Department of Health and Human Services
Health Resources and Services Administration

OMB No. 0915-0184
Expiration Date: 4/30/2014

APPLICATION FOR INSTITUTIONAL MEMBERSHIP

AS A CLINICAL TRANSPLANT HOSPITAL

IN THE ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK (OPTN)

United Network for Organ Sharing (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: ( ) _____

PUBLIC BURDEN STATEMENT: An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is 0915-0184. Public reporting burden for the applicant for this collection of information is estimated to average 45 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to HRSA Reports Clearance Officer, 5600 Fishers Lane, Room 10-33, Rockville, Maryland 20857.

CERTIFICATION

The undersigned, a duly authorized representative of the applicant, does hereby certify that the answers and attachments to this application are true, correct and complete, to the best of his or her knowledge after investigation. By submitting this application to the OPTN, the applicant agrees: (i) to be bound by the Organ Procurement and Transplantation Network's (OPTN) rules and requirements, 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:** _____

Applicant Code: _____ **Print Name:** _____

Print Title: _____

Clinical Transplant Hospital Applicant

Instructions

1. A clinical transplant hospital applicant **must** complete the Parts 1-6 that follow these instructions, including the organ specific section for each type of transplant program for which it is applying. The Criteria for Institutional Membership are found in the Bylaws.

   Transplant programs are:

   A. Kidney (including Living Donor Kidney)
   B. Heart
   C. Heart/Lung
   D. Liver (including Living Donor Liver)
   E. Pancreas
   F. Lung
   H. Islet Cell

   Additionally, the Organ Procurement and Histocompatibility Sections (Parts 5 and 6) will need to be completed.

2. By submitting this application to the OPTN, the applicant acknowledges that its duly authorized representatives have received and read the current Charter, Bylaws, and Policies of the OPTN and the applicant agrees: (i) to be bound by the terms thereof, including amendments thereto, if the applicant is granted membership and (ii) to be bound by the terms, thereof, including amendments thereto, in all matters relating to consideration of the application without regard to whether or not the applicant is granted membership. The Criteria for Institutional Membership are found in the Bylaws which can be accessed on the OPTN website at: http://optn.transplant.hrsa.gov/.

3. A duly authorized representative of the applicant must review the answers and attachments to the application, perform sufficient investigation to determine accuracy and completeness, and sign and date the certification on the cover page of the application. Failure to furnish accurate and complete information in connection with the application and requests for supplemental information constitutes grounds for denial or suspension of OPTN membership. (Authorized representatives include hospital CEO or President**. Individuals whose credentials are being submitted should not sign the application.)**

4. Attach additional pages as necessary and reference the question and page number on each attachment**. Expand table rows as needed to fully answer questions.**

5. Answer all questions in full and do not use both sides of the page. "See C.V." or “See Logs” is not an acceptable answer.

6. Supporting documentation, such as C.V.s, letters of support, letters of commitment, and patient logs, should be included as requested to document compliance with the requirements. Documentation may be blinded in such a way as to protect patient confidentiality.

7. Application responses must be typed and complete. Do not omit pages that were not used. The Membership and Professional Standards Committee (MPSC) may not accept for review applications that are not appropriately completed and that are missing the supporting documents for the proposed primary individual(s). Applications determined to be incomplete may be returned to the institution.

8. Each set (original and copy) should be loose bound with tabs. The original and copy should be organized in the following sequence:

1) Signed Cover Page
2) General Section
3) Organ Specific Application(s)
4) Signed Program Coverage Plan(s) – one must be submitted for each organ-specific application
5) OPO Section
6) Lab Section
7) Documentation of Medicare/Medicaid certification (if applicable)
8) Letters from Hospital Credentialing Committee
9) Letters of Commitment
10) Letters of Reference
11) Logs of transplant and procurement procedures (and living donor hepatectomies/nephrectomies as applicable) for the primary surgeon(s) and patient logs for the primary physician. Title each log with surgeon/physician name, date range, and hospital where the experience occurred as shown in the sample logs. Please use a separate log for each institution.
12) C.V.s (individual C.V.s must be stapled in the original and copy). Abbreviated C.V.s that do not include publications and presentations are preferred.
13) Cumulative Recipient log (Islet only)
14) Allocation Report (Islet only)

9. Return the original and one (1) complete paper copy of all application materials to UNOS at the address listed below.

Express Mail:
UNOS
Membership Services
700 North 4th Street
Richmond, VA 23219

US Mail:
UNOS
Membership Services
PO Box 2484
Richmond, VA 23218

Main Phone: (804) 782-4800

GENERAL SECTION

Applicants for initial membership: Complete all sections of Parts 1 and 2 (General and Program Specific).

Applicants for new programs in an existing member transplant hospital or for reactivation of an existing program(s): Complete all sections of Part 2 (Program Specific) only.

Expand cells and increase the number of rows in tables as needed to provide a complete response.

GENERAL: PART 1, SECTION A – TRANSPLANT HOSPITAL

Check the type(s) of organ transplant programs for which your transplant hospital is applying for membership:

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

Complete the portions of this application that apply to each program checked above.

1. The Bylaws require that an applicant has in force medical liability insurance with at least $1,000,000 limits of coverage 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 shall suffice.

   a) Is your hospital insured for professional liability with at least $1,000,000 limits of coverage per occurrence? Yes _____ No _____

   b) If no, and you have 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 your institution from the fund.

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.

Check Response	Required	Amount of Coverage/Self Insurance Required
	No	
	Yes	

GENERAL: PART 1, SECTION B – DONATION AFTER CARDIAC DEATH (DCD) PROTOCOLS

Donation after Cardiac 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 required model elements set forth in the Bylaws.

Certification Statement

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

Chief Executive Officer **Date**

_____ _____

_____

Print name

PROGRAM SPECIFIC: PART 2, SECTION A – PROGRAM DESCRIPTION

Duplicate this section for each organ application that is being submitted

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

1. Answer the questions below that describe this program (proposed program).

a) Year Program to Start/Started:			
	Yes	**No**	**Not Applicable**
b) Does/will this program perform transplants in patients under age 18?			
c) Is this hospital a stand-alone pediatric hospital?			
d) If no, is there a stand-alone pediatric hospital affiliated with this hospital? If yes, specify hospital: _____			
e) Will this program perform living donor transplants? (Applicable for kidney, liver, pancreas, and lung programs)			
f) Is this program certified by Medicare? If yes, provide the CMS provider number:_____ Certification date:_____ Attach evidence of Medicare certification.			
g) **Medicare approved programs:** If this is an application for a change in key personnel, have you notified CMS of this change?			

2. Is a Certificate of Need (CON) required by your state prior to initiation of this transplant program?
   Yes ____ No ____

If the response is "Yes" answer the questions below.

CON Required	Date Application Made	Application Approval Date	Anticipated Approval Date

PROGRAM SPECIFIC: 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.

1. Floor and Clinic Space

Floor & Clinic Space	Response
a) Operating Room(s)	
b) Recovery Room(s)	
c) ICU	
d) Surgical Intensive Care (SICU)	
e) Step-Down Unit/Floor & Clinic	
f) Total Number of Days/Hours Available for Outpatient Transplant Clinic	
Additional Information:	

PROGRAM SPECIFIC: PART 2, SECTION C – HUMAN RESOURCES

1. **Mental Health and Social Services:** Describe the support that will be provided to the transplant program in the areas below. The description should include the name of the individuals, their on site availability, their role on the transplant team, and description of their responsibility for coordinating the needs of transplant candidates, recipients, living donors (as applicable) and families.

Area	Description of Support/ Scope of Duties
Mental Health	
Social Support Services	

2. **Clinical Nursing:** Describe the nursing support that will be provided to the transplant program(s).

Area	Response
What will be the patient nurse ratio on the transplant unit?	ICU: ____ Non-ICU: ___
Will the transplant nurse specialist be active in the care of patients on the transplant unit?	
What transplant specific orientation will be provided to a nurse before she/he is given responsibility for care of transplant patients?	

3. **Clinical Transplant Coordinator(s):** Identify one or more staff members who will be responsible for coordinating clinical aspects of patient care (including the candidate phase, transplant/inpatient phase, and recipient/outpatient phase). Indicate their transplant experience and relevant certifications.

Name	Transplant Experience In years	Professional Certifications

Indicate below the role and responsibilities of the clinical transplant coordinator(s).

Role and Responsibilities	Yes	No
Designated member of the transplant team		
The coordinator is a registered nurse or other licensed clinician		
Specific responsibilities during candidate phase:		
Assures necessary studies are conducted to determine a patient's candidacy		
Participates in both patient and family education		
Assists in the evaluation and selection of potential living donors		
Monitors medical patients' status throughout work-up and while on the deceased donor organ transplant waiting list		
Specific responsibilities during transplant/inpatient phase:		
Assumes lead in directing all patient and family transplant education and understanding of the process		
Maintains communication with patients' referring physicians		
Acts as a transplant resource for all staff nurses and contributes to their education regarding transplantation		
Works as liaison between patient families and other health care staff		
Prepares patients for discharge and outpatient follow-up		
Specific responsibilities during recipient/outpatient phase:		
Monitors and follows all diagnostic studies		
Evaluates patient health status on a regular basis		
Communicates all patient issues and concerns to appropriate transplant physicians		
Coordinates comprehensive care with other team members (i.e. financial coordinator, social worker, dietician, etc.)		
Describe any other clinical transplant responsibilities:		
Involved with the organ procurement process? If Yes, explain scope of involvement.		

4. **Financial Coordinator:** All transplant hospitals should identify one or more staff members who are responsible for coordinating and assisting the patient with all financial aspects specific to transplant care.

   Indicate the number of transplant financial coordinators that support this program _____ (FTE).

   Indicate below which responsibilities are fulfilled by the financial coordinator(s).

Role and Responsibilities	Yes	No
Designated member of the transplant team		
Primarily responsible for coordinating financial services related to transplant care		
Obtains detailed patient insurance benefit information for all aspects of the transplant process, including, but not limited to, outpatient prescription drugs, organ acquisition, follow-up clinic visits, and travel and housing if necessary		
Discusses benefits and other transplant financial issues with patients and/or family members during initial evaluation.		
Advises patients on insurance and billing issues and options. Serves as a resource for patients and their family members on financial matters.		
Obtains all necessary payor authorizations. Verifies transplant coverage and other medical benefits and acquiring necessary referrals and authorizations.		

Role and Responsibilities	Yes	No
Monitors and updates information regarding insurance data, physicians, authorizations, and preferred providers. Assists patients with questions concerning insurance and other financial issues.		
Identifies and effectively communicates financial information to transplant team members, patients and their families with emphasis on identifying any potential patient out-of-pocket liability		
Works with patients, their families and team members when possible to help address insurance coverage gaps via alternative funding options		
Facilitates resolution of patient billing issues.		

5. **Clinical Transplant Pharmacist:** All transplant programs should identify one or more pharmacists who are responsible for providing pharmaceutical care to solid organ transplant recipients.

   Number of transplant pharmacists that support this program: _____(FTE).

   On average what percentage of time is spent by the pharmacist (s) on transplant related duties: _____%

   Indicate below which responsibilities are fulfilled by the transplant pharmacist(s).

Role and Responsibilities	Yes	No
Designated member of the transplant team		
Primary responsibility for providing comprehensive pharmaceutical care to transplant recipients		
The transplant pharmacist is a licensed pharmacist with experience in transplant pharmacotherapy, who performs or oversees a team of other healthcare personnel and support staff in performing the functions listed below		
Specific responsibilities during Peri-operative Phase:		
Evaluates, identifies and resolves medication related problems for transplant recipients		
Educates transplant recipients and their family members on transplant medications and adherence to medication regimen		
Acts as liaison (advocate) between patient and patients' families and other health care team members regarding medication issues		
Prepares and actively participates with discharge planning for all transplant recipients		
Provides drug information for all members of the transplant team		
Specific responsibilities during Post Transplant Phase:		
Evaluates transplant recipient medication regimens routinely		
Communicates all transplant recipient medication issues and concerns to appropriate members of the transplant team		
Assists with designing, implementing, and monitoring of comprehensive care plans with other transplant team members (i.e. physicians, transplant coordinators, financial coordinator, social worker, dietician, etc.)		
Describe additional responsibilities:		

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

   a) Does this hospital/program have a director of transplant anesthesiology and/or an anesthesiology service chief for the organ covered in this application? __ Yes __ No
      - If yes, provide this individual's C.V.

      Describe the director's experience in transplantation.

	Description		
Does the director provide clinical care for transplant recipients? If yes, for which of the following organs? (Options: kidney, liver, small bowel, pancreas, heart, lung)			
Does the director provide: (check all that apply)	___ Intraoperative care ___ Postoperative care		
Approximately how many transplants of the applied for organ type has the director participated in?	Options: • <10 ___ •10-20 ___ • 20-30 ___ •>30 ___		
	Yes	**No**	**Explanation**
Does the department of anesthesiology or the hospital medical staff have a credentialing process for transplant anesthesiologists?			If yes, (check all that apply): ___ Proctored by experienced group member ___ Visit other hospital ___ Other: (describe) ___
Has the director attended transplant-related CME meetings in the last 2 years?			
Was the director's transplant experience for the organ covered in this application obtained at this hospital? (Please describe transplant experience within the C.V.)			

b) Which of the following 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

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

# **Anesthesiologists**	**Yes**
2-4	
4-6	
6-8	
8-10	
10-15	
>15	

d) Is there a written protocol for the conduct of anesthesia? __ Yes __ No

e) 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?			

7. **Other Medical Discipline Involvement:** Describe briefly the support available to the transplant effort in the disciplines listed below. Each description should answer the following:
   - When are these services provided? (pre-, peri-, and post-operative)
   - Where are these services provided? (on site, off site, or both)
   - Is support primarily provided by one individual or a team? What is their experience in transplant?
   - Are specialty representatives participating with the transplant team in quality assessments post transplant?

Specialty Area	**Description**	**Given Role: Consultant or Transplant Staff Member**	**% Time Devoted to the Transplant Service**
Radiology			
Infectious Disease			
Pulmonary Medicine			
Pathology			
Immunology			
Physical Therapy			
Rehabilitation Medicine			
Dietary & Nutritional Support			
Laboratory Services: Does the transplant program have immediate access to the following services?			
Microbiology			
Clinical Chemistry			
Immunological Monitoring			
Blood Bank			
Others Areas as Appropriate:			
Hepatology			
Pediatrics			
Nephrology (with dialysis capability)			
Pulmonary Medicine (with respiratory therapy support)			

8. **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. In the case of a program that is reactivating, show the projected information 3 years out from the anticipated reactivation date.

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

9. **Administration:**

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

b) Describe the institutional commitment to this program and the hospital resources that are committed to this program for the next two years.

c) Describe the role of the transplant administrator and their areas of oversight.

d) Describe how the transplant program routinely reviews or will review its performance. Please indicate the type, frequency of meetings, and participants (by title).

e) Is there a plan for hospital administration to receive periodic performance reports for the transplant program? If yes, indicate frequency and the data that will be reported.

- Describe the steps taken to identify and correct problems that may affect the program's success.

- Provide a list of quality metrics that you use/will use for tracking this transplant program (include name of responsible staff member).

f) Who is responsible for ensuring that the hospital is in compliance with OPTN requirements and policies?

Name: _____
Title: _____

10. **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.

b) 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	% of Time Dedicated to this Transplant Program	Background

PROGRAM SPECIFIC: PART 2, SECTION D – PROTOCOLS/METHODS/PROCEDURES

1. Patient/Candidate Management (expand response space as needed):

a) Are there written policies and procedures for transplantation and patient management? __ Yes ___ No

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

b) Describe below how candidates/recipients 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

c) What outreach programs exist?

d) How are patient calls and questions handled? How are outpatient emergencies handled?

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

f) Who participates in transplant team meetings (by role, not name)? Are rounds conducted with a multi-disciplinary team?

2. Outpatient Care

	Response
Who directs/will direct the outpatient transplant clinic?	
Which physicians and surgeons (will) participate regularly in the transplant clinic? Include frequency of clinics.	
Who will care/cares for transplant patients after initial discharge?	
How often will/are transplant patients seen for long-term follow-up?	

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

	Response
Is there standard protocol in place for patient evaluation?	
Are there formal exclusion criteria for acceptance?	
Who gives final approval for adding patients to the waiting list?	___ Single Individual ___ Committee If committee, list members and frequency of meetings (by role).

4. **Immunosuppression**

	Yes	**No**
Is there a standard immunosuppression protocol?		
Do individual team members use separate protocols**?**		
Who manages immunosuppression? Initial hospitalization: First 3 months out-patient: Long-term (after 3 months post-op):		
Describe the interactions of team members in providing immunosuppression management.		

5. Articulate plans for any transplant-related services provided outside the hospital. This includes, but is not limited to, plans to assure immediate access to services and to assure patient safety during transports to off-site facilities.
   - Provide a letter of support or agreement from each off-site provider.

PROGRAM SPECIFIC, PART 2, SECTION E – BUSINESS/IMPLEMENTATION PLAN

The availability of a business/implementation plan is identified as a critical element in developing a successful transplant program. The OPTN requests that the CEO at each transplant hospital to certify that such a business/implementation plan exists in support of the application.

This certification is required in the following situations:

- **when applying for institutional membership**
- **establishing a new transplant program**
- **reactivating a transplant program**

The following basic factors are integral and should be addressed in any adopted Plan:

Institutional Level

- Hospital Overview (ownership, management, history, etc.)
- Market Assessment (local/regional need for transplant service line; why did the hospital decide to start a transplant program/this specific transplant program?)
- Financial Assessment (financial impact/costs/reimbursement sources)
- Commitment (money, physical plant, employee resources, etc.)
- Capability Assessment (chart to demonstrate that the institution is aware of everything that needs to be in place for a successful program)
- Organizational Chart (transplant program fits where in the hospital structure? report structure/oversight responsibility)

Program Level

- Internal and External Interactions and Responsibilities (demonstrate that the program understands all of the people/organizations they must work with – patients, hospital staff, external organizations, etc.)
- First Year Plan/Timeline
- Infrastructure/Operations
  - Staffing Model (initial, retention and succession planning)
  - Resource Assessment (physical resources, IT, collaboration with other organizations, etc.)
- Marketing (professional and community value recognition)
- Risk Assessment (financial risks, staffing succession plan, exit strategy)
- Organizational Chart (program report and staff interaction)
- Quality Assurance and Process Improvement Plan

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 Plan/Implementation Plan has been developed, adopted and will be consulted regarding the institutional commitments being made and acknowledged in this transplant program application.

Chief Executive Officer **Date**

_____ _____

_____

Print name

PROGRAM SPECIFIC: PART 2, SECTION F– ORGAN PROCUREMENT ARRANGEMENTS

1. Who takes organ offer calls? How do you handle internally?

2. Are there exiting Alternative Local Units (ALU) or variances that will be impacted by this proposed program?
   If yes, has the hospital agreed to participate?
   If no, explain.

Respond to question 3 below if you are applying for a new transplant program in an existing member transplant hospital. New transplant hospital applicants must complete Part 5 (Organ Procurement Arrangements) question 1 and either section A or B.

3. Attach a letter of agreement or contract with your OPO that specifically indicates it will provide the organs for which you are applying.

Part 3: Heart Transplant Program

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

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

Check List	Question Reference	Required Supporting Documents
	3A 1	Current C.V.

Name	Date of Appointment	Primary Areas of Responsibility

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

1. **Primary Heart Transplant Surgeon.** Refer to the Bylaws for the necessary qualifications and more specific descriptions of the required supporting documents listed below.

Check List	Question Reference	Required Supporting Documents
	3B, 1a	Current C.V.
	3B, 1b	Letter from the Credentialing Committee of the applicant hospital stating that the surgeon meets all requirements to be in good standing. Please provide an explanation of any status other than active/full.
	3B, 1c, f, g	Letter from the Surgeon detailing his/her commitment to the program and describing their transplant training/experience
	3B, 1f	Formal Training: A letter from the training director verifying that the fellow has met the requirements
	3B, 1f	Formal Training: A log (organized by date) of the transplant and procurement procedures.
	3B, 1g	Transplant Experience: A letter from the program director verifying that the individual has met the requirements
	3B, 1g	Transplant Experience: A log (organized by date) of the transplant and procurement procedures
		Other Letters of Recommendation (Reference)
		Letter of recommendation attesting to the individual's overall qualifications to act as primary surgeon and addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate.

a) Name: _____

b) Date of employment at this hospital (MM/DD/YY): _____
Date assumed role of primary surgeon (MM/DD/YY): _____

Does individual have FULL privileges at this hospital?

_____ Yes Provide copy of hospital credentialing letter.

_____ No If the individual does **not** have full privileges, explain why, and provide the date the individual will be considered for full privileges. Include an explanation that describes the scope of privileges.

c) Percentage of professional time spent at this hospital: _____% = _____ hrs/week

d) List other hospitals, health care facilities, and/or medical group practices and percentage of professional time spent on site at each:

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

e) Board certification type(s) or equivalent. If board certification is pending, indicate the date the exam has been scheduled. If individual has been recertified, please use that date.

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

f) Formal Training: List the name of the transplant hospital(s) at which heart transplant training (residency/fellowship) was received including program director(s) names, applicable dates, and the number of transplants and procurements performed. If the surgeon is qualifying as primary surgeon through residency or fellowship training, also submit the supporting documents listed below. Refer to the Bylaws for the necessary qualifications and detailed descriptions of the required supporting documents:

- A letter from the program director verifying that the individual has met the requirements.
- A log (organized by date) of the transplant and procurement procedures. The log should include a medical record/OPTN ID Number, transplant/procurement date, and the surgeon's role in the procedure (i.e., primary or 1st assistant). These logs must be signed by the director of the training program.

Date From – To MM/DD/YY	Transplant Hospital	Program Director	# Transplants as Primary Surgeon		# Transplants 1st Assistant		# of Procurements as Primary Surgeon or 1st Assistant	
			HR	HL	HR	HL	HR	HL
Residency:								
Fellowship:								

g) Transplant Experience (Post Fellowship): List the name of the hospital(s), applicable dates, and number of heart and/or heart/lung transplant and procurement procedures performed by the individual at each hospital. Refer to the Bylaws for the necessary qualifications and descriptions of the required supporting documents listed below:

- Letter(s) of reference from the program director(s) listed below.
- A log (organized by date) of the transplant and procurement procedures. The log should include a medical record/OPTN ID Number, transplant/procurement date, and the surgeon's role in the procedure (i.e., primary or 1st assistant).

The transplant log(s) should be signed by the program director, division chief, or department chair from the program where the experience was gained.

