your designated Membership Services Department Contact. Though these instructions reference all types of application forms, please refer to the initial notification from your Membership contact that outlines which form must be completed.

2. The OPTN Bylaws and Policies are found in their entirety on the OPTN website:
    a. http://optn.transplant.hrsa.gov/policiesAndBylaws/bylaws.asp and
    b. http://optn.transplant.hrsa.gov/policiesAndBylaws/policies.asp.

3. General membership requirements for histocompatibility laboratories can be found in the Bylaws under Appendix C, "Membership Requirements for Histocompatibility Laboratories". The criteria specific to program staffing, including primary transplant surgeon and physician qualifications for each organ type, can be found in the Bylaws under Appendices E-J.

4. The organizations CEO/President or OPTN representative 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. Failure to furnish accurate and complete information, in connection with the form and for supplemental information, constitutes grounds for denial or suspension of OPTN membership.

5. Supporting documentation must be included to substantiate compliance with OPTN requirements. Documentation may be blinded in such a way as to protect patient confidentiality. **Return the original of <u>all</u> application materials to UNOS at the below address. You may submit materials electronically, in addition to the hard copy original submitted by mail.**

    Sally Aungier
    Sr. Membership Standards Advisor
    UNOS
    700 N 4th Street
    Richmond, VA 23219
    Main Phone: 804-782-4800

Application Review Process

1. Appendix A of the bylaws outlines the application process followed by the Membership and Professional Standards Committee (MPSC), once a complete application is submitted.

   http://optn.transplant.hrsa.gov/ContentDocuments/OPTN_Bylaws.pdf#nameddest=Appendix_A

2. Upon submission of a complete application, the Membership staff will review the materials for completeness and communicate with the laboratory if deficiencies are identified. The laboratory is expected to satisfy the deficiencies within 14 days or as specified at the time of contact.

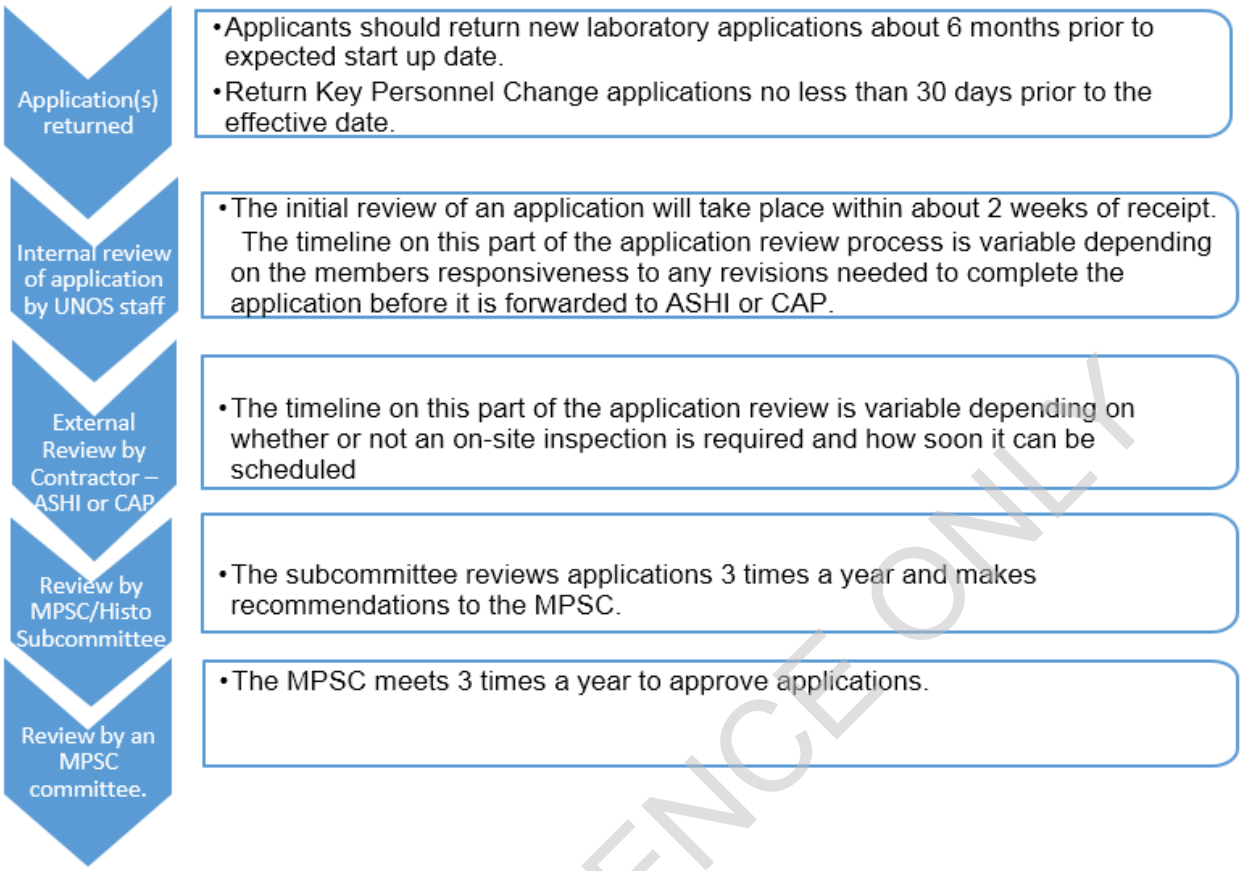
3. During this review, the staff will also contact ASHI or CAP as designated in the application; provide a copy of the application to them; and obtain their recommendation regarding the lab's ability to meet requirements.

4. A complete application includes answering questions in detail and providing all required supporting documents that are required. The application is considered complete once all documentation, including the recommendation from ASHI or CAP has been received.

5. New laboratories should apply approximately 6 months prior to the expected start-up date of the laboratory in order to allow time for on-site inspections to be scheduled, carried out, deficiencies resolved, and a favorable recommendation to be transmitted to the OPTN Contractor. Applications for changes in key personnel should be submitted no fewer than 30-days prior to the change.

6. The MPSC (Membership and Professional Standards committee) or a MPSC subcommittee including histocompatibility experts, will act on an application and provide a recommendation for interim approval or rejection within 90 days after the OPTN receives the completed application. Applications for membership will be considered in a timely and good faith manner.

7. After the MPSC or a MPSC subcommittee has reviewed an application, the laboratory will be notified of its decision in writing. Communications are distributed by secure e-mail.



Check Lists:

The following items must be included with each type of application (new laboratory or personnel change application):

Check List	Required Documents	New Lab	Personnel Change
	Signed cover/certification page	X	X
	Coverage plan	X	X
	Written agreements with each transplant program served	X	
	Written agreements with each OPO served	X	
	Personnel list	X	
	Documentation of successful performance in an external proficiency testing program within the last year.	X	

For all new histocompatibility laboratories and key personnel change applications, the following supporting documents must be submitted for the primary director, technical supervisor, and clinical consultant. Use the following checklist to keep track of the additional supporting documents that also require submission.

Check List	Required Documents	Primary Director	Tech Spvr	Clinical Consultant
	Proof of current certification	X	X	X
	Current license if a state requirement	X	X	X
	Current CV/resume	X	X	X
	Portfolio of cases if required	X	X	X
	Letter of reference from training director, if required	X	X	X
	Letter describing all experience in immunology & clinical histo testing	X	X	X

Helpful Information

- New OPTN membership and changes in key personnel (primary director, clinical consultant, and technical supervisor) require a submission of an application for approval.
- Initial notification and submission of these forms by the laboratory directly to ASHI or CAP will not initiate the application process. Notices and applications must be submitted directly to the UNOS, the OPTN contractor.
- If the director also serves the role of technical supervisor or clinical consultant, those corresponding sections do not need to be filled out in the application, but service in multiple roles should be clearly indicated in the coverage plan.
- If a laboratory has more than one director, it may only name one as the primary. Normally, this will be the director who spends the most time actively working in/with the laboratory.

APPLICATION FOR

HISTOCOMPATIBILITY LABORATORY MEMBERSHIP

IN THE ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK (OPTN)

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

Name of Histocompatibility Laboratory:	
Address:	
City, State, & Zip Code:	
Contact Person/Title:	
Phone Number:	**Email:**

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 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 10C-03I, 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. 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.

Date:	Signature:
Print Name:	Title:
Applicant #	

OPTN Histocompatibility Laboratory Membership Application

Part 1: Section A – General Information

1. OPTN Membership Type

Check One	Yes	No
Independent Histocompatibility Laboratory*		
Hospital Based Histocompatibility Laboratory		
Name of member/applicant hospital if hospital based lab applicant:		

** An Independent Laboratory is defined as having a distinct governing body separate from any transplant hospital or commonly controlled group of transplant hospitals.*

2. Upon receipt of your application, these materials will be forwarded to American Society for Histocompatibility and Immunogenetics (ASHI) or the College of American Pathologists (CAP), which have been granted deemed status to perform histocompatibility laboratory inspections for the OPTN. By completion of this application, the applicant hereby grants ASHI and/or CAP the authority to provide all ASHI and CAP accreditation records and information relevant to histocompatibility testing for organ transplantation.

   Indicate whether ASHI or CAP is the agency selected by the laboratory to perform the review for the OPTN.

[Insert detailed response here. Table will expand automatically]

3. Provide the names of the laboratory, director(s), department, and institution, as they should appear in the official OPTN record.

Position	
Histo Lab Director (Primary)	
Other Director(s)	
Director-in-Training	
Technical Supervisor	
Clinical Consultant	
General Supervisor	
Laboratory or Department Name	
Institution/Hospital	
Lab Street Address	
City, State, Zip	
Main Telephone	
Main Fax	
Website Address	http://www.
Accreditation (if applicable)	
CMS ID #	
CLIA ID #	
ASHI ID #	
CAP ID #	

4. Indentify the principal CEO/Administrator(s), and provide contact information (address, phone, e-mail)

[Insert detailed response here. Table will expand automatically]

Part 1: Section B - Areas of Accreditation

1. Check all areas in which lab is seeking accreditation:

Areas of Accreditation	To be Evaluated	Accredited by ASHI or CAP within the last 3 years? Include last certification start and end dates	
		ASHI	CAP
Solid Organ Transplantation: Deceased Donor			
Solid Organ Transplantation: Live Donor			

Part 1: Section C - Operations

1. Describe the Histocompatibility Laboratory Coverage Plan. Plan must address the elements required in the OPTN Bylaws.
   If there is more than one histocompatibility director, indicate all areas in which primary laboratory director will be involved and, if appropriate, in which area they have primary responsibility.