Date From – To MM/DD/YY	Transplant Hospital	Program Director	# Transplants as Primary		# Transplants First Assisted		# of Procurements as Primary Surgeon or 1st Assistant	
			HR	HL	HR	HL	HR	HL

h) Summarize how the surgeon's experience fulfills the membership criteria.
(Check all that apply)

Membership Criteria	Yes
1. On site	
2. Certified by the American Board of Thoracic Surgery or the foreign equivalent	
3. Thoracic Surgery Boards pending	
4. Cardiothoracic Surgery Residency	
a. Primary surgeon or 1st assistant on 20 or more heart and/or heart/lung transplants	
b. Primary surgeon or 1st assistant on 10 or more heart or heart/lung procurements	
c. Involved in all levels of pre-, peri-, and post-operative patient care within the last 2 years	
d. Training program approved by American Board of Thoracic Surgery	
5. 12-month Heart Transplant Fellowship	
a. Primary surgeon or 1st assistant on 20 or more heart and/or heart/lung transplants	
b. Primary surgeon or 1st assistant on 10 or more heart or heart/lung procurements	
c. Involved in all levels of pre-, peri-, and post-operative patient care within the last 2 years	
d. Training program approved by American Board of Thoracic Surgery	
6. Experience (Post Fellowship)	
a. Primary surgeon or 1st assistant on 20 or more heart and/or heart/lung transplants over a minimum of 2 years and a maximum of 5 years. Of these 20 transplants, at least 15 were performed as primary surgeon.	
b. Primary surgeon or 1st assistant on 10 or more heart or heart/lung procurements	
c. Involved in all levels of pre-, peri-, and post-operative patient care within the last 2 years	
7. Pediatric Pathway	
a. Program serves predominantly pediatric patients	
b. Individual has maintained current working knowledge in all aspects of heart transplantation and patient care within the last 2 years	
c. Hospital has petitioned the Membership and Professional Standards Committee for approval under this pathway	
d. A preliminary interview before the Membership and Professional Standards Committee shall be required	

i) Describe in detail the proposed primary surgeon's level of involvement in this transplant program, and if applicable, describe the surgeon's plan for coverage of transplant programs located in multiple transplant hospitals. (Expand rows below as necessary and use complete sentences [i.e. narrative descriptions] for each)

	Describe Involvement
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	

j) Describe the proposed primary surgeon's transplant training and experience in the areas listed below. (Expand rows below as necessary, and use complete sentences [i.e. narrative descriptions] for each)

	Describe Training/Experience
Pre-Operative Patient Management	
Recipient Selection	
Donor Selection	
Transplant Surgery	
Post-Operative Hemodynamic Care	
Post-Operative Immunosuppressive Therapy	
Use of Mechanical Assist Devices	
Outpatient Follow-Up	
Additional Information	

PART 3B, Section 2: Personnel – Additional/Other Surgeons

Complete this section of the application to describe the involvement, training, and experience of any other surgeons participating in the program. **Surgeons must be designated as Additional or Other as described below**. All surgeons must be listed in Table 1 (Certificate of Investigation) of this application.

The Bylaws provide the following definition of Additional Transplant Surgeon:

> *Additional Transplant Surgeons must be credentialed by the institution to provide transplant services and be able to independently manage the care of transplant patients including performing the transplant operation and procurement procedures.*

Surgeons that also support this program but who do not meet the definition of "primary" or additional," should complete this section as well. The type should be indicated as "other."

Duplicate pages as needed.

PART 3B, Section 2: Personnel – Additional/Other Surgeons

2. Additional/Other Surgeons (duplicate this page as needed). Provide the following attachments:

Check List	Question Reference	Required Supporting Documents
	3B, 2a	Current C.V.
	3B, 2b	A letter from the Credentialing Committee of the applicant hospital stating that the surgeon meets all requirements to be in good standing. Please provide an explanation of any status other than active/full.
	3B, 2c,e,f	A letter from the Surgeon detailing his/her commitment to the program and level of involvement in substantive patient care

a) Name: _____

For heart transplantation this individual is classified as ____ Additional Surgeon ___ Other Surgeon
(Check only one)

b) Date of employment at this hospital (MM/DD/YY): _____
Does individual have FULL privileges at this hospital?
_____ Yes Provide copy of hospital credentialing letter.
_____ No If the individual does **not** have full privileges, explain why, and provide the date the individual will be considered for full privileges. Include an explanation that describes the scope of privileges.

c) Percentage of professional time spent on site: _____% = _____ hrs/week

d) Board certification type(s) or equivalent. If board certification is pending, indicate the date the exam has been scheduled. If individual has been recertified, **please use that date.**

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

e) Training (Residency/Fellowship): List the name of the transplant hospital(s) at which heart transplant training (residency/fellowship) was received. Include the program director(s) names, applicable dates, and the number of heart and/or heart/lung transplants and procurements the individual performed.

Date From – To MM/DD/YY	Transplant Hospital	Program Director	# Transplants as Primary Surgeon		# Transplants 1st Assistant		# of Procurements as Primary Surgeon or 1st Assistant	
			HR	HL	HR	HL	HR	HL
Residency:								
Fellowship:								

f) Transplant Experience (Post Fellowship): List the name of the transplant hospital(s), applicable dates, and number of heart and/or heart/lung transplants and procurements performed by the individual at each hospital.

Date From – To MM/DD/YY	Transplant Hospital	Program Director	# Transplants as Primary Surgeon		# Transplants 1st Assistant		# of Procurements as Primary Surgeon or 1st Assistant	
			HR	HL	HR	HL	HR	HL

g) Describe the surgeon's level of involvement in this heart transplant program in the areas listed below. (Expand rows as necessary, and use complete sentences [i.e. narrative descriptions] for each)

	Describe Involvement
Pre-Operative Patient Management	
Recipient Selection	
Donor Selection	
Transplant Surgery	
Post-Operative Hemodynamic Care	
Post-Operative Immunosuppressive Therapy	
Use of Mechanical Assist Devices	
Outpatient Follow-Up	
Additional Information	

h) Describe the surgeon's heart transplant training and experience in the areas listed below. (Expand rows as necessary, and use complete sentences [i.e. narrative descriptions] for each)

	Describe Training/Experience
Pre-Operative Patient Management	
Recipient Selection	
Donor Selection	
Transplant Surgery	
Post-Operative Hemodynamic Care	
Post-Operative Immunosuppressive Therapy	
Use of Mechanical Assist Devices	
Outpatient Follow-Up	
Additional Information	

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

1. **Primary Heart Transplant Physician.** Refer to the Bylaws for necessary qualifications. Provide the attachments listed below:

Check List	Question Reference	Required Supporting Documents
	3C, 1a	Current C.V.
	3C, 1b	Letter from the Credentialing Committee of the applicant hospital stating that the physician meets all requirements to be in good standing. Please provide an explanation of any status other than active/full.
	3C, 1c,f,g	Letter from the Physician detailing his/her commitment to the program; level of involvement with substantive patient care; and summarizing their previous transplant experiencE
	3C, 1f	Formal Training: A letter from the training director verifying that the individual has met the requirements
	3C, 1f	Formal Training: A log (organized by date of transplant) of the transplant recipients followed
	3C, 1g	Transplant Experience: A letter from the program director verifying that the individual has met the requirements
	3C, 1g	Transplant Experience: A log (organized by date of transplant) of the transplant recipients followed
		Other Letters of Recommendation (Reference)
		Letter of recommendation attesting to the individual's overall qualifications to act as primary physician and addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate

a) Name: _____

b) Date of employment at this hospital (MM/DD/YY): _____
Date assumed role of primary physician (MM/DD/YY): _____

Does individual have FULL privileges at this hospital?

_____ Yes Provide copy of hospital credentialing letter.
_____ No If the individual does **not** have full privileges, explain why, and provide the date the individual will be considered for full privileges. Include an explanation that describes the scope of privileges.

c) Percentage of professional time on site: _____% = _____ hrs/week

d) List other hospitals, health care facilities, and medical group practices and percentage of professional time spent on site at each:

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

e) Board certification type(s) or equivalent. If board certification is pending, indicate the date the exam has been scheduled. If individual has been recertified, please use that date.

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

f) Training (Fellowship): List the program(s) at which heart transplant training was received including the name of the hospital(s), program director(s) names, applicable dates, and the number of transplant patients for whom the physician provided substantive patient care (pre-, peri- and post-operatively from the time of transplant). **If the physician is qualifying as primary physician through fellowship training**, also submit the supporting documents listed below. Refer to the Bylaws for the necessary qualifications and descriptions of the required supporting documents:

- Letters from the director of fellowship training program and the supervising physician verifying that the fellow has met the requirements.
- A recipient log that includes the date of transplant and the patient's medical record and/or OPTN ID number. Each log must be signed by the director of the training program and/or primary transplant physician at that transplant program.

Date From - To MM/DD/YY	Transplant Hospital	Program Director	# Heart Patients Followed			# Heart/Lung Patients Followed		
			Pre	Peri	Post	Pre	Peri	Post

g) Transplant Experience (Post Fellowship Only): List the name of the hospital(s), program director(s), applicable dates, and number of heart and/or heart/lung transplant patients for whom the transplant physician accepted primary responsibility for substantive patient care (pre-, peri-, and post-operatively from the time of transplant). Refer to the Bylaws for the necessary qualifications and descriptions of the required supporting documents listed below:

- A supporting letter from either the heart transplant physician or the heart transplant surgeon at the cardiologist's hospital with whom the cardiologist has been directly involved, who can certify the cardiologist's competence.
- A recipient log that includes the date of transplant, and the patient's medical record and/or OPTN ID number. Each log should be signed by the program director, division chief, or department chair from the program where the experience was gained.

Date From - To MM/DD/YY	Transplant Hospital	Program Director	# Heart Patients Followed			# Heart/Lung Patients Followed		
			Pre	Peri	Post	Pre	Peri	Post

h) Training/Experience: Describe how the physician fulfills the criteria for participation as an observer in 3 organ procurements and three transplants that include the heart, as well as observing 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.

- Provide a log of these cases that includes the date of procurement, medical record ID number and/or OPTN ID number, and the location of the donor.
- If these criteria have not been met, submit a plan explaining how the individual will fulfill them.

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 Mgmt.

i) Summarize how the transplant physician's experience fulfills the membership criteria for membership. (Check all that apply)

Membership Criteria	Yes
1. On site	
2. M.D., D.O. or equivalent degree	
3. Certified by the American Board of Internal Medicine, Pediatrics or the foreign equivalent	
4. Board certified in Cardiology	
5. Achieved eligibility in Cardiology	
6. Cardiology Fellowship	
a. Involved in the primary care of 20 or more heart and/or heart/lung transplant recipients from the time of their transplant	
b. Experience with pre-, peri-, and post-operative patient care within the last 2 years	
c. Observed 3 procurement procedures and 3 heart transplants	
d. Observed 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	
e. Fellowship training program certified by American Board of Internal Medicine (adult cardiology), or American Board of Pediatrics (pediatric cardiology), or accepted as equivalent by MPSC (foreign training)	
7. 12-month Transplant Cardiology Fellowship	
a. Involved in the primary care of 20 or more heart and/or heart/lung transplant recipients from the time of transplant	
b. Experience with pre-, peri-, and post-operative care within the last 2 years	
c. Observed 3 procurement procedures and 3 heart transplants	
d. Observed 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	
e. Fellowship training program certified by American Board of Internal Medicine (adult cardiology), or American Board of Pediatrics (pediatric cardiology), or accepted as equivalent by the Membership and Professional Standards Committee (foreign training)	
8. Acquired Clinical Experience in Heart and/or Heart/Lung Transplantation	
a. 2-5 years experience on an active heart transplant service	
b. Involved in the primary care of 20 or more heart and/or heart/lung transplant recipients for a minimum of 3 months from the time of their transplant	
c. Experience with pre-, peri-, and post-operative care within the last 2 years	
d. Observed 3 procurement procedures and 3 heart transplants	
e. Observed 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	

Membership Criteria	Yes
9. Pediatric Pathway	
a. Program serves predominantly pediatric patients	
b. Individual has maintained current working knowledge in all aspects of heart transplantation and patient care within the last 2 years	
c. Hospital has petitioned the Membership and Professional Standards Committee for approval under this pathway	
d. A preliminary interview before the Membership and Professional Standards Committee shall be required	
10. Conditional Pathway – ***Only available to existing programs***	
a. Board certified in cardiology	
b. Qualifying by virtue of training	
i. Involved in the primary care of 10 or more heart or heart/lung transplant recipients from the time of their transplant	
ii. Training hospital conducts 20 or more heart or heart/lung transplants per year	
c. Qualifying by virtue of acquired clinical experience	
i. Involved in the primary care of 10 or more heart or heart/lung transplant recipients for a minimum of 3 months from the time of their transplant	
ii. Acquired a minimum of 12 months experience on an active heart transplant service over a maximum of 2 years	
d. Consulting relationship with counterparts at another UNOS member transplant hospital approved for heart transplantation (include letter of support)	

j) Describe in detail the proposed primary transplant physician's involvement in the management of patients in this program and, if applicable, their plan for coverage of multiple transplant hospitals. (Expand rows as necessary and use complete sentences [i.e. narrative descriptions] for each)

	Describe Involvement
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	

k) Describe the proposed primary physician's transplant training and experience in the areas listed below. (Expand rows as necessary and use complete sentences [i.e. narrative descriptions] for each)

	Description 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	
Additional Information	

PART 3C, Section 2: Personnel – Additional/Other Physicians

Complete this section of the application to describe the involvement, training, and experience of additional/other physicians associated with the program. **Physicians must be designated as Additional or Other as described below**.

All physicians must be listed in Table 1 (Certificate of Investigation) in this application.

The Bylaws provide the following definition of Additional Transplant Physician:

Additional Transplant Physicians must be credentialed by the institution to provide transplant services and be able to independently manage the care of transplant patients.

Physicians that also support this program but who do not meet the definition of "primary" or "additional," should complete this section of the application. The type should be indicated as "other."

Duplicate pages as needed.

PART 3C, Section 2: Personnel – Additional/Other Physicians

2. **Additional/Other Physicians** (Duplicate this page as needed). Refer to the Bylaws for the necessary qualifications and descriptions of the required supporting documents listed below:

Check List	Question Reference	Required Supporting Documents
	3C, 2a	Current C.V.
	3C, 2b	A letter from the Credentialing Committee of the applicant hospital stating that the physician meets all requirements to be in good standing. Please provide an explanation of any status other than active/full.
	3C, 2c,e,f	A letter from the Physician detailing his/her commitment to the program and level of involvement in substantive patient care

a) Name: _____

For heart transplantation this individual is classified as __ Additional Physician __ Other Physician
(Check only one)

b) Date of employment at this hospital (MM/DD/YY): _____

Does individual have FULL privileges at this hospital?
_____ Yes Provide copy of hospital credentialing letter.
_____ No If the individual does **not** have full privileges, explain why, and provide the date the individual will be considered for full privileges. Include an explanation that describes the scope of privileges.

c) Percentage of professional time spent on site: _____% = _____ hrs/week

d) Board certification type(s) or equivalent. If board certification is pending, indicate the date the exam has been scheduled. If individual has been recertified, please use that date.

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

e) Training (Fellowship): List the program(s) at which heart transplant training was received including the name of the transplant hospital(s), program director(s) names, applicable dates, and the number of transplant patients for whom the physician provided substantive patient care (pre-, peri- and post-operatively from the time of transplant).

Date From - To MM/DD/YY	Transplant Hospital	Program Director	# Heart Patients Followed			# Heart/Lung Patients Followed		
			Pre	Peri	Post	Pre	Peri	Post

f) Transplant Experience (Post Fellowship Only): List the name of the transplant hospital(s), program director(s), applicable dates, and number of heart and/or heart/lung transplant patients for whom the transplant physician accepted primary responsibility for substantive patient care (pre-, peri-, and post-operatively from the time of transplant).

Date From - To MM/DD/YY	Transplant Hospital	Program Director	# Heart Patients Followed			# Heart/Lung Patients Followed		
			Pre	Peri	Post	Pre	Peri	Post

g) Describe in detail the transplant physician's involvement in this heart transplant program. (Expand rows as necessary and use complete sentences [i.e. narrative descriptions] for each)

	Describe Involvement
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	
Additional Information	

h) Describe the physician's transplant training and experience in the role of transplant patient management in the areas listed below. (Expand rows as necessary**,** use complete sentences [i.e. narrative descriptions] for each)

	Describe 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	
Additional Information	

Table 1: Certificate of Investigation

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

The Bylaws state that "***Each primary surgeon or primary physician*** *listed on the application as a part of the plan for who shares coverage responsibility shall submit an assessment, subject to medical peer review confidentiality requirements and which follows guidelines provided in the application and is satisfactory to the MPSC, of* ***all physicians and surgeons*** *participating in the program regarding their involvement in prior transgressions of UNOS requirements and plans to ensure that the improper conduct is not continued." (Emphasis Added)*

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

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:

*** Expand rows as needed**

Table 2: Program Coverage Plan

Please answer the questions below and provide a written copy of the current Program Coverage Plan. The plan must be signed by either:

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

In accordance with the Bylaws, the program director, in conjunction with the primary transplant surgeon and transplant physician, must submit a written Program Coverage Plan which documents how 100% medical and surgical coverage is provided by individuals credentialed by the hospital to provide transplant service for the program. 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, during the year. The Program Coverage Plan must address the following requirements:

	Yes	**No**
Is this a single surgeon program?		
Is this a single physician program?		
If the answer to either one of the above questions is "Yes," explain the protocol for notifying patients.		
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 within one-hour ground transportation time to address urgent patient issues?		
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:		

Table 3: OPTN Staffing Report

HEART TRANSPLANT PROGRAM

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

Answer the questions below for this transplant program. Since this information will be used to update UNet[sm] and the Membership Directory, make sure to include the best (most accurate) telephone number and address for each person. Use additional pages as necessary. The surgeons and physicians named below should match those listed on the Certificate of Investigation.

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

Name	Address	Phone	Fax	Email

The **surgeons** who participate in this transplant program are:

Name	Additional	Other	Address	Phone	Fax	Email

The **physicians** (internists) who participate in this transplant program are:

Name	Additional	Other	Address	Phone	Fax	Email

Identify the **hospital administrative director/manager** who will be involved with this program. **Use an * to indicate** which individual will serve as the primary transplant administrator if more than one is listed:

Name	Address	Phone	Fax	Email

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

Name	Address	Phone	Fax	Email

The **clinical transplant coordinators** who participate in this transplant program are:

Name	Address	Phone	Fax	Email

List the **data coordinators** for this transplant program below. **Use an * to indicate** which individual will serve as the primary data coordinator:

Name	Address	Phone	Fax	Email

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

Name	Address	Phone	Fax	Email

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

Name	Address	Phone	Fax	Email

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

Name	Address	Phone	Fax	Email

Table 4A: Primary Surgeon - Transplant Log (Sample)
Complete 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

#	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				

Extend lines on log as needed
Patient ID should <u>not</u> be name or Social Security Number.

Director's Signature: _____ Date: _____

Table 4B: Primary Surgeon - Procurement Log (Sample)
Complete separate form for each hospital

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

#	Date of Procurement	Medical Record/ OPTN ID # of Donor	Location of Donor (hospital)	Comments (LRD/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				
31				
32				
33				
34				
35				

Extend lines on log as needed

Director's Signature: _____ Date: _____

Table 4C: Primary Physician – Recipient Log (Sample)
Complete 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
List only those patients followed for 3 months from the time of transplant (including pre-, peri-, and post-operative management)

#	Date of Transplant	Medical Record/ OPTN ID #	Pre-Operative	Peri-Operative	Post-Operative (90-days follow-up care)	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						
26						
27						
28						
29						
30						
31						
32						
33						
34						
35						

Extend lines on log as needed

Director's Signature: _____ Date: _____

Table 4D: Primary Physician – Observation Log (Sample)

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

In the tables below, document how the physician fulfills the requirements for participation as an observer in organ procurements and transplants, as well as observing the selection and management of at least 3 multiple organ donors that include the organ for which application is being submitted. *List cases in date order.*

Procurements Observed

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

Transplants Observed

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

Donor Selection and Management

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

Part 3: Heart/Lung Transplant Program

PART 3A - Personnel – Transplant Program Director(s)

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

Check List	Question Reference	Required Supporting Documents
	3A, 1	Current C.V.

Name	Date of Appointment	Primary Areas of Responsibility

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

1. Primary Heart/Lung Transplant Surgeon. Refer to the Bylaws for the necessary qualifications and more specific descriptions of the required supporting documents listed below:

Check List	Question Reference	Required Supporting Documents
	3B, 1a	Current C.V.
	3B, 1b	Letter from the Credentialing Committee of the applicant hospital stating that the surgeon meets all requirements to be in good standing. Please provide an explanation of any status other than active/full.
	3B, 1c,g,h	Letter from the surgeon detailing his/her commitment to the program and describing their transplant experience/training
	3B, 1f	Formal Training: A letter from training director verifying that the fellow has met the requirements
	3B, 1f	Formal Training: A log (organized by date) of the transplant and procurement procedures
	3B, 1g	Transplant Experience: A letter from program director verifying that the individual has met the requirements
	3B, 1g	Transplant Experience: A log (organized by date) of the transplant and procurement procedures
		Other Letters of Recommendation (Reference)
		Letter of recommendation attesting to the individual's overall qualifications to act as primary surgeon and addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate

a) Name: _____

b) Date of employment at this hospital (MM/DD/YY): _____
Date assumed role of primary surgeon (MM/DD/YY): _____

Does individual have FULL privileges at this hospital?

_____ Yes Provide copy of hospital credentialing letter.

_____ No If the individual does **not** have full privileges, explain why, and provide the date the individual will be considered for full privileges. Include an explanation that describes the scope of privileges.

c) Percentage of professional time spent at this hospital: _____% = _____ hrs/week

d) List below the hospitals, health care facilities, and medical group practices and percentage of professional time this individual is on site at each:

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

e) Board certification type(s) or equivalent. If board certification is pending, indicate the date the exam has been scheduled. If individual has been recertified, please use that date.

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

f) Transplant Training: List the name of the transplant hospital(s) at which heart/lung, heart, and/or lung transplant training (residency/fellowship) was received. Include the program director(s) names, applicable dates, and the number of transplants and procurements performed. If the surgeon is qualifying as the primary surgeon through residency or fellowship training, also submit the supporting documents listed below. Refer to the Bylaws for the necessary qualifications and detailed descriptions of the required supporting documents:

- A letter from program director verifying that the fellow has met the requirements.
- Logs (Tables 4A and 4B) of the transplant and procurement procedures. The logs should include a patient identifier/OPTN ID number, transplant/procurement date, and the surgeon's role in the procedure (i.e., primary or 1st assistant). Each log must be signed by the director of the training program.

Date From – To MM/DD/YY	**Transplant Hospital**	**Program Director**	**# of Transplants as Primary Surgeon**			**# of Transplants as 1st Assistant**			**# of Procurements as Primary Surgeon or 1st Assistant**		
			HR	**HL**	**LU**	**HR**	**HL**	**LU**	**HR**	**HL**	**LU**
Residency:											
Fellowship:											

g) Transplant Experience (Post Fellowship): List the name of the transplant hospital(s), applicable dates, and number of heart/lung, heart, and/or lung transplants and procurements performed by the individual at each hospital. Refer to the Bylaws for the necessary qualifications and descriptions of the required supporting documents listed below:

- Letter(s) of reference from the program director(s) listed below.
- Logs (Tables 4A and 4B) of the transplant and procurement procedures. Each log should include a patient identifier/OPTN ID number, transplant/procurement date, and the surgeon's role in the procedure (i.e., primary or 1st assistant). Each transplant log(s) should be signed by the program director, division chief, or department chair from the program where the experience was gained.