   [Insert detailed response here or reference attachment. Table will expand automatically]

2. Describe current and anticipated procedures for complying with the data submission requirements of OPTN membership:

   a) List the personnel who are/or will be responsible for data collection and submission indicating their background in this area and the percentage of their time that is dedicated to data collection and submission.

Name	Background	% of Time Dedicated to Data Collection & Submission

   b) Describe the methods to be used to collect, verify, and submit data on a timely basis.
   [Insert detailed response here. Table will expand automatically]

   c) Describe the training/orientation for the data coordinator(s) supporting the Lab. Include details regarding competencies measured as part of the training.

   [Insert detailed response here, table will expand automatically.]

3. Is this histocompatibility laboratory 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 the lab 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 this laboratory.

[Insert detailed response here. Table will expand automatically]

4. Describe in detail the laboratories quality assurance/performance improvement protocol or process and how it will review its performance. Please indicate the method, frequency of reviews, and participants (by title). Expand or duplicate table as needed.

Individuals Involved: (name & title)	
Methods:	
Frequency of reviews:	
Metrics/Data Tracked:	
Detailed response:	

5. Describe the process for ensuring compliance with OPTN obligations. Include who is responsible (name and title/position) and how this process is integrated with other transplant programs and institution wide.

Name/Title:
[Insert detailed response here, table will expand automatically.]

OMB No. 0915-0184
Expiration Date: 05/31/2017

Part 1: Section D - Written Agreements

1. Histocompatibility laboratories must have written agreements with every transplant program and organ procurement organization (OPO) the laboratory serves. List the names and addresses of all clinical transplant hospitals or OPOs this lab will be serving and the type of program(s) at each transplant hospital. Attach written agreements with each clinical transplant program(s) and OPO(s) the laboratory will serve. Written agreements must include all of the elements required in the OPTN Bylaws.

Name & Address	Type of Programs/OPO

Expand rows as needed.

2. Histocompatibility laboratories may refer testing to another laboratory in accordance with the requirements in the OPTN Bylaws. List any subcontracts this laboratory will be implementing.

Lab Name & Location	Type of Testing	Is Lab ASHI or CAP certified?

OMB No. 0915-0184
Expiration Date: 05/31/2017

Part 2: Section A – Personnel Qualifications, Primary Histocompatibility Laboratory Director

The individual identified below as the Primary Histocompatibility Laboratory director must complete this section. If two or more individuals share the histocompatibility laboratory director's responsibilities, one person must be designated as the primary director.
Complete questions below and submit a copy of the following:

- Current certification
- Current licensure if a state requirement
- A current curriculum vitae or resume
- Provide portfolio of cases if required in the OPTN Bylaws
- Letter of reference from histocompatibility laboratories where training obtained if required
- A letter that describes all experience in immunology and clinical histocompatibility testing, including a summary of time spent in the laboratory, technologies used, level of responsibility, and specific tasks performed.

If the primary histocompatibility laboratory director will not serve as the clinical consultant and technical supervisor, Sections 2B and 2C of this application must also be completed.

1. Provide the following information:

Name of primary histocompatibility laboratory director	
Degree(s)	
Discipline(s)	
State Licensure in the state/district where the lab is located (provide copy of current license, if applicable)	
Certifications	
Start date at this laboratory (DD/MM/YY)	

2. List all professional positions at any institutions (director, supervisor, consultant, instructor) currently held by the director and estimated time commitment of each (hours/week):

Professional Position (Include Institution)	**Estimated Time Commitment (hours/week)**

3. Post-Doctoral Experience in Human Histocompatibility Testing for solid organ transplantation. List all laboratory specialties in which post-doctoral training was received. Expand rows as needed.

Laboratory Name	Title	Dates	Description of Duties

4. Doctoral training in directing or supervising clinical histocompatibility testing for solid organ transplantation. List all laboratory specialties in which post-doctoral training was received, including exact dates and specific training received for each. Add additional sections below as needed.

OMB No. 0915-0184
Expiration Date: 05/31/2017

Institution Name	
Laboratory Name	
Laboratory Specialty	
Instructor Name	
Dates	
Specific Training	
Hours/week	

Institution Name	
Laboratory Name	
Laboratory Specialty	
Instructor Name	
Dates	
Specific Training	
Hours/week	

5. Laboratory Involvement

   a. Detail the report review process for each laboratory report including the histocompatibility laboratory director's role. If the histocompatibility laboratory director does not review all reports, include the percentage that are reviewed and how they are selected.

   [Insert detailed response here. Table will expand automatically]

   b. Indicate the approximate number of cases up to 500 (after that just indicate >500) that the proposed laboratory director reviewed in each of the following categories:

Category	# of Cases
Kidney: Deceased donor typing	
Kidney: Deceased donor crossmatch	
Kidney: Living donor typing	
Kidney: Living donor crossmatch	
Other Organs: Deceased donor typing	
Other Organs: Deceased donor crossmatch	
Islet Cell transplantation	
Allele level typing	
HLA antibody screening	
HLA antibody characterization	
Flow cytometry crossmatch	

OMB No. 0915-0184
Expiration Date: 05/31/2017

Part 2: Section B – Personnel Qualifications, Technical Supervisor

The individual identified below as the Primary Technical Supervisor must complete this section if they are not named as the primary histocompatibility laboratory director in Section 2A of this application. If two or more individuals share the technical supervisor's responsibilities, one person must be designated as the primary.
Complete questions below and submit a copy of the following:

- Current certification
- Current licensure if a state requirement
- A current curriculum vitae or resume
- Provide portfolio of cases if required in the OPTN Bylaws
- Letter of reference from histocompatibility laboratories where training obtained if required
- A letter that describes all experience in immunology and clinical histocompatibility testing, including a summary of time spent in the laboratory, technologies used, level of responsibility, and specific tasks performed
- A summary of time spent in the laboratory, technologies used, level of responsibility, and specific tasks performed.

1. Provide the following information:

Name of primary technical supervisor	
Degree(s)	
Discipline(s)	
State Licensure in the state/district where the lab is located (provide copy of current, if applicable)	
Certifications	
Start date at this laboratory (DD/MM/YY)	

2. List all professional positions at any institutions (director, supervisor, consultant, instructor) currently held by the technical supervisor and estimated time commitment of each (hours/week):

Professional Position (Include Institution)	**Estimated Time Commitment (hours/week)**

3. Post-Doctoral Experience in Human Histocompatibility Testing for solid organ transplantation. List all laboratory specialties in which post-doctoral training was received. Expand rows as needed

Laboratory Name	Title	Dates	Description of Duties

4. Doctoral Training in directing or supervising clinical histocompatibility testing for solid organ transplantation. Add additional sections below as needed.

   List all laboratory specialties in which doctoral training was received, including exact dates and specific training received for each.

OMB No. 0915-0184
Expiration Date: 05/31/2017

Institution Name	
Laboratory Name	
Laboratory Specialty	
Instructor Name	
Dates	
Specific Training	
Hours/week	

Institution Name	
Laboratory Name	
Laboratory Specialty	
Instructor Name	
Dates	
Specific Training	
Hours/week	

5. Histocompatibility Laboratory Involvement

   a. Describe the technical supervisor's role in the report review process for this laboratory. Include the percentage of reports review and how they are selected.

   [Insert detailed response here. Table will expand automatically]

   b. Indicate the approximate number of cases up to 500 (after that just indicate >500) that that the proposed technical supervisor reviewed in each of the following categories:

Category	# of Cases
Kidney: Deceased donor typing	
Kidney: Deceased donor crossmatch	
Kidney: Living donor typing	
Kidney: Living donor crossmatch	
Other Organs: Deceased donor typing	
Other Organs: Deceased donor crossmatch	
Islet Cell transplantation	
Allele level typing	
HLA antibody screening	
HLA antibody characterization	
Flow cytometry crossmatch	

OMB No. 0915-0184
Expiration Date: 05/31/2017

Part 2: Section C – Personnel Qualifications, Clinical Consultant

The individual(s) identified below as the Clinical Consultant must complete this section **if they are not named as the primary histocompatibility laboratory director or technical supervisor in Section 2A or 2B of this application**. If two or more individuals share the Clinical Consultant's responsibilities, one person must be designated as the primary. Complete questions below and submit a copy of the following:

- Current certification
- Current licensure if a state requirement
- A current curriculum vitae or resume
- A letter that describes all experience in immunology and clinical histocompatibility testing, including a summary of time spent in the laboratory, technologies used, level of responsibility, and specific tasks performed
- A summary of time spent in the laboratory, technologies used, level of responsibility, and specific tasks

1. Provide the following information:

Name of primary clinical consultant	
Degree(s)	
Discipline(s)	
State Licensure in the state/district where the lab is located (provide copy of current license, if applicable)	
Certifications	
Start date at this laboratory (DD/MM/YY)	

2. List all professional positions at any institutions (director, supervisor, consultant, instructor) currently held by the clinical consultant supervisor and estimated time commitment of each (hours/week):

Professional Position (Include Institution)	Estimated Time Commitment (hours/week)

3. Describe the clinical consultant's responsibilities in this laboratory:

[Insert detailed response here. Table will expand automatically]

4. Describe the clinical consultant's experience in clinical transplantation

[Insert detailed response here. Table will expand automatically]

OMB No. 0915-0184
Expiration Date: 05/31/2017

Part 2 : Section D - Personnel Qualifications, General Supervisor

This section of the application must be completed by all personnel with authority to sign out reports and/or function as a general supervisor in the histocompatibility laboratory. Submit curriculum vitae for each person. If the histocompatibility laboratory director serves as general supervisor, indicate this on the cover page and leave the remainder of this section blank.

1. Provide the following information:

Name of General Supervisor	
Does the general supervisor meet the qualifications defined by CLIA (CFR. Sec 493? (Yes/No)	

2. Provide description of general supervisor's duties in this position

[Insert detailed response here. Table will expand automatically]

3. Describe how the general supervisor meets the qualifications for having at least 3 years of experience in human histocompatibility or transplant testing under the supervision of a qualified histocompatibility director or technical supervisor:

[Insert detailed response here. Table will expand automatically]

OMB No. 0915-0184
Expiration Date: 05/31/2017

Part 2: Section E - Personnel List

List all staff involved in histocompatibility testing in this laboratory.