Date From – To MM/DD/YY	Transplant Hospital	Program Director	# of Transplants as Primary Surgeon			# of Transplants as 1st Assistant			# of Procurements as Primary Surgeon or 1st Assistant		
			HR	HL	LU	HR	HL	LU	HR	HL	LU

h) Summarize how the surgeon's experience fulfills the membership criteria.
(Check all that apply)

Membership Criteria	Yes
1. On site	
2. Certified by the American Board of Thoracic Surgery or the foreign equivalent	
3. Thoracic Surgery Boards pending	
4. Cardiothoracic Surgery Residency *(may qualify via either heart or lung transplant training)*	
a. Primary surgeon or 1st assistant on 20 or more heart and/or heart/lung transplants	
b. Primary surgeon or 1st assistant on 10 or more heart or heart/lung procurements	
c. Primary surgeon or 1st assistant on 15 or more lung and/or heart/lung transplants	
d. Primary surgeon or 1st assistant on 10 or more lung procurements	
e. Involved in all levels of pre-, peri-, and post-operative patient care within the last 2 years	
f. Training program approved by American Board of Thoracic Surgery	
5. 12-month Transplant Fellowship *(may qualify via either heart or lung transplant training)*	
a. Primary surgeon or 1st assistant on 20 or more heart and/or heart/lung transplants	
b. Primary surgeon or 1st assistant on 10 or more heart or heart/lung procurements	
c. Primary surgeon or 1st assistant on 15 or more lung and/or heart/lung transplants	
d. Primary surgeon or 1st assistant on 10 or more lung procurements	
e. Involved in all levels of pre-, peri-, and post-operative patient care within the last 2 years	
f. Training program approved by American Board of Thoracic Surgery	
6. Experience (Post Fellowship) *(may qualify via either heart or lung transplant experience)*	
a. Primary surgeon or 1st assistant on 20 or more heart and/or heart/lung transplants over a minimum of 2 years and a maximum of 5 years. Of these 20, at least 15 were performed as primary surgeon.	
b. Primary surgeon or 1st assistant on 10 or more heart or heart/lung procurements	
c. Primary surgeon or 1st assistant on 15 or more lung and/or heart/lung transplants over a minimum of 2 years and a maximum of 5 years. Of these 15, at least 10 were performed as primary surgeon.	
d. Primary surgeon or 1st assistant on 10 or more lung procurements	
e. Involved in all levels of pre-, peri-, and post-operative patient care within the last 2 years	
7. Pediatric Pathway *(may qualify via either heart or lung transplant training/experience)*	
a. Program serves predominantly pediatric patients	
b. Individual has maintained current working knowledge in all aspects of **heart** transplantation and patient care within the last 2 years	
c. Individual has maintained current working knowledge in all aspects of **lung** transplantation and patient care within the last 2 years	
d. Hospital has petitioned the Membership and Professional Standards Committee (MPSC) for approval	
e. A preliminary interview before the Membership and Professional Standards Committee shall be required	

i) Describe in detail the proposed primary surgeon's level of involvement in this transplant program, and if applicable, describe the surgeon's plan for coverage of transplant programs located in multiple transplant hospitals. (Expand rows below as necessary and use complete sentences [i.e. narrative descriptions] for each)

	Describe Involvement
Pre-Operative Patient Management	
Recipient Selection	
Donor Selection	
Transplant Surgery	
Use of Mechanical Assist Devices	
Care of Acute and Chronic Lung Failure	
Cardiopulmonary Bypass	
Pre- and Postoperative Pulmonary Care	
Histologic Interpretation and Grading of Lung Biopsies for Rejection	
Post-Operative Hemodynamic Care	
Post-Operative Immunosuppressive Therapy	
Long-Term Outpatient Follow-Up	
Coverage of Multiple Transplant Hospitals (if applicable)	
Additional Information	

j) Describe the proposed primary surgeon's transplant training and experience in the areas listed below. (Expand rows below as necessary and use complete sentences [i.e. narrative descriptions] for each)

	Describe Training/Experience
Pre-Operative Patient Management	
Recipient Selection	
Donor Selection	
Transplant Surgery	
Use of Mechanical Assist Devices	
Care of Acute and Chronic Lung Failure	
Cardiopulmonary Bypass	
Pre- and Postoperative Pulmonary Care	
Histologic Interpretation and Grading of Lung Biopsies for Rejection	
Post-Operative Hemodynamic Care	
Post-Operative Immunosuppressive Therapy	
Long-Term Outpatient Follow-Up	
Additional Information	

PART 3B, Section 2: Personnel – Additional/Other Surgeons

Complete this section of the application to describe the involvement, training, and experience of any other surgeons participating in the program. **Surgeons must be designated as Additional or Other as described below**. All surgeons must be listed in Table 1 (Certificate of Investigation) in this application.

The Bylaws provide the following definition of Additional Transplant Surgeon:

> *Additional Transplant Surgeons must be credentialed by the institution to provide transplant services and be able to independently manage the care of transplant patients including performing the transplant operation and procurement procedures.*

Surgeons that also support this program but who do not meet the definition of "primary" or additional" should complete this section as well. The type should be indicated as "other."

Duplicate pages as needed.

PART 3B, Section 2: Personnel – Additional/Other Surgeons

2. Additional/Other Surgeons (duplicate this page as needed). Provide the attachments listed below:

Check List	Question Reference	Required Supporting Documents
	3B, 2a	Current C.V.
	3B, 2b	A letter from the Credentialing Committee of the applicant hospital stating that the surgeon meets all requirements to be in good standing. Please provide an explanation of any status other than active/full.
	3B, 2c,e,f	A letter from the surgeon detailing his/her commitment to the program and level of involvement in substantive patient care

a) Name: _____

For heart/lung transplantation this individual is classified as ____ Additional Surgeon ___ Other Surgeon
(Check only one)

b) Date of employment at this hospital (MM/DD/YY): _____

Does individual have FULL privileges at this hospital?

_____ Yes Provide copy of hospital credentialing letter.

_____ No If the individual does **not** have full privileges, explain why, and provide the date the individual will be considered for full privileges. Include an explanation that describes the scope of privileges.

c) Percentage of professional time spent on site: _____% = _____ hrs/week

d) Board certification type (s) or equivalent. If board certification is pending, indicate the date the exam has been scheduled. If individual has been recertified, please use that date.

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

e) Transplant Training (Residency/Fellowship): List the name of the transplant hospital(s) at which heart/lung, heart, and/or lung transplant training (residency/fellowship) was received. Include the program director(s) names, applicable dates, and the number of transplants and procurements the individual performed.

Date From – To MM/DD/YY	Transplant Hospital	Program Director	# of Transplants as Primary Surgeon			# of Transplants as 1st Assistant			# Procurements as Primary Surgeon or 1st Assistant		
			HR	HL	LU	HR	HL	LU	HR	HL	LU
Residency:											
Fellowship:											

f) Transplant Experience (Post Fellowship): List the name of the transplant hospital(s), applicable dates, and number of heart/lung, heart and/or lung transplants and procurements performed by the individual at each hospital.

Date From – To MM/DD/YY	Transplant Hospital	Program Director	# of Transplants as Primary Surgeon			# of Transplants as 1st Assistant			# Procurements as Primary Surgeon or 1st Assistant		
			HR	HL	LU	HR	HL	LU	HR	HL	LU

g) Describe the surgeon's level of involvement in this transplant program in the areas listed below. (Expand rows as necessary and use complete sentences [i.e. narrative descriptions] for each)

	Describe Involvement
Pre-Operative Patient Management	
Recipient Selection	
Donor Selection	
Transplant Surgery	
Use of Mechanical Assist Devices	
Care of Acute and Chronic Lung Failure	
Cardiopulmonary Bypass	
Pre- and Postoperative Pulmonary Care	
Histologic Interpretation and Grading of Lung Biopsies for Rejection	
Post-Operative Hemodynamic Care	
Post-Operative Immunosuppressive Therapy	
Long-Term Outpatient Follow-Up	
Additional Information	

h) Describe the surgeon's transplant training and experience in the areas listed below. (Expand rows as necessary and use complete sentences [i.e. narrative descriptions] for each)

	Describe Training/Experience
Pre-Operative Patient Management	
Recipient Selection	
Donor Selection	
Transplant Surgery	
Use of Mechanical Assist Devices	
Care of Acute and Chronic Lung Failure	
Cardiopulmonary Bypass	
Pre- and Postoperative Pulmonary Care	
Histologic Interpretation and Grading of Lung Biopsies for Rejection	
Post-Operative Hemodynamic Care	
Post-Operative Immunosuppressive Therapy	
Long-Term Outpatient Follow-Up	
Additional Information	

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

1. **Primary Heart/Lung Transplant Physician**. Refer to the Bylaws for necessary qualifications. Provide the attachments listed below:

Check List	Question Reference	Required Supporting Documents
	3C, 1a	Current C.V.
	3C, 1b	Letter from the Credentialing Committee of the applicant hospital stating that the physician meets all requirements to be in good standing. Please provide an explanation of any status other than active/full.
	3C, 1c,f,g	Letter from the physician detailing his/her commitment to the program; level of involvement with substantive patient care; and summarizing their previous transplant experience
	3C, 1f	Formal Training: A letter from training director verifying that the fellow has met the requirements
	3C, 1f	Formal Training: Log(s) (organized by date of transplant) of the transplant patients followed
	3C, 1g	Transplant Experience: A letter from program director verifying that the individual has met the requirements
	3C, 1g	Transplant Experience: Log(s) (organized by date of transplant) of the transplant patients followed
		Other Letters of Recommendation (Reference)
		Letter of recommendation attesting to the individual's overall qualifications to act as primary physician and addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate

a) Name: _____

b) Date of employment at this hospital (MM/DD/YY): _____
Date assumed role of primary physician (MM/DD/YY): _____

Does individual have FULL privileges at this hospital?
_____ Yes Provide copy of hospital credentialing letter.
_____ No If the individual does **not** have full privileges, explain why, and provide the date the individual will be considered for full privileges. Include an explanation that describes the scope of privileges.

c) Percentage of professional time on site: _____% = _____ hrs/week

d) List other hospitals, health care facilities, and medical group practices and percentage of professional time on site at each:

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

e) Board certification type(s) or equivalent. If board certification is pending, indicate the date the exam has been scheduled. If individual has been recertified, please use that date.

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

f) Transplant Training (Fellowship): List the program(s) at which heart/lung, heart, and/or lung transplant training was received. Include the name of the transplant hospital(s), program director(s) names, applicable dates, and the number of transplant patients for whom the physician provided substantive patient care (pre-, peri- and post-operatively from the time of transplant). If the physician is qualifying as the primary physician through fellowship training, also submit the supporting documents listed below. Refer to the Bylaws for the necessary qualifications and descriptions of the required supporting documents:

- Letters from the director of fellowship training program and the supervising physician verifying that the fellow has met the requirements.
- A recipient log (Table 4C) that includes the date of transplant and the patient's medical record and/or OPTN ID number. Each log must be signed by the director of the training program and/or primary transplant physician at that transplant program.

Date From – To MM/DD/YY	Transplant Hospital	Program Director	# Heart Patients Followed			# Heart/Lung Patients Followed			# Lung Patients Followed		
			Pre	Peri	Post	Pre	Peri	Post	Pre	Peri	Post

g) Transplant Experience (Post Fellowship Only): List the name of the transplant hospital(s), applicable dates, and number of heart/lung, heart, and/or lung transplant patients for whom the transplant physician accepted primary responsibility for substantive patient care (pre-, peri-, and post-operatively from the time of transplant). Refer to the Bylaws for the necessary qualifications and descriptions of the required supporting documents listed below:

- Two supporting letters - at least one must be from the heart/lung transplant surgeon with whom the physician has previously worked.
- A recipient log (Table 4C) that includes the date of transplant and the patient's medical record and/or OPTN ID number. Each log should be signed by the program director, division chief, or department chair from the program where the experience was gained.

Date From – To MM/DD/YY	Transplant Hospital	Program Director	# Heart Patients Followed			# Heart/Lung Patients Followed			# Lung Patients Followed		
			Pre	Peri	Post	Pre	Peri	Post	Pre	Peri	Post

h) Training/Experience: Describe how the physician fulfills the criteria for participating as an observer in 3 multiple organ procurements and 3 transplants that include the heart or heart/lung, as well as observing 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. Alternatively, describe how the physician fulfills the criteria for participation as an observer in 3 or more lung or heart/lung procurement procedures and subsequent transplants, as well as observing the selection and management of at least 3 multiple organ donors, which include the lung or heart/lung.

- Provide a log (Table 4D) of these cases that includes the date of procurement/transplant, medical record ID number and/or OPTN ID number, and the location of the donor.
- If these criteria have not been met, submit a plan explaining how the individual will fulfill them.

Date From - To MM/DD/YY	Transplant Hospital	Program Director	# Procurements Observed			# Transplants Observed			Observe Eval. of Donors/Donor Process			# of Multi-Organ Donors Observed Mgmt.
			HR	HL	LU	HR	HL	LU	HR	HL	LU	

i) Summarize how the transplant physician's experience fulfills the membership criteria. (Check all that apply)

Membership Criteria	Yes
1. On site	
2. M.D., D.O. or equivalent degree	
3. Board Certification	
a. Certified by the American Board of Internal Medicine, Pediatrics or the foreign equivalent in Cardiology	
b. Achieved eligibility in Cardiology	
c. Certified by the American Board of Internal Medicine, Pediatrics or the foreign equivalent in Pulmonary Medicine	
d. Achieved eligibility in Pulmonary Medicine	
4. Direct involvement in heart, lung, and/or heart/lung transplant patient care within the last 2 years	
5. Cardiology Fellowship	
a. Involved in the primary care of a minimum of 20 heart and/or heart/lung recipients from the time of transplant	
b. Experience with pre-, peri-, and post-operative care within the last 2 years	
c. Observed 3 procurements and 3 heart transplants	
d. Observed evaluation of the donor and donor process and management of at least 3 multiple organ donors that include the heart and or heart/lung	
6. 12-month Transplant Cardiology Fellowship	
a. Involved in the primary care of a minimum of 20 heart and/or heart/lung recipients from the time of transplant	
b. Experience with pre-, peri-, and post-operative care within the last 2 years	
c. Observed 3 procurements and 3 heart transplants	
d. Observed evaluation of the donor and donor process and management of at least 3 multiple organ donors that include the heart and or heart/lung	
7. Experience in Heart and Heart-Lung Transplantation	
a. 2-5 years experience on an active heart transplant service	
b. Involved in the primary care of a minimum of 20 heart and/or heart/lung recipients for a minimum of 3 months from the time of their transplant	
c. Experience with pre-, peri, and post-operative care within the last 2 years	
d. Observed 3 procurements and 3 heart transplants	
e. Observed evaluation of the donor and donor process, and management of at least 3 multiple organ donors that include the heart and/or heart/lung	
8. Pulmonary Medicine Fellowship	
a. Participated in the primary care of 15 or more lung and/or heart/lung transplant recipients for a minimum of 3 months from the time of their transplant	
b. Involved with all aspects of pre-, peri-, and post-operative lung transplant patient care within the last 2 years	
c. Training program certified by the ABIM and/or the American Board of Pediatrics	
d. Observed 3 or more lung or heart/lung procurements and transplants	
e. Observed evaluation of the donor and donor process, and management of at least 3 multiple organ donors that include the lung and/or heart/lung	
9. 12-month Transplant Pulmonology Fellowship	
a. Participated in the primary care of 15 or more lung and/or heart/lung transplant recipients for a minimum of 3 months from the time of transplant	
b. Involved with all aspects of pre-, peri-, and post-operative lung transplant patient care within the last 2 years	
c. Training program certified by the ABIM and/or the American Board of Pediatrics	
d. Observed 3 or more lung or heart/lung procurements and transplants	
e. Observed evaluation of the donor and donor process, and management of at least 3 multiple organ donors that include the lung and/or heart/lung	

Membership Criteria	Yes
10. Experience in Lung and/or Heart/Lung Transplantation (Post-Fellowship)	
a. 2-5 years experience on an active lung transplant service	
b. Participated in the primary care of 15 or more lung and/or heart/lung transplant recipients for a minimum of 3 months from the time of their transplant	
c. Involved with all aspects of pre-, peri-, and post-operative lung transplant patient care within the last 2 years	
d. Observed 3 or more lung or heart/lung procurements and transplants	
e. Observed evaluation of the donor and donor process, and management of at least 3 multiple organ donors that include the lung and/or heart/lung	
11. Pediatric Pathway	
a. Program serves predominantly pediatric patients	
b. Individual has maintained current working knowledge in all aspects of heart and/or lung transplantation and patient care within the last 2 years	
c. Hospital has petitioned the Membership and Professional Standards Committee (MPSC) for approval	
d. A preliminary interview before the Membership and Professional Standards Committee shall be required	
12. 12-Month Conditional Pathway (Heart) – ***Only available to existing programs***	
a. Board certified cardiologist	
b. Qualifying by virtue of training	
i. Involved in the primary care of 10 or more heart or heart/lung transplant recipients from the time of their transplant	
ii. Training hospital conducts 20 or more heart or heart/lung transplants per year	
c. Qualifying by virtue of acquired clinical experience	
i. Involved in the primary care of 10 or more heart or heart/lung transplant recipients for a minimum of 3 months from the time of their transplant	
ii. Acquired a minimum of 12 months experience on an active heart transplant service over a maximum of 2 years	
d. Consulting relationship established with counterparts at another UNOS member transplant hospital approved for heart transplantation (include letter of support).	
13. 12-Month Conditional Pathway (Lung) - ***Only available to existing programs***	
a. Board certified pulmonologist	
b. Participated in the primary care of 8 or more lung and/or heart/lung transplant recipients for a minimum of 3 months from the time of their transplant. At least one-half of these patients must be single and/or double lung transplant recipients.	
c. If qualifying by virtue of acquired clinical experience, this experience must be equal to 12 months on an active lung transplant service acquired over a maximum of 2 years	
d. A consulting relationship with counterparts at another UNOS member transplant hospital approved for lung transplantation has been established (include letter of support)	

j) Describe in detail the proposed primary transplant physician's involvement in the management of patients in this program and, if applicable, their plan for coverage of multiple transplant hospitals. (Expand rows as necessary and use complete sentences [i.e. narrative descriptions] for each)

	Describe Involvement
Candidate Evaluation Process	
Pre- and Post-Operative Hemodynamic Care	
Post-Operative Immunosuppressive Therapy	
Long-Term Outpatient Follow-Up	
Care of Acute and Chronic Heart and/or Lung Failure	
Use of Mechanical Assist Devices	
Donor Selection	
Recipient Selection	
Histologic Interpretation and Grading of Myocardial Biopsies for Rejection	
Cardiopulmonary Bypass	
Pre- and Postoperative Pulmonary Care	
Histologic Interpretation and Grading of Lung Biopsies for Rejection	
Coverage of Multiple Transplant Hospitals (if applicable)	
Additional Information	

k) Describe the proposed primary physician's transplant training and experience in the areas listed below. (Expand rows as necessary and use complete sentences [i.e. narrative descriptions] for each)

	Describe 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 and/or Lung Failure	
Use of Mechanical Assist Devices	
Donor Selection	
Recipient Selection	
Histologic Interpretation and Grading of Myocardial Biopsies for Rejection	
Cardiopulmonary Bypass	
Pre- and Postoperative Pulmonary Care	
Histologic Interpretation and Grading of Lung Biopsies for Rejection	
Additional Information	

PART 3C, Section 2: Personnel – Additional/Other Physicians

Complete this section of the application to describe the involvement, training, and experience of additional/other physicians associated with the program. **Physicians must be designated as Additional or Other as described below**.

All physicians must be listed in Table 1 (Certificate of Investigation) in this application.

The Bylaws provide the following definition of Additional Transplant Physician:

> *Additional Transplant Physicians must be credentialed by the institution to provide transplant services and be able to independently manage the care of transplant patients.*

Physicians that also support this program but who do not meet the definition of "primary" or "additional" should complete this section of the application. The type should be indicated as "other."

Duplicate pages as needed.

PART 3C, Section 2: Personnel – Additional/Other Physicians

2. **Additional/Other Physicians (Duplicate this section as needed).** Refer to the Bylaws for the necessary qualifications and descriptions of the required supporting documents listed below:

Check List	Question Reference	Required Supporting Documents
	3C, 2a	Current C.V.
	3C, 2b	A letter from the Credentialing Committee of the applicant hospital stating that the physician meets all requirements to be in good standing. Please provide an explanation of any status other than active/full.
	3C, 2c,e,f	A letter from the Physician detailing his/her commitment to the program and level of involvement in substantive patient care

a) Name: _____

For heart/lung transplantation this individual is classified as ____ Additional Physician ___ Other Physician
(Check only one)

b) Date of employment at this hospital (MM/DD/YY): _____

Does individual have FULL privileges at this hospital?
_____ Yes Provide copy of hospital credentialing letter.
_____ No If the individual does **not** have full privileges, explain why, and provide the date the individual will be considered for full privileges. Include an explanation that describes the scope of privileges.

c) Percentage of professional time spent on site: _____% = _____ hrs/week

d) Board certification type (s) or equivalent. If board certification is pending, indicate the date the exam has been scheduled. If individual has been recertified, please use that date.

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

e) Training (Fellowship): List the program(s) at which heart/lung, heart and/or lung transplant training was received. Include the name of the transplant hospital(s), program director(s) names, applicable dates, and the number of transplant patients followed for whom the physician provided substantive care (pre-, peri- and post-operatively from the time of transplant).

Date From - To MM/DD/YY	Transplant Hospital	Program Director	# Heart Patients Followed			# Heart/Lung Patients Followed			# Lung Patients Followed		
			Pre	Peri	Post	Pre	Peri	Post	Pre	Peri	Post

f) Transplant Experience (Post Fellowship Only): List the name of the transplant hospital(s), applicable dates, and the number of heart/lung, heart and/or lung patients for whom the transplant physician accepted primary responsibility for substantive patient care (pre-, peri- and post-operatively from the time of transplant).