Start Date M/YY	Name	Position	Degrees	Certifications	Yrs HHT	% FTE Clinical HHT	On-Call	Total CE Hours

Expand rows as needed.

OMB No. 0915-0184
Expiration Date: 05/31/2017

Part 2, Section F - Competency Testing

1. The laboratory must have a process for annually testing its staff for competency in performing test procedures. Provide documentation of a plan for competency testing and continuing education of staff.

   [Insert detailed response here. Table will expand automatically]

2. Laboratories must document that proficiency testing and competency requirements in the Bylaws have been met. Provide documentation demonstrating a successful performance in an external proficiency testing program within the last year.

OMB No. 0915-0184
Expiration Date: 5/31/2017

CHANGE IN KEY PERSONNEL APPLICATION

HISTOCOMPATIBILITY LABORATORY MEMBERSHIP

IN THE ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK (OPTN)

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

Name of Histocompatibility Laboratory:	
Address:	
City, State, & Zip Code:	
Contact Person/Title:	
Phone Number:	**Email:**

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 this collection of information is estimated to average 2 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 10C-03I, 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. 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.

Date:	Signature:
Print Name:	Title:
Applicant #	

OMB No. 0915-0184
Expiration Date: 5/31/2017

OPTN Change in Key Personnel Application - Histocompatibility Laboratory

Part 1: General Information

1. Upon receipt of your application, these materials will be forwarded to American Society for Histocompatibility and Immunogenetics (ASHI) or the College of American Pathologists (CAP), which have been granted deemed status to perform histocompatibility laboratory inspections for the OPTN. By completion of this application, the applicant hereby grants ASHI and/or CAP the authority to provide all ASHI and CAP accreditation records and information relevant to histocompatibility testing for organ transplantation.

   Indicate whether ASHI or CAP is the agency selected by the laboratory to perform the review for the OPTN.

   [Insert detailed response here. Table will expand automatically]

2. Indicate which change(s) in key personnel is being submitted and complete the relevant section(s) of this application (Section A, B or C).

	Check all that Apply	**Effective Date of Change**
Primary Histocompatibility Laboratory Director		
Technical Supervisor		
Clinical Consultant		

3. Describe the Histocompatibility Laboratory Coverage Plan. Plan must address the elements required in the OPTN Bylaws and any changes that are occurring as a result of this change in key personnel. If there is more than one histocompatibility director, indicate all areas in which named director, technical supervisor, and clinical consultant will be involved and, if appropriate, in which area they have primary responsibility.

   [Insert detailed response here. Table will expand automatically]

OMB No. 0915-0184
Expiration Date: 5/31/2017

Part 2: Section A - Personnel Qualifications, Primary Histocompatibility Laboratory Director

The individual identified below as the Primary Histocompatibility Laboratory director must complete this section. If two or more individuals share the histocompatibility laboratory director's responsibilities, one person must be designated as the primary director.
Complete questions below and submit a copy of the following:

- Current certification
- Current licensure if a state requirement
- A current curriculum vitae or resume
- Provide portfolio of cases if required in the OPTN Bylaws
- Letter of reference from histocompatibility laboratories where training obtained if required
- A letter that describes all experience in immunology and clinical histocompatibility testing, including a summary of time spent in the laboratory, technologies used, level of responsibility, and specific tasks performed.

If the primary histocompatibility laboratory director will not serve as the clinical consultant and technical supervisor, Section 2B and 2C of this application must also be completed.

1. Provide the following information:

Name of primary histocompatibility laboratory director	
Degree(s)	
Discipline(s)	
State Licensure in the state/District where the lab is located (provide copy of current license, if applicable)	
Certifications	
Start date at this laboratory (DD/MM/YY)	

2. List all professional positions at any institutions (director, supervisor, consultant, instructor) currently held by the director and estimated time commitment (hours/week) of each. Expand rows as needed.

Professional Position (Include Institution)	**Estimated Time Commitment (hours/week)**

3. Post-Doctoral Experience in Human Histocompatibility Testing for solid organ transplantation. List all laboratory specialties in which post-doctoral training was received. Expand rows as needed.

Laboratory Name	Title	Dates	Description of Duties

4. Doctoral training in directing or supervising clinical histocompatibility testing for solid organ transplantation. List all laboratory specialties in which post-doctoral training was received, including exact dates and specific training received for each.

Institution Name	
Laboratory Name	
Laboratory Specialty	
Instructor Name	
Dates	
Specific Training	
Hours/week	

Institution Name	
Laboratory Name	
Laboratory Specialty	
Instructor Name	
Dates	
Specific Training	
Hours/week	

Add additional sections above as needed.

5. Laboratory Involvement:
   a. Detail the report review process for each laboratory report including the histocompatibility laboratory director's role. If the histocompatibility laboratory director does not review all reports, include the percentage that are reviewed and how they are selected.