Date From - To MM/DD/YY	Transplant Hospital	Program Director	# Heart Patients Followed			# Heart/Lung Patients Followed			# Lung Patients Followed		
			Pre	Peri	Post	Pre	Peri	Post	Pre	Peri	Post

g) Describe in detail the transplant physician's involvement in this heart/lung transplant program. (Expand rows as necessary and use complete sentences [i.e. narrative descriptions] for each)

	Describe Involvement
Candidate Evaluation Process	
Pre- and Post-Operative Hemodynamic Care	
Post-Operative Immunosuppressive Therapy	
Long-Term Outpatient Follow-Up	
Care of Acute and Chronic Heart and/or Lung Failure	
Use of Mechanical Assist Devices	
Donor Selection	
Recipient Selection	
Histologic Interpretation and Grading of Myocardial Biopsies for Rejection	
Cardiopulmonary Bypass	
Pre- and Postoperative Pulmonary Care	
Histologic Interpretation and Grading of Lung Biopsies for Rejection	
Additional Information	

h) Describe the physician's transplant training and experience in the role of transplant patient management in the areas listed below. (Expand rows as necessary and use complete sentences [i.e. narrative descriptions] for each)

	Describe 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 and/or Lung Failure	
Use of Mechanical Assist Devices	
Donor Selection	
Recipient Selection	
Histologic Interpretation and Grading of Myocardial Biopsies for Rejection	
Cardiopulmonary Bypass	
Pre- and Postoperative Pulmonary Care	
Histologic Interpretation and Grading of Lung Biopsies for Rejection	
Additional Information	

Table 1: Certificate of Investigation

List all transplant surgeons and physicians currently involved in this program.

The Bylaws state that "***Each primary surgeon or primary physician**, listed on the application as a part of the plan for who shares coverage responsibility, shall submit an assessment, subject to medical peer review confidentiality requirements and which follows guidelines provided in the application and is satisfactory to the MPSC, of **all physicians and surgeons** participating in the program regarding their involvement in prior transgressions of UNOS requirements and plans to ensure that the improper conduct is not continued." (Emphasis Added)*

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

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:

* Expand rows as needed.

Table 2: Program Coverage Plan

Please answer the questions below and provide a written copy of the current Program Coverage Plan. The plan must be signed by either:

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

In accordance with the Bylaws, the program director, in conjunction with the primary transplant surgeon and transplant physician, must submit to UNOS a written Program Coverage Plan which documents how 100% medical and surgical coverage is provided by individuals credentialed by the transplant hospital to provide transplant service for the program. 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, during the year. The Program Coverage Plan must address the following requirements:

	Yes	**No**
Is this a single surgeon program?		
Is this a single physician program?		
If the answer to either one of the above questions is "Yes," explain the protocol for notifying patients.		
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 within one-hour ground transportation time to address urgent patient issues?		
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:		

Table 3: OPTN Staffing Report

HEART/LUNG TRANSPLANT PROGRAM

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

Answer the questions below for this transplant program. Since this information will be used to update UNet[sm] and the Membership Directory, make sure to include the best (most accurate) telephone number and address for each person. Use additional pages as necessary. The surgeons and physicians named below should match those listed on the Certificate of Investigation.

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

Name	Address	Phone	Fax	Email

The **surgeons** who perform transplants are:

Name	Additional	Other	Address	Phone	Fax	Email

The **physicians** (internists) who participate in this transplant program are:

Name	Additional	Other	Address	Phone	Fax	Email

Identify the **hospital administrative director/manager** who will be involved with this program. **Use an * to indicate** which individual will serve as the primary transplant administrator if more than one is listed:

Name	Address	Phone	Fax	Email

Identify the **Financial Counselor(s)** who will be involved with this program:

Name	Address	Phone	Fax	Email

The **clinical transplant coordinators** who participate in this transplant program are:

Name	Address	Phone	Fax	Email

List the **data coordinators** for this transplant program below. **Use an * to indicate** which individual will serve as the primary data coordinator:

Name	Address	Phone	Fax	Email

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

Name	Address	Phone	Fax	Email

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

Name	Address	Phone	Fax	Email

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

Name	Address	Phone	Fax	Email

Table 4A: **Primary Surgeon - Transplant Log** (Sample)

Complete a separate form for each transplant hospital

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

List cases in date order

#	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				

Extend lines on log as needed
Patient ID should <u>not</u> be name or Social Security Number

Director's Signature: _____ Date: _____

Table 4B: Primary Surgeon - Procurement Log (Sample)

Complete separate form for each transplant center

Organ:	
Name of proposed primary surgeon:	
Name of transplant 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

#	Date of Procurement	Medical Record/ OPTN ID # of Donor	Location of Donor (hospital)	Comments (LRD/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				
31				
32				
33				
34				
35				

Extend lines on log as needed

Director's Signature: _____ **Date:** _____

Table 4C: Primary Physician – Recipient Log (Sample)

Complete separate form for each transplant hospital

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. List only those patients followed for 3 months from the time of transplant (including pre-, peri-, and post-operative management)

#	Date of Transplant	Medical Record/ OPTN ID #	Pre-Operative	Peri-Operative	Post-Operative (90-days follow-up care)	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						
26						
27						
28						
29						
30						
31						
32						
33						
34						
35						

Extend lines on log as needed

Director's Signature: _____ Date: _____

Table 4D: Primary Physician – Observation Log (Sample)

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

In the tables below, document how the physician fulfills the requirements for participation as an observer in organ procurements and transplants, as well as observing the selection and management of at least 3 multiple organ donors that include the organ for which application is being submitted. *List cases in date order.*

Procurements Observed

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

Transplants Observed

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

Donor Selection and Management

#	Date of Procurement	Medical Record/ OPTN ID #	Location of Donor (Hospital)	Heart/Lung, Lung, Heart, or or Multi-organ
1				
2				
3				
4				
5				

Part 3: Lung Transplant Program

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

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

Check List	Question Reference	Required Supporting Documents
	3A, 1	Current C.V.

Name	Date of Appointment	Primary Areas of Responsibility

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

1. **Primary Lung Transplant Surgeon.** Refer to the Bylaws for the necessary qualifications and more specific descriptions of the required supporting documents listed below.

Check List	Question Reference	Required Supporting Documents
	3B, 1a	Current C.V.
	3B, 1b	Letter from the Credentialing Committee of the applicant hospital stating that the surgeon meets all requirements to be in good standing. Please provide an explanation of any status other than active/full.
	3B, 1c,g,h	Letter from the surgeon detailing his/her commitment to the program and describing their transplant experience/training
	3B, 1f	Formal Training: A letter from training director verifying that the fellow has met the requirements
	3B, 1f	Formal Training: A log (organized by date) of the transplant and procurement procedures
	3B, 1g	Transplant Experience: A letter from program director verifying that the individual has met the requirements
	3B, 1g	Transplant Experience: A log (organized by date) of the transplant and procurement procedures
		Other Letters of Recommendation (Reference)
		Letter of recommendation attesting to the individual's overall qualifications to act as primary surgeon and addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate.

a) Name: _____

b) Date of employment at this hospital (MM/DD/YY): _____
Date assumed role of primary surgeon (MM/DD/YY): _____
Does individual have FULL privileges at this hospital?
_____ Yes Provide copy of hospital credentialing letter.
_____ No If the individual does **not** have full privileges, explain why, and provide the date the individual will be considered for full privileges. Include an explanation that describes the scope of privileges.

c) Percentage of professional time spent at this hospital: _____% = _____ hrs/week

d) List below the hospitals, health care facilities, and medical group practices and percentage of professional time this individual is on site at each:

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

e) Board certification type(s) or equivalent. If board certification is pending, indicate the date the exam has been scheduled. If individual has been recertified, please use that date.

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

f) Transplant Training: List the name of the transplant hospital(s) at which lung and/or heart/lung transplant training (residency/fellowship) was received including program director(s) names, applicable dates, and the number of transplants and procurements performed. If the surgeon is qualifying as the primary surgeon through residency or fellowship training also submit the supporting documents listed below. Refer to the Bylaws for the necessary qualifications and detailed descriptions of the required supporting documents:

- A letter from program director verifying that the fellow has met the requirements.
- Logs (Tables 4A and 4B) of the transplant and procurement procedures. The logs should include a patient identifier/OPTN ID Number, transplant/procurement date, and the surgeon's role in the procedure (i.e., primary or 1st assistant). These logs must be signed by the director of the training program.

Date From – To MM/DD/YY	**Transplant Hospital**	**Program Director**	**# of Transplants as Primary Surgeon**		**# of Transplants as 1st Assistant**		**# of Procurements as Primary Surgeon or 1st Assistant**	
			LU	**HL**	**LU**	**HL**	**LU**	**HL**
Residency:								
Fellowship:								

g) Transplant Experience (Post Fellowship): List the name of the transplant hospital(s), applicable dates, and number of lung and/or heart/lung transplants and procurements performed by the individual at each hospital. Refer to the Bylaws for the necessary qualifications and descriptions of the required supporting documents listed below:

- Letter(s) of reference from the program director(s) listed below.
- Logs (Tables 4A and 4B) of the transplant and procurement procedures. Each log should include a patient identifier/OPTN ID number, transplant/procurement date, and the surgeon's role in the procedure (i.e., primary or 1st assistant).

The transplant log(s) should be signed by the program director, division chief, or department chair from the program where the experience was gained.

Date From – To MM/DD/YY	**Transplant Hospital**	**Program Director**	**# of Transplants as Primary Surgeon**		**# of Transplants as 1st Assistant**		**# of Procurements as Primary Surgeon or 1st Assistant**	
			LU	**HL**	**LU**	**HL**	**LU**	**HL**

h) Summarize how the surgeon's experience fulfills the membership criteria.
(Check all that apply)

Membership Criteria	Yes
1. On site	
2. Certified by the American Board of Thoracic Surgery or the foreign equivalent	
3. Thoracic Surgery Boards pending	
4. Cardiothoracic Surgery Residency	
a. Primary surgeon or 1st assistant on 15 or more lung and/or heart/lung transplants	
b. Primary surgeon or 1st assistant on 10 or more lung procurements	
c. Involved in all levels of pre-, peri-, and post-operative patient care within the last 2 years	
d. Training program approved by American Board of Thoracic Surgery	
5. 12-Month Transplant Fellowship	
a. Primary surgeon or 1st assistant on 15 or more lung and/or heart/lung transplants	
b. Primary surgeon or 1st assistant on 10 or more lung procurements	
c. Involved in all levels of pre-, peri-, and post-operative patient care within the last 2 years	
d. Training program approved by American Board of Thoracic Surgery	
6. Experience (Post Fellowship)	
a. Primary surgeon or 1st assistant on 15 or more lung transplants over a minimum of 2 years and a maximum of 5 years. Of these 15, at least 10 were performed as primary surgeon	
b. Primary surgeon or 1st assistant on 10 or more lung procurements	
c. Involved in all levels of pre-, peri-, and post-operative patient care within the last 2 years	
7. Pediatric Pathway	
a. Program serves predominantly pediatric patients	
b. Individual has maintained current working knowledge in all aspects of lung transplantation and patient care within the last 2 years	
c. Hospital has petitioned the Membership and Professional Standards Committee (MPSC) for approval	
d. A preliminary interview before the Membership and Professional Standards Committee shall be required	

i) Describe in detail the proposed primary surgeon's level of involvement in this transplant program, and if applicable, describe the surgeon's plan for coverage of transplant programs located in multiple transplant hospitals. (Expand rows below as necessary and use complete sentences [i.e. narrative descriptions] for each)

	Describe Involvement
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	

j) Describe the proposed primary surgeon's transplant training and experience in the areas listed below. (Expand rows below as necessary and use complete sentences [i.e. narrative descriptions] for each)

	Describe Experience/Training
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	
Additional Information	

PART 3B, Section 2: Personnel – Additional/Other Surgeons

Complete this section of the application to describe the involvement, training, and experience of any other surgeons participating in the program. **Surgeons must be designated as Additional or Other as described below**. All surgeons must be listed on Table 1 (Certificate of Investigation) in this application.

The Bylaws provide the following definition of Additional Transplant Surgeon:

Additional Transplant Surgeons must be credentialed by the institution to provide transplant services and be able to independently manage the care of transplant patients including performing the transplant operation and procurement procedures.

Surgeons that also support this program but who do not meet the definition of "primary" or additional," should complete this section as well. The type should be indicated as "other."

Duplicate pages as needed.

PART 3B, Section 2: Personnel – Additional/Other Surgeons

2. Additional/Other Surgeons (Duplicate this section as needed). Provide the attachments listed below:

Check List	Question Reference	Required Supporting Documents
	3B, 2a	Current C.V.
	3B, 2b	A letter from the Credentialing Committee of the applicant hospital stating that the surgeon meets all requirements to be in good standing. Please provide an explanation of any status other than active/full.
	3B 2c,e,f	A letter from the Surgeon detailing his/her commitment to the program and level of involvement in substantive patient care

a) Name: _____

For lung transplantation this individual is classified as ____ Additional Surgeon ___ Other Surgeon
(Check only one)

b) Date of employment at this hospital (MM/DD/YY): _____

Does individual have FULL privileges at this hospital?

_____ Yes Provide copy of hospital credentialing letter.

_____ No If the individual does **not** have full privileges, explain why, and provide the date the individual will be considered for full privileges. Include an explanation that describes the scope of privileges.

c) Percentage of professional time spent on site: _____% = _____ hrs/week

d) Board certification type (s) or equivalent. If board certification is pending, indicate the date the exam has been scheduled. If individual has been recertified, please use that date.

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

e) Transplant Training (Residency/Fellowship): List the name of the transplant hospital(s) at which lung and/or heart/lung transplant training (residency/fellowship) was received. Include the program director(s) names, applicable dates, and the number of transplants and procurements the individual performed.

Date From – To MM/DD/YY	Transplant Hospital	Program Director	# of Transplants as Primary Surgeon		# of Transplants as 1st Assistant		# of Procurements as Primary Surgeon or 1st Assistant	
			LU	HL	LU	HL	LU	HL
Residency:								
Fellowship:								

f) Transplant Experience (Post Fellowship): List the name of the transplant hospital(s), applicable dates, and number of lung and/or heart/lung transplants and procurements performed by the individual at each hospital.

Date From – To MM/DD/YY	Transplant Hospital	Program Director	# of Transplants as Primary Surgeon		# of Transplants as 1st Assistant		# of Procurements as Primary Surgeon or 1st Assistant	
			LU	HL	LU	HL	LU	HL

g) Describe the surgeon's level of involvement in this transplant program in the areas listed below. (Expand rows as necessary and use complete sentences [i.e. narrative descriptions] for each)

	Describe Involvement
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	
Additional Information	

h) Describe the surgeon's transplant training and experience in the areas listed below. (Expand rows as necessary and use complete sentences [i.e. narrative descriptions] for each)

	Describe Experience/Training
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	
Additional Information	

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

1. Primary Lung Transplant Physician. Refer to the Bylaws for necessary qualifications. Provide the attachments listed below:

Check List	Question Reference	Required Supporting Documents
	3C, 1a	Current C.V.
	3C, 1b	Letter from the Credentialing Committee of the applicant hospital stating that the physician meets all requirements to be in good standing. Please provide an explanation of any status other than active/full.
	3C, 1c,f,g	Letter from the physician detailing his/her commitment to the program; level of involvement with substantive patient care; and summarizing their previous transplant experience.
	3C, 1f	Formal Training: A letter from training director verifying that the fellow has met the requirements
	3C, 1f	Formal Training: Log(s) (organized by date of transplant) of the transplant patients followed
	3C, 1g	Transplant Experience: A letter from program director verifying that the individual has met the requirements
	3C, 1g	Transplant Experience: Log(s) (organized by date of transplant) of the transplant patients followed
		Other Letters of Recommendation (Reference)
		Letter of recommendation attesting to the individual's overall qualifications to act as primary physician and addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate

a) Name:_____

b) Date of employment at this hospital (MM/DD/YY): _____
Date assumed role of primary physician (MM/DD/YY): _____

Does individual have FULL privileges at this hospital?
_____ Yes Provide copy of hospital credentialing letter.
_____ No If the individual does **not** have full privileges, explain why and provide the date the individual will be considered for full privileges. Include an explanation that describes the scope of privileges.

c) Percentage of professional time on site: _____% = _____ hrs/week

d) List other hospitals, health care facilities, and medical group practices and percentage of professional time on site at each:

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

e) Board certification type(s) or equivalent. If board certification is pending, indicate the date the exam has been scheduled. If individual has been recertified, please use that date.

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

f) Training (Fellowship): List the program(s) at which lung and/or heart/lung transplant training was received. Include the name of the transplant hospital(s), program director(s) names, applicable dates, and the number of transplant patients for whom the physician provided substantive patient care (pre-, peri- and post-operatively from the time of transplant). If the physician is qualifying as the primary physician through fellowship training, also submit the supporting documents listed below. Refer to the Bylaws for the necessary qualifications and descriptions of the required supporting documents:

- Letters from the director of fellowship training program and the supervising physician verifying that the fellow has met the requirements.
- A recipient log(s) (Table 4C) that includes the date of transplant and the patient's medical record and/or OPTN ID number. Each log must be signed by the director of the training program and/or primary transplant physician at that transplant program.

Date From – To MM/DD/YY	Transplant Hospital	Program Director	# Lung Patients Followed			# Heart/Lung Patients Followed		
			Pre	Peri	Post	Pre	Peri	Post

g) Transplant Experience (Post Fellowship Only): List the name of the transplant hospital(s), applicable dates, and number of lung and/or heart/lung transplant patients for whom the Transplant Physician accepted primary responsibility for substantive patient care (pre-, peri-, and post-operatively from the time of transplant). Refer to the Bylaws for the necessary qualifications and descriptions of the required supporting documents listed below:

- Two supporting letters - at least one must be from the lung transplant surgeon with whom the pulmonologist has previously worked.
- A recipient log(s) (Table 4C) that includes the date of transplant and the patient's medical record and/or OPTN ID number. Each log should be signed by the program director, division chief, or department chair from the program where the experience was gained.

Date From – To MM/DD/YY	Transplant Hospital	Program Director	# Lung Patients Followed			# Heart/Lung Patients Followed		
			Pre	Peri	Post	Pre	Peri	Post

h) Training/Experience: Describe how the physician fulfills the criteria for participating as an observer in 3 multiple organ procurements and 3 transplants that include the lung, as well as observing 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.

- Provide a log (Table 4D) of these cases that includes the date of procurement/transplant, medical record ID number and/or OPTN ID number, and the location of the donor.
- If these criteria have not been met, submit a plan explaining how the individual will fulfill them.

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 Mgmt.

i) Summarize how the transplant physician's experience fulfills the membership criteria. (Check all that apply)

Membership Criteria	Yes
1. On site	
2. M.D., D.O. or equivalent degree	
3. Certified in pulmonary medicine by the American Board of Internal Medicine, Pediatrics or the foreign equivalent	
4. Achieved Eligibility in Pulmonary Medicine	
5. Direct Involvement in Lung Transplant Patient Care Within the Last 2 Years	
6. Pulmonary Medicine Fellowship	
a. Participated in the primary care of 15 or more lung and/or heart/lung transplant recipients for a minimum of 3 months from the time of their transplant	
b. Involved with all aspects of lung transplant patient care	
c. Observed 3 or more lung or heart/lung procurements and transplants	
d. Observed 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	
7. 12-Month Transplant Pulmonology Fellowship	
a. Participated in the primary care of 15 or more lung and/or heart/lung transplant recipients for a minimum of 3 months from the time of their transplant	
b. Involved with all aspects of lung transplant patient care	
c. Observed 3 or more lung or heart/lung procurements and transplants	
d. Observed the evaluation of the donor and donor process and management of at least 3 multiple organ donors that include the lung and/or heart/lung	
8. Experience in Lung Transplantation (Post-Fellowship)	
a. 2-5 years experience on an active lung transplant service	
b. Participated in the primary care of 15 or more lung and/or heart/lung transplant recipients for a minimum of 3 months from the time of their transplant	
c. Observed 3 or more lung or heart/lung procurements and transplants	
d. Observed the evaluation of the donor and donor process and management of at least 3 multiple organ donors that include the lung or heart/lung	
9. Pediatric Pathway	
a. Program serves predominantly pediatric patients	
b. Individual has maintained current working knowledge in all aspects of lung transplantation and patient care within the last 2 years	

Membership Criteria	Yes
c. Hospital has petitioned the Membership and Professional Standards Committee (MPSC) for approval	
d. A preliminary interview before the Membership and Professional Standards Committee shall be required	
10. 12-Month Conditional Pathway - ***Only available to existing programs***	
a. Board Certified Pulmonologist	
b. Participated in the primary care of 8 or more lung and/or heart/lung transplant recipients for a minimum of 3 months from the time of their transplant. At least one-half of these patients must be single and/or double lung transplant recipients	
c. If qualifying by virtue of acquired clinical experience, this experience must be equal to 12 months on an active lung transplant service acquired over a maximum of 2 years	
d. A consulting relationship with counterparts at another member transplant hospital approved for lung transplantation has been established (include letter of support)	

j) Describe in detail the proposed primary transplant physician's involvement in the management of patients in this program and, if applicable, their plan for coverage of multiple transplant hospitals. (Expand rows as necessary and use complete sentences [i.e. narrative descriptions] for each)

	Describe Involvement
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	

k) Describe the proposed primary physician's transplant training and experience in the areas listed below. (Expand rows as necessary and use complete sentences [i.e. narrative descriptions] for each)

	Describe 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	
Additional Information	

PART 3C, Section 2: Personnel – Additional/Other Physicians

Complete this section of the application to describe the involvement, training, and experience of additional/other physicians associated with the program. **Physicians must be designated as Additional or Other as described below**.

All physicians must be listed in Table 1 (Certificate of Investigation) in this application.

The Bylaws provide the following definition of Additional Transplant Physician:

Additional Transplant Physicians must be credentialed by the institution to provide transplant services and be able to independently manage the care of transplant patients.

Physicians that also support this program but who do not meet the definition of "primary" or "additional," should complete this section of the application. The type should be indicated as "other."

Duplicate pages as needed.

PART 3C, Section 2: Personnel – Additional/Other Physicians

2. **Additional/Other Physicians (Duplicate this section as needed)**. Refer to the Bylaws for the necessary qualifications and descriptions of the required supporting documents listed below:

Check List	Question Reference	Required Supporting Documents
	3C, 2a	Current C.V.
	3C, 2b	A letter from the Credentialing Committee of the applicant hospital stating that the physician meets all requirements to be in good standing. Please provide an explanation of any status other than active/full.
	3C, 2c,e,f	A letter from the Physician detailing his/her commitment to the program and level of involvement in substantive patient care

a) Name: _____

For lung transplantation this individual is classified as ____ Additional Physician ___ Other Physician
(Check only one)

b) Date of employment at this hospital (MM/DD/YY): _____

Does individual have FULL privileges at this hospital?

_____ Yes Provide copy of hospital credentialing letter.

_____ No If the individual does **not** have full privileges, explain why, and provide the date the individual will be considered for full privileges. Include an explanation that describes the scope of privileges.

c) Percentage of professional time spent on site: _____% = _____ hrs/week

d) Board certification type (s) or equivalent. If board certification is pending, indicate the date the exam has been scheduled. If individual has been recertified, please use that date.

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

e) Training (Fellowship): List the program(s) at which lung and/or heart/lung transplant training was received including the name of the transplant hospital(s), program director(s) names, applicable dates, and the number of transplant patients followed for whom the physician provided substantive care (pre-, peri- and post-operatively from the time of transplant).