[Insert detailed response here. Table will expand automatically]

   b. Indicate the approximate number of cases up to 500 (after that just indicate >500) that the proposed laboratory director reviewed in each of the following categories:

Category	**# of Cases**
Kidney: Deceased donor typing	
Kidney: Deceased donor crossmatch	
Kidney: Living donor typing	

Kidney: Living donor crossmatch	
Other Organs: Deceased donor typing	
Other Organs: Deceased donor crossmatch	
Islet Cell transplantation	
Allele level typing	
HLA antibody screening	
HLA antibody characterization	
Flow cytometry crossmatch	

Part 2: Section B - Personnel Qualifications, Technical Supervisor

The individual identified below as the Primary Technical Supervisor must complete this section **if they are not named as the primary histocompatibility laboratory director in Section 2A** of this application. If two or more individuals share the technical supervisor's responsibilities, one person must be designated as the primary.

Complete questions below and submit a copy of the following:

- Current certification
- Current licensure if a state requirement
- A current curriculum vitae or resume
- Provide portfolio of cases if required in the OPTN Bylaws
- Letter of reference from histocompatibility laboratories where training obtained if required
- A letter that describes all experience in immunology and clinical histocompatibility testing, including a summary of time spent in the laboratory, technologies used, level of responsibility, and specific tasks performed.

1. Provide the following information:

Name of primary technical supervisor	
Degree(s)	
Discipline(s)	
State Licensure in the state/district where the lab is located (provide copy of current license if applicable)	
Certifications	
Start date at this laboratory (DD/MM/YY)	

2. List all professional positions at any institutions (director, supervisor, consultant, instructor) currently held by the technical supervisor and estimated time commitment of each (hours/week). Expand rows as needed:

Professional Position (Include Institution)	**Estimated Time Commitment (hours/week)**

3. Post-Doctoral Experience in Human Histocompatibility Testing for solid organ transplantation: List all laboratory specialties in which post-doctoral training was received. Expand rows as needed

Laboratory Name	**Title**	**Dates**	**Description of Duties**

4. Doctoral Training in directing or supervising clinical histocompatibility testing for solid organ transplantation: List all laboratory specialties in which doctoral training was received, including exact dates and specific training received for each. Add additional sections below as needed.

Institution Name	
Laboratory Name	
Laboratory Specialty	
Instructor Name	
Dates	
Specific Training	
Hours/week	

Institution Name	
Laboratory Name	
Laboratory Specialty	
Instructor Name	
Dates	
Specific Training	
Hours/week	

5. Histocompatibility Laboratory Involvement:
   a. Describe the technical supervisor's role in the report review process for this laboratory. Include the percentage of reports review reviewed and how they are selected.

[Insert detailed response here. Table will expand automatically]

   b. Indicate the approximate number of cases up to 500 (after that just indicate >500) that that the proposed technical supervisor reviewed in each of the following categories:

Category	**# of Cases**
Kidney: Deceased donor typing	
Kidney: Deceased donor crossmatch	
Kidney: Living donor typing	

Kidney: Living donor crossmatch	
Other Organs: Deceased donor typing	
Other Organs: Deceased donor crossmatch	
Islet Cell transplantation	
Allele level typing	
HLA antibody screening	
HLA antibody characterization	
Flow cytometry crossmatch	

Part 2: Section C – Personnel Qualifications, Clinical Consultant

The individual identified below as the Primary Clinical Consultant must complete this section **if they are not named as the primary histocompatibility laboratory director or technical supervisor in Sections 2A or 2B of this application**. If two or more individuals share the Clinical Consultant's responsibilities, one person must be designated as the primary. Complete questions below and submit a copy of the following:

- Current certification
- Current licensure if a state requirement
- A current curriculum vitae or resume
- A letter that describes all experience in immunology and clinical histocompatibility testing, including a summary of time spent in the laboratory, technologies used, level of responsibility, and specific tasks performed
- A summary of time spent in the laboratory, technologies used, level of responsibility, and specific tasks

1. Provide the following information:

Name of primary clinical consultant	
Degree(s)	
Discipline(s)	
State Licensure in the state/District where the lab is located (provide copy of current license, if applicable)	
Certifications	
Start date at this laboratory (DD/MM/YY)	

2. List all professional positions at any institutions (director, supervisor, consultant, teacher) currently held by the clinical consultant supervisor and estimated time commitment of each (hours/week):

Professional Position (Include Institution)	**Estimated Time Commitment (hours/week)**

3. Describe the clinical consultant's responsibilities in this laboratory:

[Insert detailed response here. Table will expand automatically]

4. Describe the clinical consultant's experience in clinical transplantation:

[Insert detailed response here. Table will expand automatically]

OPTN APPLICATION INSTRUCTIONS

Individual

Medical/Scientific Organization

Public Organization

Business

Version 1.0, effective July 18, 2014

Table of Contents

General Instructions 2

Criteria for Membership: 2

Application Review Process 3

Helpful Information 4

General Instructions

1. Please read these instructions carefully. If you have questions throughout the process, please contact your designated Membership Services Department Contact. Though these instructions reference all types of application forms, please refer to the initial notification from your Membership contact that outlines which form must be completed.

Criteria for Membership:

2. The OPTN Bylaws and Policies are found in their entirety on the OPTN website:
    a. http://optn.transplant.hrsa.gov/policiesAndBylaws/bylaws.asp and
    b. http://optn.transplant.hrsa.gov/policiesAndBylaws/policies.asp.