Date From - To MM/DD/YY	Transplant Hospital	Program Director	# Lung Patients Followed			# Heart/Lung Patients Followed		
			Pre	Peri	Post	Pre	Peri	Post

f) Transplant Experience (Post Fellowship Only): List the name of the transplant hospital(s), applicable dates, and the number of lung and/or heart-lung patients for whom the transplant physician accepted primary responsibility for substantive patient care (pre-, peri- and post-operatively from the time of transplant).

Date From - To MM/DD/YY	Transplant Hospital	Program Director	# Lung Patients Followed			# Heart/Lung Patients Followed		
			Pre	Peri	Post	Pre	Peri	Post

g) Describe in detail the transplant physician's involvement in this lung transplant program. (Expand rows as necessary and use complete sentences [i.e. narrative descriptions] for each)

	Describe Involvement
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	
Additional Information	

h) Describe the physician's transplant training and experience in the role of transplant patient management in the areas listed below. (Expand rows as necessary and use complete sentences [i.e. narrative descriptions] for each)

	Describe 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	
Additional Information	

Table 1: Certificate of Investigation

List all transplant surgeons and physicians currently involved in this program.

The Bylaws state that "***Each primary surgeon or primary physician****, listed on the application as a part of the plan for who shares coverage responsibility, shall submit an assessment, subject to medical peer review confidentiality requirements and which follows guidelines provided in the application and is satisfactory to the MPSC, of* ***all physicians and surgeons*** *participating in the program regarding their involvement in prior transgressions of UNOS requirements and plans to ensure that the improper conduct is not continued." (Emphasis Added)*

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

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:

* Expand rows as needed

Table 2: Program Coverage Plan

Please answer the questions below and provide a written copy of the current Program Coverage Plan. The plan must be signed by either:

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

In accordance with the Bylaws, the program director, in conjunction with the primary transplant surgeon and transplant physician, must submit to UNOS a written Program Coverage Plan which documents how 100% medical and surgical coverage is provided by individuals credentialed by the transplant hospital to provide transplant service for the program. 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, during the year. The Program Coverage Plan must address the following requirements:

	Yes	**No**
Is this a single surgeon program?		
Is this a single physician program?		
If the answer to either one of the above questions is "Yes," explain the protocol for notifying patients.		
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 within one-hour ground transportation time to address urgent patient issues?		
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:		

Table 3 - OPTN Staffing Report

LUNG TRANSPLANT PROGRAM

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

Answer the questions below for this transplant program. Since this information will be used to update UNet[sm] and the Membership Directory, make sure to include the best (most accurate) telephone number and address for each person. Use additional pages as necessary. The surgeons and physicians named below should match those listed on the Certificate of Investigation.

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

Name	Address	Phone	Fax	Email

The **surgeons** who perform transplants are:

Name	Additional	Other	Address	Phone	Fax	Email

The **physicians** (internists) who participate in this transplant program are:

Name	Additional	Other	Address	Phone	Fax	Email

Identify the **hospital administrative director/manager** who will be involved with this program. **Use an * to indicate** which individual will serve as the primary transplant administrator if more than one is listed:

Name	Address	Phone	Fax	Email

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

Name	Address	Phone	Fax	Email

The **clinical transplant coordinators** who participate in this transplant program are:

Name	Address	Phone	Fax	Email

List the **data coordinators** for this transplant program below. **Use an * to indicate** which individual will serve as the primary data coordinator:

Name	Address	Phone	Fax	Email

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

Name	Address	Phone	Fax	Email

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

Name	Address	Phone	Fax	Email

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

Name	Address	Phone	Fax	Email

Table 4A - Primary Surgeon - Transplant Log (Sample)
Complete a separate form for each transplant hospital

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

List cases in date order

#	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				

Extend lines on log as needed
Patient ID should <u>not</u> be name or Social Security Number

Director's Signature: _____ Date: _____

Table 4B - Primary Surgeon - Procurement Log (Sample)
Complete separate form for each transplant hospital

Organ:	
Name of proposed primary surgeon:	
Name of transplant 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

#	Date of Procurement	Medical Record/ OPTN ID # of Donor	Location of Donor (hospital)	Comments (LRD/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				
31				
32				
33				
34				
35				

Extend lines on log as needed

Director's Signature: _____ **Date:** _____

Table 4C - Primary Physician – Recipient Log (Sample)
Complete separate form for each transplant hospital

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

List only those patients followed for 3 months from the time of transplant (including pre-, peri-, and post-operative management)

#	Date of Transplant	Medical Record/OPTN ID #	Pre-Operative	Peri-Operative	Post-Operative (90-days follow-up care)	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						
26						
27						
28						
29						
30						
31						
32						
33						
34						
35						

Extend lines on log as needed

Director's Signature: _____ **Date:** _____

Table 4D - Primary Physician – Observation Log (Sample)

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

In the tables below, document how the physician fulfills the requirements for participation as an observer in organ procurements and transplants, as well as observing the selection and management of at least 3 multiple organ donors that include the organ for which application is being submitted. *List cases in date order*.

Procurements Observed

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

Transplants Observed

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

Donor Selection and Management

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

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

This application is for (check all that apply):

	Kidney Transplantation	Living Donor Kidney Transplantation	
		Open Nephrectomy	Laparoscopic Nephrectomy
New Program/ Initial Application			
Key Personnel Change			

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

1. Identify the Transplant Program Surgical and/or Medical Director(s) of the kidney transplant program (include C.V.). Briefly describe the leadership responsibilities for each individual, including their role in living donor kidney transplantation if applicable.

Check list	Question Reference	Required Supporting Documents
	3A, 1	Current C.V.

Name	Date of Appointment	Primary Areas of Responsibility

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

1. Primary kidney transplant surgeon. Refer to the Bylaws for the necessary qualifications and more specific descriptions of the required supporting documents listed below.

Check List	Question Reference	Required Supporting Documents
	3B, 1a	Current C.V.
	3B, 1c	Letter from the Credentialing Committee of the applicant hospital stating that the surgeon meets all requirements to be in good standing. Please provide an explanation of any status other than active/full
	3B, 1d, g, & h	Letter from the surgeon detailing his/her commitment to the program and describing their transplant experience/training
	3B, 1g	Formal Training: A letter from the training director verifying that the fellow has met the requirements
	3B, 1g	Formal Training: A log (organized by date) of the transplant and procurement procedures (Tables 1 & 2)
	3B, 1h	Transplant Experience: A letter from the program director verifying that the individual has met the primary surgeon requirements and is qualified to direct a kidney transplant program.
	3B, 1h	Transplant Experience: A log (organized by date) of the transplant and procurement procedures
		Other Letters of Recommendation (Reference)
		Letter of recommendation attesting to the individual's overall qualifications to act as primary surgeon and addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate

a) Name: _____

b) This surgeon participates in (check all that apply):

	Kidney Transplantation
	Living Donor Kidney Transplantation

c) Date of employment at this hospital (MM/DD/YY): _____
Date assumed role of primary surgeon (MM/DD/YY): _____

Does individual have FULL privileges at this hospital?
_____ Yes Provide copy of hospital credentialing letter.
_____ No If the individual does **not** have full privileges, explain why, and provide the date the individual will be considered for full privileges. Also, include an explanation that describes the scope of these privileges.

d) Percentage of professional time spent at this hospital: _____% = _____ hrs/week

e) List other hospitals, health care facilities, and medical group practices and percentage of professional time this individual is on site at each:

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

f) Board certification type (s) or equivalent. If board certification is pending, indicate the date the exam has been scheduled. If individual has been recertified, please use that date.

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

g) Transplant Training (Fellowship): List the name of the transplant hospital(s) at which kidney transplant training (fellowship) was received including program director(s) names, applicable dates, and the number of transplants performed. If the surgeon is qualifying as the primary surgeon through fellowship training, also submit the supporting documents listed below. Refer to the Bylaws for the necessary qualifications and descriptions of the required supporting documents.

- A letter from program director verifying that the fellow has met the requirements.
- Logs (Tables 4A and 4B) of the transplant and procurement procedures. The logs should include a patient identifier/OPTN ID Number, transplant/procurement date, and the surgeon's role in the procedure (i.e., primary or 1st assistant). These logs must be signed by the director of the training program.

Date From – To (MM/DD/YY)	Transplant Hospital	Program Director	# KI Transplants as Primary	# KI Transplants First Assistant	# of KI Procurements as Primary or 1st Assistant

h) Transplant Experience (Post Fellowship):
List the name of the transplant hospital(s), applicable dates, program director's names, and number of kidney transplants and procurements performed by the individual at each transplant hospital. Refer to the Bylaws for the necessary qualifications and descriptions of the required supporting documents listed below.

- Letter(s) of reference from the program director(s) listed below.
- Logs (Tables 4A and 4B) of the transplant and procurement procedures. The log should include a patient identifier/OPTN ID Number, transplant/procurement date, and the surgeon's role in the procedure (i.e., primary or 1st assistant).

Date From – To (MM/DD/YY)	Transplant Hospital	Program Director	# KI Transplants as Primary	# KI Transplants First Assistant	# of KI Procurements as Primary or 1st Assistant

i) Summarize how the surgeon's experience fulfills the membership criteria. (Check all that apply)

Membership Criteria	Yes
1. On site	
2. Certified by the American Board of Surgery, Urology, Osteopathic Surgery or the foreign equivalent	
3. 2 year Kidney Transplant Fellowship	
a. Primary surgeon or 1st assistant on at least 30 kidney transplants over the 2 year period	
b. Involved in all levels of pre-, peri-, and post-operative patient care within the last 2 years	
c. Training program approved by American Board of Surgery	
d. Primary surgeon or 1st assistant on at least 15 or more kidney procurement procedures. At least 3 of these donors must be multiple organ and at least 10 must be deceased.	
4. Experience (Post Fellowship)	
a. Primary surgeon or 1st assistant on 45 kidney transplants over a minimum of 2 years and a maximum of 5 years	
b. Involved in all levels of pre-, peri-, and post-operative patient care within the last 2 years	
c. Primary surgeon or 1st assistant on at least 15 kidney procurement procedures. At least 3 of these donors must be multiple organ and at least 10 must be deceased.	
5. Pediatric Pathway	
a. Program serves predominantly pediatric patients	
b. The individual has maintained current working knowledge in all aspects kidney transplantation and patient care within the last 2 years	
c. Hospital has petitioned the Membership and Professional Standards Committee (MPSC) for approval	
d. A preliminary interview before the Membership and Professional Standards Committee shall be required	

j) Describe in detail the proposed primary surgeon's level of involvement in this transplant program, and if applicable, describe the surgeon's plan for coverage of transplant programs located in multiple transplant centers. Expand rows below as necessary and use complete sentences (i.e. narrative descriptions) for each.

	Describe Involvement
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:	

k) Describe the proposed primary surgeon's transplant training and experience in the areas listed below. (Expand rows below as necessary and use complete sentences (i.e. narrative descriptions) for each).

	Describe Training/Experience
Pre-Operative Patient Management	
Recipient Selection	
Donor Selection	
Transplant Surgery	
Post-Operative Care	
Post-Operative Immunosuppressive Therapy	
Additional Information	

PART 3B, Section 2: Personnel – Additional/Other Surgeons

Complete this section of the application to describe the involvement, training, and experience of any other surgeons participating in the program. **Surgeons must be designated as Additional or Other as described below**. All surgeons must be listed in Table 1 (Certificate of Investigation) in this application.

The Bylaws provide the following definition of Additional Transplant Surgeon:

> *Additional Transplant Surgeons must be credentialed by the institution to provide transplant services and be able to independently manage the care of transplant patients including performing the transplant operation and procurement procedures.*

Surgeons that also support this program but who do not meet the definition of "primary" or additional," should complete this section as well. The type should be indicated as "other."

Duplicate pages as needed.

PART 3B, Section 2: Personnel – Additional/Other Surgeons

2. Additional and Other Surgeons (duplicate this section as needed). Provide the requested attachments.

Check List	Question Reference	Required Supporting Documents
	3B, 2a	Current C.V.
	3B, 2c	A letter from the Credentialing Committee of the applicant hospital stating that the surgeon meets all requirements to be in good standing. Please provide an explanation of any status other than active/full.
	3B, 2d, f, & g	A letter from the surgeon detailing his/her commitment to the program and level of involvement in substantive patient care.

a) Name: _____

b) This surgeon participates in (check all that apply):

	Type	
	Additional	**Other**
Kidney Transplantation		
Living Donor Kidney Transplantation		

c) Date of employment at this hospital (MM/DD/YY): _____

Does individual have FULL privileges at this hospital?

_____ Yes Provide copy of hospital credentialing letter.

_____ No If the individual does **not** have full privileges, explain why, and provide the date the individual will be considered for full privileges. Include an explanation that describes the scope of these privileges.

d) Percentage of professional time spent on site: _____% = _____ hrs/week

e) Board certification type (s) or equivalent. If board certification is pending, indicate the date the exam has been scheduled. If individual has been recertified, please use that date.

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

f) Transplant Training (Fellowship): List the name of the transplant hospital(s) at which kidney transplant training (fellowship) was received. Include program director(s) names, applicable dates, and the number of transplants and procurements the individual performed.

Date From – To (MM/DD/YY)	Transplant Hospital	Program Director	# KI Transplants as Primary	# KI Transplants First Assistant	# of KI Procurements as Primary or 1st Assistant

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

Date From – To (MM/DD/YY)	Transplant Hospital	Program Director	# KI Transplants as Primary	# KI Transplants First Assistant	# of KI Procurements as Primary or 1st Assistant

h) Describe the surgeon's level of involvement in this kidney transplant program in the areas listed below. Expand rows as necessary and use complete sentences (i.e. narrative description) for each.

	Describe Involvement
Pre-Operative Patient Management	
Recipient Selection	
Donor Selection	
Transplant Surgery	
Post-Operative Care	
Post-Operative Immunosuppressive Therapy	
Outpatient Follow-Up	
Living Donor Transplantation (if applicable)	
Coverage of Multiple Transplant Centers (if applicable)	
Additional Information	

i) Describe the surgeon's kidney transplant training and experience in the areas listed below. Expand rows as necessary and use complete sentences (i.e. narrative descriptions) for each.

	Describe Training/Experience
Pre-Operative Patient Management	
Recipient Selection	
Donor Selection	
Transplant Surgery	
Post-Operative Care	
Post-Operative Immunosuppressive Therapy	
Additional Information	

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

1. Primary Kidney Transplant Physician. Refer to the Bylaws for necessary qualifications. Provide the attachments listed below.

Check List	Question Reference	Required Supporting Documents
	3C, 1a	Current C.V.
	3C, 1c	Letter from the Credentialing Committee of the applicant hospital stating that the physician meets all requirements to be in good standing. Please provide an explanation of any status other than active/full.
	3C, 1d, g & h	Letter from the physician detailing his/her commitment to the program; level of involvement with substantive patient care; and summarizing their previous transplant experience.
	3C, 1g	Formal Training: A letter from the training director verifying that the fellow has met the requirements
	3C, 1g	Formal Training: A log (organized by date) of the transplant patients followed.
	3C, 1h	Transplant Experience: A letter from the program director verifying that the individual has met the primary physician requirements and is qualified to direct a kidney transplant program.
	3C, 1h	Transplant Experience: A log (organized by date) of the transplant patients followed.
	3C, 1i	Training/Experience – participation as observer in procurements, transplant procedures, etc.
		Other Letters of Recommendation (Reference).
		Letter of recommendation attesting to the individual's overall qualifications to act as primary physician and addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate

a) Name:_____

b) Date of employment at this hospital (MM/DD/YY): _____
Date assumed role of primary physician (MM/DD/YY): _____

Does individual have FULL privileges at this hospital?
_____ Yes Provide copy of hospital credentialing letter.
_____ No If the individual does **not** have full privileges, explain why, and provide the date the individual will be considered for full privileges. Also, include an explanation that describes the scope of these privileges.

c) Percentage of professional time on site: _____% = _____ hrs/week.

d) List other hospitals, health care facilities, and medical group practices and percentage of professional time on site at each:

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

e) Board certification type (s) or equivalent. If board certification is pending, indicate the date the exam has been scheduled. If individual has been recertified, please use that date.

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

f) Training (Fellowship): List the program(s) in which kidney transplant training was received including the name of the transplant hospital(s). Include the program director(s) names, applicable dates, and the number of kidney transplant patients for whom the physician provided substantive patient care (pre-, peri-, and post-operatively from the time of transplant).

If the physician is qualifying as primary physician through fellowship training, also submit the supporting documents listed below.

Refer to the Bylaws for the necessary qualifications and descriptions of the required supporting documents

- Letters from the director of the fellowship training program and the supervising physician verifying that the fellow has met the requirements.
- Recipient log(s) (see Table 4C) that includes the date of transplant, and the patient's medical record and/or OPTN ID number. This log must be signed by the director of the training program and/or primary transplant physician at that transplant program.

Date From - To (MM/DD/YY)	Transplant Hospital	Program Director	# KI Patients Followed:		
			Pre	Peri	Post

g) Transplant Experience (Post Fellowship): List the name of the transplant hospital(s), program director name(s), applicable dates, and the number of kidney transplant patients at the hospital for whom the Transplant Physician accepted primary responsibility for substantive patient care (pre-, peri-, and post-operatively from the time of transplant). Refer to the Bylaws for the necessary qualifications and descriptions of the required supporting documents listed below.

- Two supporting letters - at least one must be from the kidney transplant surgeon with whom the nephrologist has previously worked.
- Recipient log(s) (See Table 4C) that includes the date of transplant, the patient's name, and/or OPTN ID number. This log should be signed by the program director, division chief, or department chair from the program where the experience was gained.

Date From - To (MM/DD/YY)	Transplant Hospital	Program Director	# KI Patients Followed:		
			Pre	Peri	Post

h) Training/Experience. Describe how the physician fulfills the criteria for participating as an observer in 3 multiple organ procurements and 3 transplants that include the kidney, as well as observing the evaluation of the donor and donor process, and management of at least 3 multiple organ donors

- Provide a log of these cases that includes the date of procurement, medical record ID number and/or OPTN ID number, and the location of the donor. Complete Table 4D.
- If these criteria have not been met, submit a plan explaining how the individual will fulfill them.

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

i) Summarize how the transplant physician's experience fulfills the membership criteria for membership. (Check all that apply)

Membership Criteria	Yes
1. On site	
2. M.D., D.O. or equivalent degree	
3. Certified by the American Board of Internal Medicine, Pediatrics or the foreign equivalent	
4. Board certified in Nephrology	
5. Transplant Nephrology Fellowship	
a. Participated in 12 month specialized training, which consist of clinical transplant service, tissue typing laboratory, and solid organ transplant service.	
b. Minimum of 30 kidney patients followed for a minimum of three months from the time of transplant	
c. Experience with pre-, peri-, and post-operative care within the last 2 years	
d. Observed 3 procurement procedures and 3 kidney transplants	
e. Observe the evaluation of the donor and donor process, and management of at least 3 multiple organ donors which include the kidney	
6. Experience in kidney transplantation (Post Fellowship) involving:	
a. 2-5 years experience on an active kidney transplant service	
b. Minimum of 45 or more kidney patients followed from the time of their transplant for a minimum of 3 months	
c. Experience with pre-, peri-, and post-operative care within the last 2 years	
d. Observed 3 procurement procedures and 3 kidney transplants	
e. Observe the evaluation of the donor and donor process, and management of at least 3 multiple organ donors which include the kidney and/or kidney/pancreas	
7. Pediatric Pathway	
a. Program serves predominantly Pediatric Patients	
b. Demonstrate that the individual has maintained current working knowledge in all aspects of kidney transplantation and patient care within the last 2 years.	
c. May petition the Membership and Professional Standards Committee (MPSC) for and receive approval	
d. A preliminary interview before the Membership and Professional Standards Committee shall be required.	
8. Pediatric Nephrology Fellowship (3 years)	
a. Fellowship training program accredited by the ACGME RRC-Ped	
b. Transplant program at which training takes place performs an average of at least 10 pediatric kidney transplants per year	
c. Involved with 10 or more pediatric kidney transplant recipients	
d. Followed 30 patients a minimum of 6 months from the time of their transplant	
e. Experience with pre-, peri-, and post-operative care of 10 pediatric kidney transplants	
f. Observed 3 organ procurement procedures and 3 kidney transplants	
g. Observed the evaluation of the donor and donor process and management of at least 3 multiple organ donors that include the kidney	

Membership Criteria	Yes
9. Transplant Medicine Fellowship – *for board certified or eligible Pediatric Nephrologists*	
a. Involved with 10 or more pediatric kidney transplants	
b. Followed 30 patients a minimum of 6 months post-transplant	
c. Experience with pre-, peri-, and post-operative care of 10 pediatric kidney transplants	
d. Observed 3 organ procurement procedures and 3 kidney transplants	
e. Observed the evaluation of the donor and donor process and management of at least 3 multiple organ donors that include the kidney	
10.Pediatric - Combined Training/Experience - *for board certified or eligible Pediatric Nephrologists*	
a. Two or more years experience (gained during or after fellowship or as an accumulation during both periods)	
b. Involved in the primary care of 10 or more kidney transplants on pediatric patients (including pre-, peri-, and post-operative care)	
c. Followed 30 patients a minimum of 6 months post-transplant	
d. Observed 3 organ procurement procedures and 3 kidney transplants	
e. Observed the evaluation of the donor and donor process and management of at least 3 multiple organ donors that include the kidney	
11. Conditional Pathway – ***Only available to Existing Programs***	
a. Center conducts 60 or more kidney transplants per year	
b. Physician provides primary care for 23 or more kidney transplants recipients from the time of their transplant	
c. Minimum of 12 months on an active kidney transplant service acquired over a maximum of 2 years	
d. Consulting relationship with counterparts at another approved kidney transplant center (include letter of support)	

j) Describe in detail the proposed primary transplant physician's involvement in the management of patients in this program and, if applicable, their plan for coverage of multiple transplant centers. Expand rows as necessary, and use complete sentences (i.e. narrative descriptions) for each.

	Describe Involvement
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)	
Additional Information	

k) Describe the proposed primary physician's transplant training and experience in the areas listed below. Individuals certified in pediatric nephrology should address these areas as they pertain to the pediatric kidney candidate/recipient. Expand rows as necessary, and use complete sentences (i.e. narrative descriptions) for each.

	Describe Training/Experience
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	
Candidate Evaluation Process	
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)	
Care of Living Donors (if applicable)	
Additional Information	

PART 3C, Section 2: Personnel – Additional/Other Physicians

Complete this section of the application to describe the involvement, training, and experience of other physicians associated with the program. **Physicians must be designated as Additional or Other as described below**. All physicians must be listed on Table 1 (Certificate of Investigation) in this application.

The Bylaws provide the following definition of Additional Transplant Physician:

> *Additional Transplant Physicians must be credentialed by the institution to provide transplant services and be able to independently manage the care of transplant patients.*

Physicians that also support this program but who do not meet the definition of "primary" or "additional," should complete this section of the application. The type should be indicated as "other."

Duplicate pages as needed

PART 3C, Section 2: Personnel – Additional/Other Physicians

2. Additional/Other Physicians (duplicate this section as needed). Refer to the Bylaws for the necessary qualifications and descriptions of the required supporting documents listed below.

Check List	Question Reference	Required Supporting Documents
	3C, 2a	Current C.V.
	3C, 2c	A letter from the Credentialing Committee of the applicant hospital stating that the physician meets all requirements to be in good standing. Please provide an explanation of any status other than active/full.
	3C, 2d, f, & g	A letter from the physician detailing his/her commitment to the program and level of involvement in substantive patient care.

a) Name: _____

b) This physician participates in (check all that apply):

	Type	
	Additional	**Other**
Kidney Transplantation		
Care of Living Kidney Donors		

c) Date of employment at this hospital (MM/DD/YY)? _____

Does individual have FULL privileges at this hospital?

_____ Yes Provide copy of hospital credentialing letter.

_____ No If the individual does **not** have full privileges, explain why, and provide the date the individual will be considered for full privileges. Also, include an explanation that describes the scope of these privileges.

d) Percentage of professional time spent on site: _____% = _____ hrs/week

e) Board certification type (s) or equivalent. If board certification is pending, indicate the date the exam has been scheduled. If individual has been recertified, please use that date.

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

f) Transplant Training (Fellowship): List the program(s) at which kidney transplant training was received including name of transplant hospital(s). Include the program director(s) names, applicable dates, and the number of kidney transplant patients for whom the physician provided substantive care (pre-, peri-, and post-operatively from the time of transplant).

Date From - To (MM/DD/YY)	Transplant Hospital	Program Director	# KI Patients Followed:		
			Pre	Peri	Post

g) Transplant Experience (Post Fellowship): List the name of transplant hospital(s), applicable dates, and the number of kidney transplant patients at the hospital for whom the transplant physician accepted primary responsibility for substantive patient care (pre-, peri- and post-operatively from the time of transplant).

Date From - To (MM/DD/YY)	Transplant Hospital	Program Director	# KI Patients Followed:		
			Pre	Peri	Post

h) Describe in detail the transplant physician's involvement in this kidney transplant program. Expand rows as necessary, use complete sentences (i.e. narrative descriptions) for each.

	Describe Involvement
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)	
Additional Information	

i) Describe the physician's transplant training and experience in the role of transplant patient management in the areas listed below. Individuals certified in pediatric nephrology should address these areas as they pertain to the pediatric kidney candidate/recipient. Expand rows as necessary, use complete sentences (i.e. narrative descriptions) for each.

	Describe Training/Experience
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	
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)	
Care of Living Donors (if applicable)	
Additional Information	

Part 3D: Living Donor Kidney Transplantation

Complete this section only if submitting a new application for living donor kidney transplantation.

It is recognized that in the case of pediatric living donor transplantation, the living organ donation may occur at a transplant hospital that is distinct from the approved transplant center. If this program performs pediatric transplants, please list any other hospitals where the donor evaluation and surgery may routinely occur.

Hospital Name	Location

Part 3D, Section 1 Personnel – Primary Renal Donor Surgeon – Open Nephrectomy

The laparoscopic and open donor nephrectomy expertise may reside within the same or different individuals. Refer to the Bylaws for the necessary qualifications and provide the following documents:

Check List	Question Reference	Required Supporting Documents
	4A, 1	Current C.V.
	4A, 1d	Letter from the Credentialing Committee of the applicant hospital stating that the surgeon meets all requirements to be in good standing. Please provide an explanation of any status other than active/full.
	4A, 1c, e, & f	Letter from the surgeon detailing his/her commitment to the program and describing their previous experience/training.
	4A, 1e, i	ASTS Certificate in kidney (as applicable)
	4A, 1g	Log of nephrectomies

1. Name: _____

   a) This surgeon participates in ____ Open Nephrectomies ____ Laparoscopic Nephrectomies (Check all that apply)

   b) Date of employment at this hospital (MM/DD/YY): _____
   Date assumed role of primary surgeon (MM/DD/YY): _____

   c) Percentage of professional time spent supporting living kidney transplantation: _____% = _____ hrs/week

   d) Does individual have FULL privileges at this hospital?
   _____ Yes Provide copy of hospital credentialing letter.
   _____ No If the individual does **not** have full privileges, explain why, and provide the date the individual will be considered for full privileges. Include an explanation that describes the scope of privileges.

   e) Experience/ Training
      i) Qualifying by ASTS Fellowship with a certificate in kidney

	Yes	No
Did this individual 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:		
Date of training (MM/DD/YY) Start: _____ End: _____		

ii) Qualifying by Experience/Training:

	Yes	No
Has this individual performed at least 10 open nephrectomies (living donor nephrectomies, deceased donor nephrectomies, and/or removal of polycystic or diseased kidneys) as the primary surgeon or first assistant within the past 5 years?		

f) Complete TABLE 4E (at the end of this document) summarizing this individual's training and experience. Include the number of open nephrectomies (and laparoscopic if applicable) in which the individual participated as the primary surgeon or first assistant.

g) Donor Recovery Log: Provide documentation that demonstrates that this individual 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) within the past 5 years. A blank log for documenting open and laparoscopic living donor nephrectomies has been provided as TABLE 4F in this application.

Documentation should include the date of the surgery, medical records identification, and/or UNOS identification number, the role of the surgeon in the operative procedure, and the type of procedure. A current Procedural Terminology (CPT) code for the procedure is included.

h) Describe the proposed primary donor surgeon's level of involvement in the program for which the application is being made. If applicable, describe the surgeon's plan for coverage of transplant programs located in multiple transplant centers.

Part3D, Section 2: Personnel – Primary Renal Donor Surgeon - Laparoscopic Nephrectomy

The laparoscopic and open nephrectomy expertise may reside within the same or different individuals.

Refer to the Bylaws for the necessary qualifications and provide the following documents:

Check List	Question Reference	Required Supporting Documents
	4B, 1	Current C.V.
	4B, 1d	Letter from the Credentialing Committee of the applicant hospital stating that the surgeon meets all requirements to be in good standing. Please provide an explanation of any status other than active/full.
	4B, 1c, e, f, & h	Letter from the surgeon detailing his/her commitment to the program and describing their previous experience/training
	4B, 1g	Log of nephrectomies

1. Name: _____

   a) This surgeon participates in ____ Open Nephrectomies ____ Laparoscopic Nephrectomies (Check all that apply)

   b) Date of employment at this hospital (MM/DD/YY): _____
   Date assumed role of primary surgeon (MM/DD/YY): _____

   c) Percentage of professional time spent supporting living kidney transplantation: _____% = _____ hrs/week

   d) Does individual have FULL privileges?
   _____ Yes Provide copy of hospital credentialing letter.
   _____ No If the individual does **not** have full privileges, explain why, and provide the date the individual will be considered for full privileges. Include an explanation that describes the scope of these privileges.

   e) Experience/Training:

	Yes	No
Does this individual have experience as the primary surgeon or first assistant in at least 15 laparoscopic nephrectomies (living donor nephrectomies, deceased donor nephrectomies, and/or removal of polycystic or diseased kidneys) within the past 5 years?		

   f) Complete TABLE 4E in this document summarizing this individual's training and experience. Include the number of laparoscopic nephrectomies (and open nephrectomies if applicable) in which the individual participated as the primary surgeon or first assistant.

g) Donor Recovery Log: Provide documentation that demonstrates that this individual has experience as the primary surgeon or first assistant in performing at least 15 laparoscopic nephrectomies within the past 5 years. A blank log for documenting open and laparoscopic living donor nephrectomies has been provided as TABLE 4F in this application (duplicate as necessary).

Documentation should include the date of the surgery, medical records identification, and/or UNOS identification number, the role of the surgeon in the operative procedure, and the type of procedure. A current Procedural Terminology (CPT) code for the procedure is optional but recommended. It is recognized that in the case of pediatric kidney donor transplantation, the live organ donation may occur at a center that is distinct from the approved transplant center.

h) Describe the proposed primary donor surgeon's level of involvement in the program for which the application is being made or associated recovery hospital. If applicable, describe the surgeon's plan for coverage of transplant programs located in multiple transplant centers.

i) 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.

Part3D, Section 3: Personnel – Renal Donor Surgeons

Open and Laparoscopic Donor Nephrectomy Surgeons. Complete this section for each surgeon, other than the designated primary(ies) who will be performing living donor nephrectomies at this center. Provide the following documents:

If this application is being submitted for a change in personnel then you only need to complete this section for individuals whose credentials were not submitted in a previous application from this hospital.

Check List	Question Reference	Required Supporting Documents
	4C, 1	Current C.V.
	4C, 1d	Letter from the Credentialing Committee of the applicant hospital stating that the surgeon meets all requirements to be in good standing. Provide an explanation of any status other than active/full.
	4C, 1c, e, & f	Letter from the surgeon detailing his/her commitment to the program and describing their previous experience/training.

1. Name: _____

   a) This surgeon participates in ____ Open Nephrectomies ____ Laparoscopic Nephrectomies (Check all that apply)

   b) Date of employment at this hospital (MM/DD/YY): _____

   c) Percentage of professional time spent supporting living kidney transplantation: _____% = _____ hrs/week

   d) Does individual have FULL privileges at this hospital?
   _____ Yes Provide copy of hospital credentialing letter.
   _____ No If the individual does **not** have full privileges, explain why and provide the date the individual will be considered for full privileges. Include an explanation that describes the scope of privileges.

   e) Complete TABLE 4E (at the end of this document) summarizing this individual's training and experience. Include the number of open and laparoscopic nephrectomies in which the individual participated as the primary surgeon or first assistant.

   f) Describe the donor surgeon's level of involvement in the program for which the application is being made.

Part 3D, Section 4: Other Staff and Resources

Complete this section only if applying for initial approval for living donor kidney transplantation.

1. How does the center assess that the short and long term risks for the potential living donor are acceptable to the medical staff at the transplant center and the donor? The response needs to address the following: evaluation, consent, surgical risk, and long-term donor considerations for being made uninephric.

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 (expand rows as needed).

Name	Role in Providing Support to Living Donors

Does the program have the ability to perform a psychosocial assessment of the donor to

- make an informed decision? Yes ____ No ____
- affirm voluntary nature of proceeding with the evaluation and donation? Yes ____ No ____

3. 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.

Part 3D, Section 5: Protocols

1. Kidney transplant programs that perform living donor kidney recoveries must demonstrate that they have written protocols as listed below. Submission of protocols 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: Include the following elements: • 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, and • 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 and Donor Nephrectomy: • 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		

2. Describe how the hospital will assess its compliance with each protocol listed above. (Use complete sentences)

Table 1: Certificate of Investigation

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

The Bylaws state that "*Each primary surgeon or primary physician, listed on the application as a part of the plan for who shares coverage responsibility, shall submit an assessment, subject to medical peer review confidentiality requirements and which follows guidelines provided in the application and is satisfactory to the MPSC, of all physicians and surgeons participating in the program regarding their involvement in prior transgressions of UNOS requirements and plans to ensure that the improper conduct is not continued." (Emphasis Added)*

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

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:

* Expand rows as needed.

Table 2 – Program Coverage Plan

Please answer the questions below and provide a written copy of the current Program Coverage Plan. The plan must be signed by either:

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

In accordance with the Bylaws, the program director, in conjunction with the primary transplant surgeon and transplant physician, must submit a written Program Coverage Plan, which documents how 100% medical and surgical coverage is provided by individuals credentialed by the hospital to provide transplant service for the program. 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, during the year. The Program Coverage Plan must address the following requirements:

	Yes	**No**
Is this a single surgeon program?		
Is this a single physician program?		
If the answer to either one of the above questions is "Yes," explain the protocol for notifying patients.		
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 within one-hour ground transportation time to address urgent patient issues?		
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:		

Table 3: OPTN Staffing Report

KIDNEY TRANSPLANT PROGRAM

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

Answer the questions below for this transplant program. Since this information will be used to update UNET[sm] and the Membership Directory, make sure to include the best (most accurate) telephone number and address for each person. Check "L" and/or "D" to specify each individual's involvement with deceased donor kidney transplantation, living donor kidney transplantation, or both as applicable. Add additional rows as necessary. The surgeons and physicians named below should match those listed on the Certificate of Investigation.

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

Name	L	D	Address	Phone	Fax	Email

Identify all **surgeons** who perform transplants:
Indicate if they are an "additional" or "other" surgeon in the columns labeled "A" and "O".

Name	A	O	Address	Phone	Fax	Email

Identify **living donor recovery surgeons**:

Name	Open	Lap	Address	Phone	Fax	Email

Identify all **physicians** (internists) who participate in this transplant program.
Indicate if they are an "additional" or "other" physician in the columns labeled "A" and "O".

Name	A	O	Address	Phone	Fax	Email

Identify the **hospital administrative director/manager** who will be involved with this program:
Use an * to indicate which individual will serve as the primary transplant administrator if more than one.

Name	L	D	Address	Phone	Fax	Email

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

Name	L	D	Address	Phone	Fax	Email

The **clinical transplant coordinators** who participate in this transplant program are:

Name	L	D	Address	Phone	Fax	Email

List the **data coordinators** for this transplant program:
Use an * to indicate which individual will serve as the primary data coordinator.

Name	L	D	Address	Phone	Fax	Email

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

Name	L	D	Address	Phone	Fax	Email

List the **Independent Donor Advocate(s) (IDA)** who participate in the care of living donors:
Complete only if the application includes living donor transplantation.

Name	Address	Phone	Fax	Email

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

Name	L	D	Address	Phone	Fax	Email

Identify the d**irector of anesthesiology** who will be involved with this program:

Name	L	D	Address	Phone	Fax	Email

Table 4– Sample Logs

TABLE 4A – 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

#	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				

Extend lines on log as needed
Patient ID should <u>not</u> be name or Social Security Number.

Director's Signature: _____ Date: _____

TABLE 4B – 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

#	Date of Procurement	Donor ID Number	Location of Donor (Hospital)	(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				
31				
32				
33				
34				
35				

Extend lines on log as needed
Patient ID should <u>not</u> be name or Social Security Number.

Director's Signature: _____ Date: _____

TABLE 4C – Primary Physician – Recipient Log (Sample)

List only those patients followed for 3 months from the time of transplant (including pre-, peri-, and post-operative management). Complete separate form for each transplant hospital

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

#	Date of Transplant	Medical Record/ OPTN ID #	Pre-Operative	Peri-Operative	Post-Operative (90-days follow-up care)	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						
26						
27						
28						
29						
30						
31						
32						
33						
34						
35						

Extend lines on log as needed
Patient ID should <u>not</u> be name or Social Security Number.

Director's Signature: _____ **Date:** _____

TABLE 4D – Primary Physician – Observation Log (Sample)

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

In the tables below document how the physician fulfills the requirements for participation as an observer in organ procurements and transplants, as well as observing the selection and management of at least 3 multiple organ donors that include the organ for which application is being submitted. *List cases in date order.*

Procurements Observed

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

Transplants Observed

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

Donor Selection and Management

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

TABLE 4E – Primary Donor Surgeon(s) - Open and Laparoscopic Nephrectomies *(Duplicate as needed)*

SUMMARY OF EXPERIENCE AND TRAINING FOR DR. _____

This summary must document (at a minimum) that the individual:

1) Performed at least 10 open nephrectomies (living donor nephrectomies, deceased donor nephrectomies, and/or removal of polycystic or diseased kidneys) as primary surgeon or first assistant within the past 5 years; and/or
2) Performed at least 15 laparoscopic nephrectomies as the primary surgeon or first assistant within the past 5 years.

List each transplant hospital on a separate row.
Periods of training and post-fellowship experience must be listed on separate rows.

Date From - To (MM/DD/YY)	Transplant Hospital	Program Director	# Open Nephrectomies as Primary	# Open Nephrectomies as 1st Assistant	#Laparoscopic Nephrectomies as Primary	# Laparoscopic Nephrectomies as 1st Assistant

The numbers entered above should be validated by the attached log.
Insert additional rows as needed

TABLE 4F - Primary Donor Surgeon – Donor Recovery Log

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

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

This log must document (at a minimum) that the individual:

1) Performed at least 10 open nephrectomies (living donor nephrectomies, deceased donor nephrectomies, and/or removal of polycystic or diseased kidneys) as primary surgeon or first assistant within the past 5 years; and/or
2) Performed at least 15 laparoscopic nephrectomies as the primary surgeon or first assistant within the past 5 years.

Cases should be listed by type then date order.
Applicable CPT codes are listed on the next page.

#	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								

Insert additional rows as needed.

Applicable CPT Codes

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 Laparoscope proc, renal

PART 3: Liver Transplant Program
Including Programs Performing Living Donor Liver Transplantation

This application is for (check all that apply):

	Liver Transplantation	Living Donor Liver Transplantation
New Program/ Initial Application		
Key Personnel Change		

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

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

Check list	Question Reference	Required Supporting Documents
	3A, 1	Current C.V.

Name	Date of Appointment	Primary Areas of Responsibility

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

1. **Primary Liver and/or Living Donor Liver Transplant Surgeon.** Refer to the Bylaws for the necessary qualifications and more specific descriptions of the required supporting documents listed below.

Check List	Question Reference	Required Supporting Documents
	3B, 1a	Current C.V.
	3B, 1d	Letter from the Credentialing Committee of the applicant hospital stating that the surgeon meets all requirements to be in good standing. Please provide an explanation of any status other than active/full.
	3B, 1e,h,i	Letter from the surgeon detailing his/her commitment to the program and describing their transplant training/experience
	3B, 1h	Formal Training: A letter from the training director verifying that the fellow has met the requirements
	3B, 1h	Formal Training: Log(s) (organized by date) of the transplant and procurement procedures
	3B, 1i	Transplant Experience: A letter from the program director verifying that the individual has met the primary surgeon requirements and is qualified to direct a liver transplant program
	3B, 1i	Transplant Experience: Log(s) (organized by date) of the transplant and procurement procedures
	3B, 1m	Living Donor Liver Experience: A log (organized by date) of major hepatic resection surgeries and living donor hepatectomies performed within the past 5 years. **Required only for programs performing or seeking to perform living donor liver transplantation or for changes in the primary living donor liver transplant surgeon(s).**
		Other Letters of Recommendation (Reference)
		Letter of recommendation attesting to the individual's overall qualifications to act as primary surgeon and addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate

a) Name: _____

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

	Primary Liver Transplant Surgeon
	Primary Living Donor Liver Transplant Surgeon [must complete question c) below]

c) **Living Donor Liver applicants only:**
Is this individual currently designated as the OPTN primary liver transplant surgeon for the liver transplant program at this hospital? _____ Yes _____ No

If Yes, supply the documents requested in lines 1, 2, 3, 8 and 10 of the checklist above and answer questions j) and m) below. If "No," complete questions d) through l) below. **NOTE: If the individual is being proposed simultaneously as the primary liver transplant surgeon and one of the two primary living donor liver transplant surgeons, all questions in this section must be answered and all required supporting documentation must be submitted.**

d) Date of employment at this hospital (MM/DD/YY): _____
Date assumed role of primary surgeon (MM/DD/YY): _____

Does individual have FULL privileges at this hospital?
_____ Yes Provide copy of hospital credentialing letter.
_____ No If the individual does **not** have full privileges, explain why and provide the date the individual will be considered for full privileges. Include an explanation that describes the scope of these privileges.

e) Percentage of professional time spent at this hospital: _____% = _____ hrs/week.

f) List below the hospitals, health care facilities, and medical group practices and percentage of professional time this individual is on site at each:

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

g) Board certification type(s) or equivalent. If board certification is pending, indicate the date the exam has been scheduled. If individual has been recertified, please use that date.

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

h) Transplant Training (Fellowship): List the name of the transplant hospital(s) at which liver transplant training (fellowship) was received. Include the program director(s) names, applicable dates, and the number of transplants performed. If the surgeon is qualifying as the primary surgeon through fellowship training, also submit the supporting documents listed below. Refer to the Bylaws for the necessary qualifications and descriptions of the required supporting documents.

- A letter from program director verifying that the fellow has met the requirements.
- Logs (see Tables 4A and 4B) of the transplant and procurement procedures. The logs should include a patient identifier/OPTN ID Number, transplant/procurement date and the surgeon's role in the procedure (i.e., primary or 1st assistant). These logs must be signed by the director of the training program.

Date From – To MM/DD/YY	**Transplant Hospital**	**Program Director**	**# LI Transplants as Primary**	**# LI Transplants 1st Assistant**	**# of LI Procurements as Primary or 1st Assistant**

i) Transplant Experience (Post Fellowship): List the name of the transplant hospital(s), program director name(s), applicable dates, and number of liver transplants performed by the individual at each transplant hospital. Refer to the Bylaws for the necessary qualifications and descriptions of the required supporting documents listed below.

- Letter(s) of reference from the program director(s) listed below.
- Logs (see Tables 4A and 4B) of the transplant and procurement procedures. The logs should include a patient identifier/OPTN ID Number, transplant/procurement date, and the surgeon's role in the procedure (i.e., primary or 1st assistant).
  The transplant log(s) should be signed by the program director, division chief, or department chair from the program where the experience was gained.

Date From – To MM/DD/YY	**Transplant Hospital**	**Program Director**	**# LI Transplants as Primary**	**# LI Transplants 1st Assistant**	**# of LI Procurements as Primary or 1st Assistant**

j) Summarize how the surgeon's experience fulfills the membership criteria.
(Check all that apply)

Membership Criteria	Yes
1. On site	
2. Certified by the American Board of Surgery, Urology, Osteopathic Surgery, or the foreign equivalent	
3. Two-year liver transplant fellowship	
a. Primary surgeon or 1st assistant on at least 45 liver transplants	
b. Primary surgeon or 1st assistant on at least 20 liver procurements of which at least 3 include the selection and management of the donor	
c. Involved in all levels of pre-, peri-, and post-operative patient care within the last 2 years	
4. Experience (Post Fellowship)	
a. Primary surgeon or 1st assistant on 60 or more liver transplants over a minimum of 2 years and a maximum of 5 years	
b. Primary surgeon or 1st assistant on at least 30 liver procurement procedures of which 3 include selection and management of the donor	
c. Involved in all levels of pre-, peri-, and post-operative patient care within the last 2 years	
5. Pediatric Pathway	
a. Program serves predominantly pediatric patients	
b. Individual has maintained current working knowledge in all aspects liver transplantation and patient care within the last 2 years.	
c. Hospital has petitioned the Membership and Professional Standards Committee (MPSC) for approval	
d. A preliminary interview before the Membership and Professional Standards Committee shall be required	
6. Living Donor Liver Experience – Criteria for Full Approval	
a. Primary surgeon or 1st assistant on 20 major hepatic resection surgeries, including at least 7 living donor hepatectomies, within the past 5 years	
7. Living Donor Liver Experience – Criteria for Conditional Approval	
a. Primary surgeon or 1st assistant on 20 major hepatic resection surgeries within the past 5 years	

k) Describe in detail the proposed primary surgeon's level of involvement in this transplant program, and if applicable, describe the surgeon's plan for coverage of transplant programs located in multiple transplant hospitals. Expand rows below as necessary and use complete sentences (i.e. narrative descriptions) for each.