3. General membership requirements can be found in the following section of Bylaws under Article I, "Membership".
    a. 1.5 – Medical/Scientific Members
    b. 1.6 – Public Organization Members
    c. 1.7 – Business Members
    d. 1.8 – Individual Members

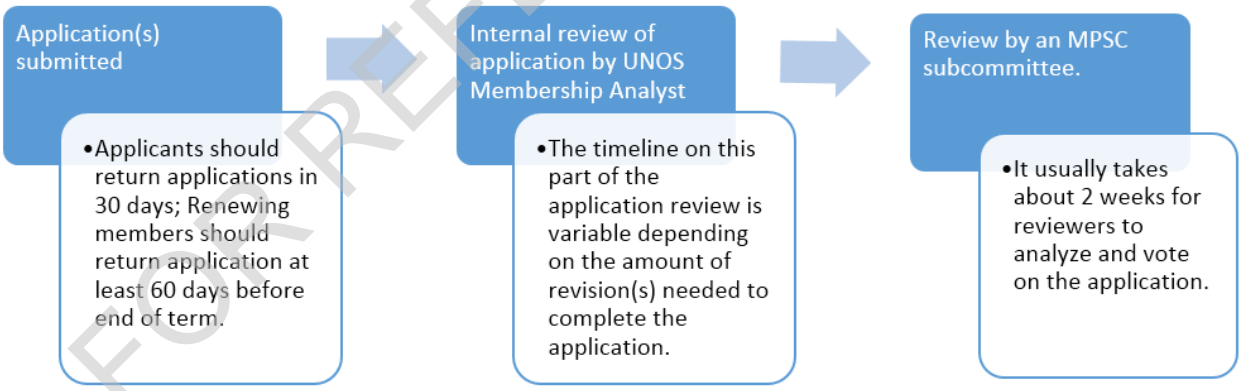
4. Do not overwrite or remove questions contained within the application form. Modified application forms will not be accepted. Answer all questions within the application.
5. Application responses must be typed.
6. Attach additional pages as necessary and reference the question and page number on each attachment.
7. For the organizational types of membership, the CEO/President or OPTN representative 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. Failure to furnish accurate and complete information, in connection with the form and for supplemental information, constitutes grounds for denial of OPTN membership.
8. An electronic version (MS Word) of this application is available upon request.
9. Supporting documentation must be included to substantiate compliance with OPTN requirements. You may submit materials electronically, in addition to the hard copy original submitted by mail. Return the original of all application materials to UNOS at the address below.

Sally Aungier
Sr. Membership Standards Advisor
Membership Services
UNOS
700 N 4th Street
Richmond, VA 23219
Main Phone: 804-782-4800

Application Review Process

1. Upon submission of a complete application, the Membership staff will review the materials for completeness and communicate with the applicant if deficiencies are identified in the application.
2. A complete application includes answering questions in detail and providing all required supporting documents.
3. The applicant is expected to satisfy any cited deficiencies within 14 days or as specified at the time of contact.
4. Appendix A of the Bylaws outlines the application and approval process, once a complete application is submitted. Link to Appendix A:

   http://optn.transplant.hrsa.gov/ContentDocuments/OPTN_Bylaws.pdf#nameddest=Appendix_A



5. The MPSC (Membership and Professional Standards committee) or a MPSC subcommittee will act on an application and provide a recommendation for interim approval or rejection within 90 days after the OPTN receives the completed application. Applications for membership will be considered in a timely and good faith manner.
6. After the MPSC or a MPSC subcommittee has reviewed an application, the applicant will be notified of its decision in writing. Communications are distributed by e-mail.

Helpful Information

- OPTN membership requires submission of an application for approval.
- Membership Terms: These four types of non-institutional members are approved for two-year terms. Members may apply to serve for unlimited sequential terms by submitting an application no less than 60 days prior to the end of the last term.
- The two-year term of approval starts when the application is initially approved by an MPSC subcommittee or MPSC.
- If a member allows its two-year membership term to expire, its membership will cease. Membership can be restarted by submitting a new application and successfully completing the review process.

OMB No. 0915-0184
Expiration Date: 5/17/2017

APPLICATION FOR

MEDICAL/SCIENTIFIC ORGANIZATION MEMBERSHIP

IN THE

ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK (OPTN)

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

Name of Organization:	
Address:	
City, State, & Zip Code:	
Contact Person:	
Phone Number:	**Email:**

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 this collection of information is estimated to average 2 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 10C-03I, 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. 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.

Date:	Signature:
Print Name:	Title:
Applicant #	

OMB No. 0915-0184
Expiration Date: 5/31/2017

Application for Medical/Scientific Membership

1. Provide the following documents:

   a) A current roster of the organization's board of directors and officers.

   b) A copy of the organization's Articles of Incorporation and Bylaws.

   c) A copy of the organization's IRS non-profit status letter.

   d) A copy of the organization's last annual report or annual financial report.

2 Describe how this organization/institution meets the requirement for being an organization whose members include medical or scientific professional members with an interest in organ donation or transplantation. Provide the documentation as required in either question 2a or 2b (below).

[Insert detailed response here. Table will expand automatically]

   a) Provide documentation that demonstrates that this organization has been in operation for a least one year.

[Insert detailed response here or reference attachment. Table will expand automatically]

   b) Provide letters of recommendation from at least three OPTN members (transplant hospital, OPO, histocompatibility laboratory, public organization, or medical/scientific members).