	Describe Involvement
Management of Patients With End Stage Liver Disease	
Recipient Selection	
Donor Selection	
Histocompatibility and Tissue Typing	
Transplant Surgery	
Post-operative and Continuing Inpatient Care	
Use of Immunosuppressive Therapy	
Differential Diagnosis of liver Allograft Dysfunction	
Histologic Interpretation of Allograft Biopsies	
Interpretation of Ancillary Tests for Liver Dysfunction	
Long Term Outpatient Care	
Coverage of Multiple Transplant Hospitals (if applicable)	
Living Donor Transplantation (if applicable)	
Additional Information	

l) Describe the proposed primary surgeon's transplant training and experience in the areas listed below. (Expand rows below as necessary and use complete sentences (i.e. narrative descriptions) for each).

	Describe Training/Experience
Management of Patients with End Stage Liver Disease	
Recipient Selection	
Donor Selection	
Histocompatibility and Tissue Typing	
Transplant Surgery	
Post-Operative and Continuing Inpatient Care	
Use of Immunosuppressive Therapy	
Differential Diagnosis of Liver Allograft Dysfunction	
Histologic Interpretation of Allograft Biopsies	
Interpretation of Ancillary Tests for Liver Dysfunction	
Long Term Outpatient Care	
Additional Information	

m) Living Donor Liver Applicants Only:

Provide documentation (complete Table 4C) that demonstrates 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, within the past 5 years.

These cases must be documented. 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, the type of procedure and the Current Procedural Terminology (CPT) code for the procedure. A blank log for documenting these procedures has been provided at the end of this application (Table 4C). 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.

Please note: 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 (e.g., left lobectomy – donor).

2. **Primary Living Donor Liver Transplant Surgeon #2.** Complete this section ONLY if applying for approval to perform living donor liver transplantation or a change in key personnel for one of the primary living donor liver transplant surgeons. Refer to the Bylaws for the necessary qualifications and more specific descriptions of the required supporting documents listed below.

Check List	Question Reference	Required Supporting Documents
	3B, 2a	Current C.V.
	3B, 2c	Letter from the Credentialing Committee of the applicant hospital stating that the surgeon meets all requirements to be in good standing. Please provide an explanation of any status other than active/full.
	3B, 2d, g, & h	Letter from the surgeon detailing his/her commitment to the program and describing their transplant experience/training
	3B, 2g	Formal Training: A letter from the training director verifying that the individual has met the requirements
	3B, 2g	Formal Training: Log(s) (organized by date) of the transplant and procurement procedures
	3B, 2h	Transplant Experience: A letter from the program director verifying that the individual has met the primary surgeon requirements and is qualified to direct a liver transplant program
	3B, 2h	Transplant Experience: Log(s) (organized by date) of the transplant and procurement procedures
	3B, 2l	Living Donor Liver Experience: Log(s) (organized by date) of major hepatic resection surgeries and living donor hepatectomies performed within the past 5 years. **Required only for programs performing or seeking to perform living donor liver transplantation or for changes in the primary living donor liver transplant surgeon(s).**
		Other Letters of Recommendation (Reference)
		Letter of recommendation attesting to the individual's overall qualifications to act as primary surgeon and addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate

a) Name: _____

b) Is this individual currently designated as the OPTN primary liver transplant surgeon for the liver transplant program at this hospital? _____ Yes _____ No
If "Yes," supply the documents requested in lines 1, 2, 3, 8, and 10 of the checklist above and answer questions i) and l) below. If "No," complete questions c) through k) below.

c) Date of employment at this hospital (MM/DD/YY: _____
Date assumed role of primary surgeon (MM/DD/YY): _____

Does individual have FULL privileges at this hospital?
_____ Yes Provide copy of hospital credentialing letter.
_____ No If the individual does **not** have full privileges, explain why and provide the date the individual will be considered for full privileges. Include an explanation that describes the scope of these privileges.

d) Percentage of professional time spent at this hospital: _____% = _____ hrs/week

e) List below the hospitals, health Care facilities, and/or medical group practices and percentage of professional time this individual is on site at each:

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

f) Board certification type(s) or equivalent. If board certification is pending, indicate the date the exam has been scheduled. If individual has been recertified, please use that date.

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

g) Transplant Training (Fellowship): List the name of the transplant hospital(s) at which liver transplant training (fellowship) was received. Include the program director(s) names, applicable dates, and the number of transplants performed. If the surgeon is qualifying as a primary surgeon through fellowship training, also submit the supporting documents listed below. Refer to the Bylaws for the necessary qualifications and descriptions of the required supporting documents

- A letter from program director verifying that the fellow has met the requirements.
- Logs (see Tables 4A and 4B) of the transplant and procurement procedures. The logs should include a medical record/OPTN ID number, transplant/procurement date, and the surgeon's role in the procedure (i.e., primary or 1st assistant). These logs must be signed by the director of the training program.

Date From – To MM/DD/YY	**Transplant Hospital**	**Program Director**	**# LI Transplants as Primary**	**# LI Transplants 1st Assistant**	**# of LI Procurements as Primary or 1st Assistant**

h) Transplant Experience (Post fellowship): List the name of the transplant hospital(s), program director(s) names, applicable dates, and number of liver transplants performed by the individual at each hospital. Refer to the Bylaws for the necessary qualifications and descriptions of the required supporting documents listed below.

- Letter(s) of reference from the program director(s) listed below.
- Logs (see Tables 4A and 4B) of the transplant and procurement procedures. The logs should include a medical record/OPTN ID Number, transplant/procurement date, and the surgeon's role in the procedure (i.e., primary or 1st assistant).
  The transplant log(s) should be signed by the program director, division chief, or department chair from the program where the experience was gained.

Date From – To MM/DD/YY	**Transplant Hospital**	**Program Director**	**# LI Transplants as Primary**	**# LI Transplants 1st Assistant**	**# of LI Procurements as Primary or 1st Assistant**

i) Summarize how the surgeon's experience fulfills the membership criteria.
(Check all that apply)

Membership Criteria	Yes
1. On site	
2. Certified by the American Board of Surgery, Urology, Osteopathic Surgery or the foreign equivalent	
3. Two-year liver transplant fellowship	
a. Primary surgeon or 1st assistant on at least 45 liver transplants	
b. Primary surgeon or 1st assistant on at least 20 liver procurements of which at least 3 include the selection and management of the donor	
c. Involved in all levels of pre-, peri-, and post-operative patient care within the last 2 years	
4. Experience (Post Fellowship)	
a. Primary surgeon or 1st assistant on 60 or more liver transplants over a minimum of 2 years and a maximum of 5 years	
b. Primary surgeon or 1st assistant on at least 30 liver procurement procedures of which 3 include selection and management of the donor	
c. Involved in all levels of pre-, peri-, and post-operative patient care within the last 2 years	
5. Pediatric Pathway	
a. Program serves predominantly pediatric patients	
b. Demonstrate that the individual has maintained current working knowledge in all aspects liver transplantation and patient care within the last 2 years.	
c. The hospital has petitioned the Membership and Professional Standards Committee (MPSC) for approval	
d. A preliminary interview before the Membership and Professional Standards Committee shall be required	
6. Living Donor Liver Experience – Criteria for Full Approval	
a. Primary surgeon or 1st assistant on 20 major hepatic resection surgeries, including at least 7 living donor hepatectomies, within the past 5 years	
7. Living Donor Liver Experience – Criteria for Conditional Approval	
a. Primary surgeon or 1st assistant on 20 major hepatic resection surgeries within the past 5 years.	

j) Describe in detail the proposed primary surgeon's level of involvement in this transplant program, and if applicable, describe the surgeon's plan for coverage of transplant programs located in multiple transplant hospitals. Expand rows below as necessary and use complete sentences (i.e. narrative descriptions) for each.

	Describe Involvement
Management of Patients With End Stage Liver Disease	
Recipient Selection	
Donor Selection	
Histocompatibility and Tissue Typing	
Transplant Surgery	
Post-Operative and Continuing Inpatient Care	
Use of Immunosuppressive Therapy	
Differential Diagnosis of Liver Allograft Dysfunction	
Histologic Interpretation of Allograft Biopsies	
Interpretation of Ancillary Tests for Liver Dysfunction	
Long term outpatient Care	
Coverage of Multiple Transplant Hospitals (if applicable)	
Living Donor Transplantation (if applicable)	
Additional Information	

k) Describe the proposed primary surgeon's transplant training and experience in the areas listed below. Expand rows below as necessary and use complete sentences (i.e. narrative descriptions) for each.

	Describe Training/Experience
Management of Patients with End Stage Liver Disease	
Recipient Selection	
Donor Selection	
Histocompatibility and Tissue Typing	
Transplant Surgery	
Post-Operative and Continuing Inpatient Care	
Use of Immunosuppressive Therapy	
Differential Diagnosis of Liver Allograft Dysfunction	
Histologic Interpretation of Allograft Biopsies	
Interpretation of Ancillary Tests for Liver Dysfunction	
Long Term Outpatient Care	
Additional Information	

l) Provide documentation (complete Table 4C) that demonstrates 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, within the past 5 years.

These cases must be documented. Documentation should include the date of the surgery, medical records identification and/or UNOS identification number, the role of the surgeon in the operative procedure, the type of procedure and a current Procedural Terminology (CPT) code for the procedure. A blank log for documenting these procedures (Table 4C) has been provided at the end of this application. 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.

Please note: 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 (e.g., left lobectomy – donor).

Additional Instructions for PART 3B, Section 3: Personnel – Additional/Other Surgeons

Complete this section of the application to describe the involvement, training, and experience of other surgeons associated with the program. **Surgeons must be designated as Additional or Other as described below.** All surgeons must be listed in Table 1 (Certificate of Investigation) in this application.

The Bylaws provide the following definition of Additional Transplant Surgeon:

> *Additional Transplant Surgeons must be credentialed by the institution to provide transplant services and be able to independently manage the care of transplant patients including performing the transplant operation and procurement procedures.*

Surgeons that also support this program but who do not meet the definition of "primary" or additional" should complete this section as well. The type should be indicated as "other."

Duplicate pages as needed.

PART 3B, Section 3: Personnel – Additional/ Other Surgeons

3. Additional and Other Surgeons (Duplicate this section as needed). Provide the attachments listed below.

Check List	Question Reference	Required Supporting Documents
	3B, 3a	Current C.V.
	3B, 3c	A letter from the Credentialing Committee of the applicant hospital stating that each surgeon meets all requirements to be in good standing. Please provide an explanation of any status other than active/full
	3B, 3d, f, & g	A letter from each surgeon detailing his/her commitment to the program and level of involvement in substantive patient care

a) Name: _____

b) This surgeon participates in (check all that apply):

	Type	
	Additional	**Other**
Liver Transplantation		
Living Donor Liver Transplantation		

c) Date of employment at this hospital (MM/DD/YY): _____

Does individual have FULL privileges at this hospital?

_____ Yes Provide copy of hospital credentialing letter.

_____ No If the individual does **not** have full privileges, explain why, and provide the date the individual will be considered for full privileges. Include an explanation that describes the scope of privileges.

d) Percentage of professional time spent on site: _____% = _____ hrs/week

e) Board certification type(s) or equivalent. If board certification is pending, indicate the date the exam has been scheduled. If individual has been recertified, **please use that date.**

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

f) Transplant Training (Fellowship): List the name of the transplant hospital(s) at which liver transplant training (fellowship) was received. Include program director(s) names, applicable dates, and the number of transplants the individual performed.

Date From – To MM/DD/YY	**Transplant Hospital**	**Program Director**	**# LI Transplants as Primary**	**# LI Transplants 1st Assistant**	**# of LI Procurements as Primary or 1st Assistant**

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

Date From – To MM/DD/YY	**Transplant Hospital**	**Program Director**	**# LI Transplants as Primary**	**# LI Transplants 1st Assistant**	**# of LI Procurements as Primary or 1st Assistant**

h) Describe the surgeon's level of involvement in this liver transplant program in the areas listed below. (Expand rows as necessary and use complete sentences (i.e. narrative descriptions) for each).

	Describe Involvement
Management of Patients with End Stage Liver Disease	
Recipient Selection	
Donor Selection	
Histocompatibility and Tissue Typing	
Transplant Surgery	
Post-Operative and Continuing Inpatient Care	
Use of Immunosuppressive Therapy	
Differential Diagnosis of Liver Allograft Dysfunction	
Histologic Interpretation of Allograft Biopsies	
Interpretation of Ancillary Tests for Liver Dysfunction	
Long term Outpatient Care	
Living Donor Transplantation (if applicable)	
Additional Information	

i) Describe the surgeon's liver transplant training and experience in the areas listed below. (Expand rows as necessary and use complete sentences (i.e. narrative descriptions) for each).

	Describe Training/Experience
Management of Patients with End Stage Liver Disease	
Recipient Selection	
Donor Selection	
Histocompatibility and Tissue Typing	
Transplant Surgery	
Post-Operative and Continuing Inpatient Care	
Use of Immunosuppressive Therapy	
Differential Diagnosis of Liver Allograft Dysfunction	
Histologic Interpretation of Allograft Biopsies	
Interpretation of Ancillary Tests for Liver Dysfunction	
Long Term Outpatient Care	
Additional Information	

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

1. **Primary Liver Transplant Physician**. Refer to the Bylaws for necessary qualifications. Provide the attachments listed below:

Check list	Question Reference	Required Supporting Documents
	3C, 1a	Current C.V.
	3C, 1c	Letter from the Credentialing Committee of the applicant hospital stating that the physician meets all requirements to be in good standing. Please provide an explanation of any status other than active/full
	3C, 1d, g, & h	Letter from the Physician detailing his/her commitment to the program; level of involvement with substantive patient care; and summarizing their previous transplant experience
	3C, 1g	Formal Training: A letter from the training director verifying that the individual has met the requirements
	3C, 1g	Formal Training: Log(s) (organized by date) of the transplant patients followed.
	3C, 1h	Transplant Experience: A letter from the program director verifying that the individual has met the primary physician requirements and is qualified to direct a liver transplant program
	3C, 1h	Transplant Experience: Log(s) (organized by date) of the transplant patients followed
		Other Letters of Recommendation (Reference)
		Letter of recommendation attesting to the individual's overall qualifications to act as primary physician and addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate

a) Name: _____

b) Does this individual participate in the care of living liver donors? _____ Yes _____ No
Is this individual currently designated as the OPTN primary liver transplant physician for the liver transplant program at this hospital? _____ Yes _____ No.
If "Yes," supply the documents requested in lines 1, 2, 3 and 9 of the checklist above and answer question j) below. If "No," complete questions c) through l) below.

c) Date of employment at this hospital (MM/DD/YY): _____
Date assumed role of primary physician (MM/DD/YY): _____

Does individual have FULL privileges at this hospital?
_____ Yes Provide copy of hospital credentialing letter.
_____ No If the individual does **not** have full privileges, explain why and provide the date the individual will be considered for full privileges. Include an explanation that describes the scope of privileges.

d) Percentage of professional time on site: _____% = _____ hrs/week

e) List other hospitals, health care facilities, and/or medical group practices and percentage of professional time on site at each:

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

f) Board certification type(s) or equivalent. If board certification is pending, indicate the date the exam has been scheduled. If individual has been recertified, please use that date.

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

g) Transplant Training (Fellowship): List the program(s) at which liver transplant training was received. Include the name of the transplant hospital(s), program director(s) names, applicable dates, and the number of transplant patients for which the physician provided substantive patient care (pre-, peri- and post-operatively from the time of transplant). If the physician is qualifying as the primary physician through fellowship training, also submit the supporting documents listed below:

Refer to the Bylaws for the necessary qualifications and descriptions of the required supporting documents.

- Letters from the director of fellowship training program and the supervising physician verifying that the fellow has met the requirements.
- Recipient logs (see Table 4D) that includes the date of transplant, the patient's medical record and/or OPTN ID number. This log must be signed by the director of the training program and/or primary transplant physician at that transplant program.

Date From - To MM/DD/YY	Transplant Hospital	Program Director	# Liver Patients Followed		
			Pre	Peri	Post

h) Transplant Experience (Post fellowship only): List the name of the transplant hospital(s), program director name(s), applicable dates, and number of liver transplants performed at the transplant hospital for whom the transplant physician accepted primary responsibility for substantive patient care (pre-, peri-, and post-operatively from the time of transplant). Refer to the Bylaws for the necessary qualifications and descriptions of the required supporting documents listed below.

- Supporting letter(s) from the qualified liver transplant physician and/or liver transplant surgeon with whom the proposed primary physician has previously worked.
- Recipient log (see Table 4D) that includes the date of transplant and the patient's medical record and/or OPTN ID number. This log should be signed by the program director, division chief, or department chair from the program where the experience was gained.

Date From - To MM/DD/YY	Transplant Hospital	Program Director	# Liver Patients Followed		
			Pre	Peri	Post

i) Transplant Training/Experience. Describe how the physician fulfills the criteria for participating as an observer in 3 multiple organ procurements and 3 transplants that include the liver, as well as observing the evaluation of the donor and donor process, and management of at least 3 multiple organ donors which include the liver.

- Provide a log (Complete Table 4E) of these cases that includes the date of procurement, medical record ID number and/or OPTN ID number, and the location of the donor.
- If these requirements have not been met, submit a plan explaining how the individual will fulfill them.

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

j) Summarize how the transplant physician's experience fulfills the membership criteria. (Check all that apply)

Membership Criteria	Yes
1. On site	
2. M.D., D.O. or equivalent degree from another country	
3. Certified in Gastroenterology by the American Board of Internal Medicine, American Board of Pediatrics or the foreign equivalent	
4. Direct involvement in liver transplant patient care within the last 2 years.	
5. Transplant Hepatology Fellowship	
a. Participated in 12 month transplant hepatology fellowship	
b. Participated in primary care of 30 or more liver transplant recipients for a minimum of 3 months from the time of their transplant	
c. Observed 3 organ procurement procedures and 3 liver transplants	
d. Observed the evaluation of the donor and donor process and management of at least 3 multiple organ donors that include the liver	
6. Experience in Liver Transplantation (Post Fellowship)	
a. 2-5 years experience on an active liver transplant service	
b. Participated in the primary care of 50 or more liver transplant recipients for a minimum of 3 months from the time of their transplant over a 2-5 year period	
c. Observed 3 organ procurement procedures and 3 liver transplants	
d. Observed the evaluation of the donor and donor process and management of at least 3 multiple organ donors that include the liver	
7. Pediatric Gastroenterology Fellowship (3 years)	
a. Fellowship training program accredited by the ACGME RRC-Ped	
b. Transplant program at which training takes place performs an average of at least 10 liver transplants on pediatric patients per year.	
c. Participated in the primary care of 10 or more pediatric liver transplant recipients	
d. Followed 20 liver transplant recipients for a minimum of 3 months from the time of their transplant	
e. Direct involvement in the pre-, peri-, and post-operative care of 10 or more pediatric liver recipients	
f. Observed 3 organ procurement procedures and 3 liver transplants	

Membership Criteria	Yes
g. Observed the evaluation of the donor and the donor process and management of at least 3 multiple organ donors that include the liver	
8. Transplant Medicine Fellowship – ***for Board-Certified or Eligible Pediatric Gastroenterologists***	
a. Transplant program at which training takes place performs an average of at least 10 liver transplants on pediatric patients per year.	
b. Participated in the primary care of 10 or more pediatric liver transplant recipients	
c. Followed 20 liver transplant recipients for a minimum of 3 months from the time of their transplant	
d. Direct involvement in the pre-, peri-, and post-operative care of 10 or more pediatric liver recipients	
e. Observed 3 organ procurement procedures and 3 liver transplants	
f. Observed the evaluation of the donor and the donor process and management of at least 3 multiple organ donors that include the liver	
9. Combined Training/Experience – ***for Board-Certified or Eligible Pediatric Gastroenterologists***	
a. Two or more years of experience accumulated during fellowship, after fellowship or during both periods at a UNOS-approved liver transplant hospital	
b. Participated in the primary care of 10 or more liver transplants on pediatric patients	
c. Followed 20 liver transplant recipients for a minimum of 6 months from the time of their transplant	
d. Directly involved in the pre-, peri- and post-operative care of 10 or more liver transplants in pediatric patients	
e. Observed 3 organ procurement procedures and 3 liver transplants	
f. Observed the evaluation of the donor and the donor process and management of at least 3 multiple organ donors that include the liver	
10. Pediatric Pathway	
a. Program serves predominantly pediatric patients	
b. Individual has maintained current working knowledge in all aspects of liver transplantation and patient care within the last 2 years	
c. Hospital has petitioned the Membership and Professional Standards Committee (MPSC) for approval	
d. A preliminary interview before the Membership and Professional Standards Committee shall be required	
11. 12-month Conditional Pathway - ***Only available to Existing Programs***	
a. Board Certified Gastroenterologist/Hepatologist	
b. Involved in the primary care of 25 or more liver transplant recipients for a minimum of 3 months from the time of their transplant	
c. Minimum of 12 months on an active liver transplant service acquired over a maximum of 2 years for individuals qualifying by virtue of acquired clinical experience	
d. Consulting relationship with counterparts at another approved liver transplant hospital established (include letter of support)	

k) Describe in detail the proposed primary transplant physician's involvement in the management of patients in this program and, if applicable, their plan for coverage of multiple transplant hospitals. (Expand rows as necessary and use complete sentences (i.e. narrative descriptions) for each).

	Describe Involvement
Management of Patients with End Stage Liver Disease	
Care of Acute Liver Failure	
Recipient Selection	
Donor Selection	
Histocompatibility and Tissue Typing	
Post-Operative and Continuing Inpatient Care	
Use of Immunosuppressive Therapy	
Differential Diagnosis of Liver Allograft Dysfunction	
Histologic Interpretation of Allograft Biopsies	
Interpretation of Ancillary Tests for Liver Dysfunction	
Long Term Outpatient Care	
Care of the Living Liver Donor (if applicable)	
Coverage of Multiple Transplant Hospitals (if applicable)	
Care of Living Donors (as applicable)	
Additional Information	

l) Describe the proposed primary physician's transplant training and experience in the areas listed below. For individuals certified in pediatric gastroenterology, please address these areas as they pertain to the pediatric liver candidate/recipient. Expand rows as necessary and use complete sentences (i.e. narrative descriptions) for each.