OMB No. 0915-0184
Expiration Date: 5/31/2017

APPLICATION FOR PUBLIC ORGANIZATION MEMBERSHIP

IN THE

ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK (OPTN)

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

Name of Organization:	
Address:	
City, State, & Zip Code:	
Contact Person:	
Phone Number:	**Email**

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 this collection of information is estimated to average 2 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 10C-03I, 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. 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.

Date:	**Signature**:
Print Name:	**Title**:
Applicant #	

OMB No. 0915-0184
Expiration Date: 5/31/2017

Application for Public Organization Membership

1. Provide the following documents:

   a) A current roster of the organization/institution's board of directors and officers.

   b) A copy of the organization/institution's Articles of Incorporation and Bylaws.

   c) A copy of the organization/institution's last annual report or annual financial report.

2. A Public Organization Member is an organization with an interest in organ donation or transplantation and must have been in operation for at least one year. Explain how this organization's interest in organ donation or transplantation satisfies this requirement:

   [Insert detailed response here. Table will expand automatically]

   Provide documentation as described in items a, b, or c below:

   a) Provide documentation that demonstrates that the hospital refers at least one potential organ or tissue donor per year.

      [Insert detailed response here or reference attachment. Table will expand automatically]

   b) Describe how this organization/institution meets the requirement for being a non-profit organization or institution that engages in organ donation activities, or represents or directly provides support and services to transplant candidates, recipients or their families. Attach a copy of the organization/institution's IRS non-profit status letter.

      [Insert detailed response here. Table will expand automatically]

   c) Provide letters of recommendation from at least three OPTN members (transplant hospital, OPO, histocompatibility laboratory, public organization, or medical/scientific member). Attach a copy of the organization/institution's IRS non-profit status letter.

Department of Health and Human Services
Health Resources and Services Administration

OMB No. 0915-0184
Expiration Date: 5/31/2017

APPLICATION FOR

BUSINESS MEMBERSHIP IN THE

ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK (OPTN)

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

Name of Organization:	
Address:	
City, State, & Zip Code:	
Contact Person/Title:	
Phone Number:	**Email:**

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 this collection of information is estimated to average 2 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 10C-03I, Rockville, Maryland 20857.

CERTIFICATION

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Date:	Signature:
Print Name:	Title:
Applicant #	

OMB No. 0915-0184
Expiration Date: 5/31/2017

Application for Business Membership

1. Provide the following documents:

   a) Current roster of the organization/institution's board of directors and officers.

   b) Organization/institution's Articles of Incorporation and Bylaws.

   c) Organization/institution's last annual report or annual financial report.

   d) Documentation that demonstrates that the organization is actively engaged in commercial activities with two or more active OPTN members.

   e) Documentation that demonstrates that this organization has been in operation for a least one year.

2. Explain how this organization/institution fulfills the requirement for having an interest in the fields of organ donation or transplantation.

[Insert detailed response here. Table will expand automatically]

Department of Health and Human Services
Health Resources and Services Administration

OMB No. 0915-0184
Expiration Date: 5/31/2017

APPLICATION FOR INDIVIDUAL MEMBERSHIP IN THE

ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK (OPTN)

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

Name of Applicant:	
Address:	
City, State, & Zip Code:	
Contact Person:	
Phone Number:	**Email:**

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 this collection of information is estimated to average 1 hour 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 10C-03I, 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. 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.

Date:	Signature:
Print Name:	Title:
Applicant #	

Answer at least one of the questions 1-6

1. Do you presently serve or have you formerly served on the OPTN Board of Directors or an OPTN Committee?

Yes:	No:

If "yes," indicate the name of the specific committee(s) (or board) and the term(s) of service.

[Insert detailed response here. Table will expand automatically]

2. Are you or a family member a transplant candidate, transplant recipient, living donor, tissue donor (indicate all that apply):

	Self	Family	Organ
Transplant Candidate			
Transplant Recipient			
Living Donor			
Tissue Donor			

3. Are you presently employed by or are you an independent contractor with an organ procurement organization (OPO), transplant hospital, or histocompatibility laboratory?

Yes:	No:

If "yes", explain below.

[Insert detailed response here. Table will expand automatically]

4. Were you formerly employed by or were you formerly an independent contractor with OPOs, transplant hospitals, or histocompatibility laboratories?

Yes:	No:

If "yes", describe and explain how you have continued to demonstrate an active interest in and involvement with the fields of organ donation or transplantation.

[Insert detailed response here. Table will expand automatically]

5. Were you formerly employed by a Federal or State government agency involved in the fields of organ donation and transplantation?

Yes:	No:

If "yes", explain how you have continued to demonstrate an active interest and involvement in organ donation or transplantation.

[Insert detailed response here. Table will expand automatically]

6. Do you have an active interest and involvement in organ donation or transplantation?

Yes:	No:

If you are utilizing this option to request membership, you must provide at least three letters of recommendation for membership from three other OPTN individual members. Attach these letters of support.

7. Attach a copy of your resume or curriculum vitae.

8. Explain your reason for wanting to be an Individual Member of the OPTN.
(Confine your statement to approximately one page)

[Insert detailed response here. Table will expand automatically]