	Describe Training/Experience
Management of Patients with End Stage Liver Disease	
Care of Acute Liver Failure	
Recipient Selection	
Donor Selection	
Histocompatibility and Tissue Typing	
Post-Operative and Continuing Inpatient Care	
Use of Immunosuppressive Therapy	
Differential Diagnosis of Liver Allograft Dysfunction	
Histologic Interpretation of Allograft Biopsies	
Interpretation of Ancillary Tests for Liver Dysfunction	
Long Term Outpatient Care	
Fluid and Electrolyte Management (Peds GI Only)	
Effects of Transplantation and Immunosuppressive Agents on Growth and Development (Peds GI Only)	
Manifestation of Rejection in the Pediatric Patient (Peds GI Only)	
Additional Information	

Additional Instructions for PART 3C, Section 2: Personnel –Additional/Other Physician(s)

Complete this section of the application to describe the involvement, training, and experience of other physicians associated with the program. **Physicians must be designated as Additional or Other as described below.** All physicians must be listed in Table 1 (Certificate of Investigation) in this application.

The Bylaws provide the following definition of Additional Transplant Physician:

> *Additional Transplant Physicians must be credentialed by the institution to provide transplant services and be able to independently manage the care of transplant patients.*

Physicians that also support this program, but who do not meet the definition of "primary" or "additional" should complete this section as well. The type should be indicated as "other."

Duplicate pages as needed.

PART 3C, Section 2: Personnel –Additional/Other Physician(s)

2. **Additional and Other Physicians (Duplicate this section as needed).** Refer to the Bylaws for the necessary qualifications and descriptions of the required supporting documents listed below.

Check List	Question Reference	Required Supporting Documents
	3C, 2a	Current C.V.
	3C, 2c	A letter from the Credentialing Committee of the applicant hospital stating that the physician meets all requirements to be in good standing. Please provide an explanation of any status other than active/full.
	3C, 2d, f, & g	A letter from the Physician detailing his/her commitment to the program and level of involvement in substantive patient care.

a) Name: _____

b) This physician participates in (check all that apply):

	Type	
	Additional	**Other**
Liver Transplantation		
Care of Living Liver Donors		

c) Date of employment at this hospital (MM/DD/YY): _____

Does individual have FULL privileges at this hospital?

_____ Yes Provide copy of hospital credentialing letter.

_____ No If the individual does **not** have full privileges, explain why and provide the date the individual will be considered for full privileges. Include an explanation that describes the scope of privileges.

d) Percentage of professional time spent on site: _____% = _____ hrs/week

e) Board certification type (s) or equivalent. If board certification is pending, indicate the date the exam has been scheduled. If individual has been recertified, please use that date.

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

f) Transplant Training (Fellowship): List the program(s) at which liver transplant training was received. Include the name of the transplant hospital(s), program director(s) names, applicable dates, and the number of transplant patients followed for whom the physician provided substantive care (pre-, peri- and post-operatively from the time of transplant).

Date From - To MM/DD/YY	Transplant Hospital	Program Director	# Liver Patients Followed		
			Pre	Peri	Post

g) Transplant Experience (Post Fellowship): List the name of transplant hospital(s), program director(s) names, applicable dates, and the number of liver transplants performed at the hospital for whom the transplant physician accepted primary responsibility for substantive patient care (pre-, peri- and post-operatively from the time of transplant).

Date From - To MM/DD/YY	Transplant Hospital	Program Director	# Liver Patients Followed		
			Pre	Peri	Post

h) Describe in detail the transplant physician's involvement in this liver transplant program. Expand rows as necessary and use complete sentences (i.e. narrative descriptions) for each.

	Describe Involvement
Management of Patients with End Stage Liver Disease	
Care of Acute Liver Failure	
Recipient Selection	
Donor Selection	
Histocompatibility and Tissue Typing	
Post-Operative and Continuing Inpatient Care	
Use of Immunosuppressive Therapy	
Differential Diagnosis of Liver Allograft Dysfunction	
Histologic Interpretation of Allograft Biopsies	
Interpretation of Ancillary Tests for Liver Dysfunction	
Long Term Outpatient Care	
Care of the Living Liver Donor (if applicable)	
Additional Information	

i) Describe the physician's transplant training and experience in the role of transplant patient management in the areas listed below. For individuals certified in pediatric gastroenterology, please address these areas as they pertain to the pediatric liver candidate/recipient. Expand rows as necessary and use complete sentences (i.e. narrative descriptions) for each.

	Describe Training/Experience
Management of Patients with End Stage Liver Disease	
Care of Acute Liver Failure	
Recipient Selection	
Donor Selection	
Histocompatibility and Tissue Typing	
Post-Operative and Continuing Inpatient Care	
Use of Immunosuppressive Therapy	
Differential Diagnosis of Liver Allograft Dysfunction	
Histologic Interpretation of Allograft Biopsies	
Interpretation of Ancillary Tests for Liver Dysfunction	
Long Term Outpatient Care	
Fluid and Electrolyte Management (Peds GI Only)	
Effects of Transplantation and Immunosuppressive Agents on Growth and Development (Peds GI Only)	
Manifestation of Rejection in the Pediatric Patient (Peds GI Only)	
Care of the Living Liver Donor (if applicable)	
Additional Information	

PART 3D: Living Donor Liver Transplantation

Complete this section ONLY if applying for initial approval for living donor liver transplantation.

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. If this program performs pediatric transplants, please list any other hospitals where the donor evaluation and surgery may routinely occur.

Hospital Name	Location

PART 3D, 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.

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. (Expand rows as needed.)

Name	Role in Providing Support to Living Donors

Does the program have the ability to perform a psychosocial assessment of the donor to:

- make an informed decision? Yes ____ No ____
- affirm voluntary nature of proceeding with the evaluation and donation? Yes ____ No ____

3. 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.

Part 3D, Section 2: Living Donor Liver Transplantation – Protocols

1. Liver transplant programs that perform living donor liver 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 Include the following elements: • 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 liver 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		
Radiographic assessment to ensure adequate anatomy and volume of the donor and of the remnant liver		
Informed consent for donor evaluation process and donor hepatectomy: • 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 hospital 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 hospital 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-years 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		

2. Describe how the hospital will assess compliance with each protocol listed above. (Use complete sentences.)

Table 1: Certificate of Investigation

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

The Bylaws state that "***Each primary surgeon or primary physician**, listed on the application as a part of the plan for who shares coverage responsibility, shall submit an assessment, subject to medical peer review confidentiality requirements and which follows guidelines provided in the application and is satisfactory to the MPSC, of **all physicians and surgeons** participating in the program regarding their involvement in prior transgressions of UNOS requirements and plans to ensure that the improper conduct is not continued." (Emphasis Added)*

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

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:

*additional rows may be added as necessary

Table 2– Program Coverage Plan

Please answer the questions below and provide a written copy of the current Program Coverage Plan. The plan must be signed by either:

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

In accordance with the Bylaws, the program director, in conjunction with the primary transplant surgeon and transplant physician, must submit a written Program Coverage Plan, which documents how 100% medical and surgical coverage is provided by individuals credentialed by the hospital to provide transplant service for the program. 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, during the year. The Program Coverage Plan must address the following requirements:

	Yes	**No**
Is this a single surgeon program?		
Is this a single physician program?		
If the answer to either one of the above questions is "Yes," explain the protocol for notifying patients		
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 within one-hour ground transportation time to address urgent patient issues?		
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:		

Table 3: OPTN Staffing Report

LIVER TRANSPLANT PROGRAM

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

Answer the questions below for this transplant program. Since this information will be used to update UNET[sm] and the Membership Directory, make sure to include the best (most accurate) telephone number and address for each person. Check "L" and/or "D" to specify each individual's involvement with living donor liver transplantation, deceased donor liver transplantation, or both as applicable. Add extra rows or use additional pages as necessary. The surgeons and physicians named below should match those listed on the Certificate of Investigation.

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

Name	**L**	**D**	**Address**	**Phone**	**Fax**	**Email**

Identify the **surgeons** who perform transplants. Indicate if they are an "additional" (A) or "other" (O) surgeon in the columns labeled L (living donor) and D (deceased donor)

Name	**L**	**D**	**Address**	**Phone**	**Fax**	**Email**

Identify the **physicians** (internists) who participate in this transplant program. Indicate if they are an "additional" (A) or "other" (O) physician in the columns labeled L (living donor) and D (deceased donor)

Name	L	D	Address	Phone	Fax	Email

Identify the **hospital administrative director/manager** who will be involved with this program: **Use an * to indicate** which individual will serve as the primary Transplant Administrator if more than one is listed.

Name	L	D	Address	Phone	Fax	Email

Identify the **Financial Counselor(s)** who will be involved with this program:

Name	L	D	Address	Phone	Fax	Email

The **clinical transplant coordinators** who participate in this transplant program are:

Name	L	D	Address	Phone	Fax	Email

List the **data coordinators** for this transplant program below. **Use an * to indicate** which individual will serve as the primary data coordinator.

Name	L	D	Address	Phone	Fax	Email

Identify the **social worker(s)** and other **mental health professionals** who will be involved with this program:

Name	L	D	Address	Phone	Fax	Email

List the **Independent Donor Advocate(s) (IDA)** who participate in the care of living donors (complete only if applications includes living donor liver transplantation):

Name	Address	Phone	Fax	Email

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

Name	L	D	Address	Phone	Fax	Email

Identify the **director(s) of anesthesiology** who will be involved with this program:

Name	L	D	Address	Phone	Fax	Email

TABLE 4A – 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

#	Date of Transplant	Medical Record/ OPTN PT 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				

Extend lines on log as needed
Patient ID should <u>not</u> be name or Social Security Number.

Director's Signature: _____ Date: _____

TABLE 4B – Primary Surgeon - Procurement Log (Sample)
Complete separate form for each transplant hospital

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

#	Date of Procurement	Donor ID Number	Location of Donor (hospital)	Comments (LRD/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				
31				
32				
33				
34				
35				

Extend lines on log as needed

Director's Signature: _____ Date: _____

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

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

Log should demonstrate 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, within the past 5 years.

These cases must be documented. Documentation should include the date of the surgery, medical records identification and/or UNOS identification number, the role of the surgeon in the operative procedure, the type of procedure, and a Current Procedural Terminology (CPT) code for the procedure. 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.

Please note: 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 (e.g., left lobectomy – donor).

List cases in date order

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

Extend lines on log as needed

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

Live Donor
47140 Live Donor Hepatectomy (segments II, III - left lateral segment)
47141 Live Donor Hepatectomy (segments II, III, IV -- left lobe)
47142 Live 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

TABLE 4D – Primary Physician – Recipient Log (Sample)

Complete a separate form for each transplant hospital.

List only those patients followed for 3 months from the time of transplant (including pre-, peri-, and post-operative management).

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

#	Date of Transplant	Medical Record/ OPTN ID #	Pre-Operative	Peri-Operative	Post- Operative (90 days Follow-Up Care)	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						
26						
27						
28						
29						
30						
31						
32						
33						
34						
35						

Extend lines on log as needed

Director's Signature: _____ **Date:** _____

TABLE 4E - Primary Physician – Observation Log (Sample)

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

In the tables below, document how the physician fulfills the requirements for participation as an observer in organ procurements and transplants, as well as observing the selection and management of at least 3 multiple organ donors that include the organ for which application is being submitted.

List cases in date order.

Procurements Observed

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

Transplants Observed

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

Donor Selection and Management

#	Date of Procurement	Medical Record/ OPTN ID #	Location of Donor (Hospital)	Liver or Multi-organ?
1				
2				
3				
4				
5				

Part 3: Pancreas Transplant Program

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

1. Identify the Surgical and/or Medical Director(s) of the pancreas transplant program (include C.V.). Briefly describe the leadership responsibilities for each.

Check list	Question Reference	Required Supporting Documents
	3A, 1	Current C.V.

Name	Date of Appointment	Primary Areas of Responsibility

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

1. **Primary Pancreas Transplant Surgeon**. Refer to the Bylaws for the necessary qualifications and more specific descriptions of the required supporting documents. Provide the attachments listed below.

Check list	Question Reference	Required Supporting Documents
	3B, 1a	Current C.V.
	3B, 1b	Letter from the Credentialing Committee of the applicant hospital stating that the surgeon meets all requirements to be in good standing. Please provide an explanation of any status other than active/full.
	3B, 1c,g,h	Letter from the surgeon detailing his/her commitment to the program and describing his/her transplant experience/training.
	3B, 1f	Formal Training: A letter from the training director verifying that the fellow has met the requirements.
	3B, 1f	Formal Training: A log (organized by date) of the transplant and procurement procedures.
	3B, 1g	Transplant Experience: A letter from the program director verifying that the individual has met the requirements.
	3B, 1g	Transplant Experience: A log (organized by date) of the transplant and procurement procedures.
		Other Letters of Recommendation (Reference).
	Table 1	Letter(s) of recommendation from person(s) named as primary surgeon and program director attesting to the individual's overall qualifications to act as primary surgeon and addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate.

a) Name: _____

b) Date of employment at this hospital (MM/DD/YY): _____
Date assumed role of primary surgeon (MM/DD/YY): _____
Does individual have FULL privileges at this hospital?

_____ Yes Provide copy of hospital credentialing letter.
_____ No If the individual does **not** have full privileges, explain why, and provide the date the individual will be considered for full privileges. Include an explanation that describes the scope of privileges.

c) Percentage of professional time spent at this hospital: _____% = _____ hrs/week

d) List below the hospitals, health care facilities, and medical group practices and percentage of professional time this individual is on site at each:

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

e) Board certification type(s) or equivalent. If board certification is pending, indicate the date the exam has been scheduled. If individual has been recertified, please use that date.

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

f) Transplant Training (Fellowship): List the name of the transplant hospital(s) at which pancreas and/or kidney/pancreas transplant training (fellowship) was received. Include the program director(s) name(s), applicable dates, and the number of transplants and procurements performed. If the surgeon is qualifying as primary surgeon through fellowship training, also submit the supporting documents listed below. Refer to the Bylaws for the necessary qualifications and detailed descriptions of the required supporting documents:

- A letter from the program director verifying that the fellow has met the requirements.
- Logs of the transplant and procurement procedures (Tables 4A and 4B). The logs should include patient identifier/OPTN ID Number, transplant/procurement date, and the surgeon's role in the procedure (i.e., primary or 1st assistant). These logs must be signed by the director of the training program.

Date From – To MM/DD/YY	**Transplant Hospital**	**Program Director**	**# Transplants as Primary Surgeon**		**# Transplants as 1st Assistant**		**# of Procurements as Primary Surgeon or 1st Assistant**	
			PA	**KP**	**PA**	**KP**	**PA**	**KP**

g) Transplant Experience (Post Fellowship):
List the name of the hospital(s), the program director(s) name(s), applicable dates, and number of pancreas and/or kidney/pancreas transplants and procurements performed by the individual at each hospital. Refer to the Bylaws for the necessary qualifications and descriptions of the required supporting documents listed below.

- Letter(s) of reference from the program director(s) listed below.
- Logs of the transplant and procurement procedures (Tables 4A and 4B). The logs should include patient identifier/OPTN ID Number, transplant/procurement date, and the surgeon's role in the procedure (i.e., primary or 1st assistant).
  Transplant log(s) should be signed by the program director, division chief, or department chair from the program where the experience was gained.

Date From – To MM/DD/YY	**Transplant Hospital**	**Program Director**	**# Transplants as Primary Surgeon**		**# Transplants as 1st Assistant**		**# of Procurements as Primary Surgeon or 1st Assistant**	
			PA	**KP**	**PA**	**KP**	**PA**	**KP**

h) Summarize how the surgeon's experience fulfills the membership criteria.
(Check all that apply)

Membership Criteria	Yes
1. On site	
2. Certified by the American Board of Surgery, Urology, Osteopathic Surgery, or the foreign equivalent	
3. Two Year Transplant Fellowship	
a. Primary Surgeon or 1st assistant on at least 15 pancreas transplants	
b. Primary Surgeon or 1st assistant on at least 10 pancreas procurements	
c. Involved in all levels of pre-, peri-, and post-operative patient care within the last 2 years	
d. Training program approved by the Education Committee of the American Society of Transplant Surgeons or UNOS, or the foreign equivalent	
4. Experience (Post Fellowship)	
a. Primary surgeon or 1st assistant on 20 or more pancreas transplants over a minimum of 2 years and a maximum of 5 years	
b. Primary surgeon or 1st assistant on 10 or more pancreas procurements	
c. Involved in all levels of pre-, peri-, and post-operative patient care within the last 2 years	
5. Pediatric Pathway	
a. Program serves predominantly pediatric patients	
b. Individual has maintained current working knowledge in all aspects of pancreas transplantation and patient care within the last 2 years	
c. Transplant hospital has petitioned the Membership and Professional Standards Committee (MPSC) for approval under this pathway	
d. A preliminary interview before the MPSC shall be required	

i) Describe in detail the proposed primary surgeon's level of involvement in this transplant program, and if applicable, describe the surgeon's plan for coverage of transplant programs located in multiple transplant hospitals. Expand rows below as necessary and use complete sentences (i.e. narrative descriptions) for each.

	Describe Involvement
Management of 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	

	Describe Involvement
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	
Coverage of Multiple Transplant Hospitals (if applicable)	
Additional Information	

j) Describe the proposed primary surgeon's transplant training and experience in the areas listed below. Expand rows below as necessary and use complete sentences (i.e. narrative descriptions) for each.

	Describe Training/Experience
Management of Patients with Diabetes Mellitus	
Recipient Selection	
Donor Selection	
Histocompatibility and Tissue Typing	
Transplant Surgery	
Immediate Post-Operative and Continuing Inpatient Care	

	Describe Training/Experience
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	
Coverage of Multiple Transplant Hospitals (if applicable)	
Additional Information	

PART 3B, Section 2: Personnel – Additional/Other Surgeons

Complete this section of the application to describe the involvement, training, and experience of any other surgeons participating in the program. **Surgeons must be designated as Additional or Other as described below**. All surgeons must be listed on Table 1 (Certificate of Investigation) in this application.

The Bylaws provide the following definition of Additional Transplant Surgeon:

> *Additional Transplant Surgeons must be credentialed by the institution to provide transplant services and be able to independently manage the care of transplant patients including performing the transplant operation and procurement procedures.*

Surgeons that also support this program but who do not meet the definition of "primary" or additional" should complete this section as well. The type should be indicated as "other."

Duplicate pages as needed.

PART 3B, Section 2: Personnel – Additional/Other Surgeons

2. Additional/Other Surgeons (duplicate this section as needed). Provide the attachments listed below.

Check list	Question Reference	Required Supporting Documents
	3B, 2a	Current C.V.
	3B, 2b	A letter from the Credentialing Committee of the applicant hospital stating that the surgeon meets all requirements to be in good standing. Please provide an explanation of any status other than active/full.
	3B, 2c,e,f	A letter from the Surgeon detailing his/her commitment to the program and level of involvement in substantive patient care.

a) Name: _____

For pancreas transplantation this individual is classified as ____Additional Surgeon ___Other Surgeon
(Check only one)

b) Date of employment at this hospital (MM/DD/YY): _____

Does individual have FULL privileges at this hospital?

____ Yes Provide copy of hospital credentialing letter.
____ No If the individual does **not** have full privileges, explain why and provide the date the individual will be considered for full privileges. Include an explanation that describes the scope of privileges.

c) Percentage of professional time spent at this hospital: _____% = _____ hrs/week

d) Board certification type(s) or equivalent. If board certification is pending, indicate the date the exam has been scheduled. If individual has been recertified, **please use that date.**

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

e) Transplant Training (Fellowship): List the name of the transplant hospital(s) at which pancreas and/or kidney/pancreas transplant training (fellowship) was received. Include the program director(s) name(s), applicable dates, and the number of transplants and procurements the individual performed.

Date From – To MM/DD/YY	Transplant Hospital	Program Director	# Transplants as Primary Surgeon		# Transplants as 1st Assistant		# of Procurements as Primary Surgeon or 1st Assistant	
			PA	KP	PA	KP	PA	KP

f) Transplant Experience (Post Fellowship): List the name of the transplant hospital(s), the program director(s) name(s), applicable dates, and number of pancreas and/or kidney/pancreas transplants and procurements performed by the individual at each hospital.

Date From – To MM/DD/YY	Transplant Hospital	Program Director	# Transplants as Primary Surgeon		# Transplants as 1st Assistant		# of Procurements as Primary Surgeon or 1st Assistant	
			PA	KP	PA	KP	PA	KP

g) Describe in detail the surgeon's level of involvement in this pancreas transplant program in the areas listed below. Expand rows as necessary and use complete sentences (i.e. narrative descriptions) for each.

	Describe Involvement
Management of 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	
Coverage of Multiple Transplant Hospitals (if applicable)	
Additional Information	

h) Describe the surgeon's transplant training and experience in the areas listed below. Expand rows as necessary and use complete sentences (i.e. narrative descriptions) for each.

	Describe Training/Experience
Management of 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	
Additional Information	

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

1. **Primary Pancreas Transplant Physician.** Refer to the Bylaws for necessary qualifications and more specific descriptions of the required supporting documents listed below. Provide the attachments listed below.

Check List	Question Reference	Required Supporting Documents
	3C, 1a	Current C.V.
	3C, 1b	Letter from the Credentialing Committee of the applicant hospital stating that the physician meets all requirements to be in good standing. Please provide an explanation of any status other than active/full.
	3C, 1c,f,g	Letter from the Physician detailing his/her commitment to the program; level of involvement with substantive patient care; and summarizing his/her previous transplant experience.
	3C, 1f	Formal Training: A letter from training director verifying that the fellow has met the requirements.
	3C, 1f	Formal Training: A letter from supervising qualified pancreas transplant physician verifying that the fellow has met the requirements.
	3C, 1f	Formal Training: Log(s) (organized by date of transplant) of the transplant recipients followed.
	3C, 1g	Transplant Experience: A letter from qualified transplant physician and/or pancreas transplant surgeon directly involved with the individual verifying that the individual has met the requirements.
	3C, 1g	Transplant Experience: Log(s) (organized by date of transplant) of the transplant recipients followed.
		Other Letters of Recommendation (Reference)
	Table 1	Letter(s) of recommendation from person(s) named as primary physician and program director attesting to the individual's overall qualifications to act as primary physician and addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate.

a) Name: _____

b) Date of employment at this hospital (MM/DD/YY): _____
Date assumed role of primary physician (MM/DD/Y): _____

Does individual have FULL privileges at this hospital?
____ Yes Provide copy of hospital credentialing letter.
____ No If the individual does **not** have full privileges, explain why and provide the date the individual will be considered for full privileges. Include an explanation that describes the scope of privileges.

c) Percentage of professional time spent at this hospital: _____% = _____ hrs/week

d) List below other hospitals, health care facilities, and medical group practices and percentage of professional time this individual is on site at each:

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

e) Board certification type(s) or equivalent. If board certification is pending, indicate the date the exam has been scheduled. If individual has been recertified, please use that date.

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

f) Transplant Training (Fellowship): List the program(s) at which pancreas and/or kidney/pancreas transplant training was received. Include the name of the hospital(s), program director(s) name(s), applicable dates, and the number of transplant patients for whom the physician provided substantive patient care (pre-, peri- and post-operatively from the time of transplant). If the physician is qualifying as the primary physician through fellowship training, also submit the supporting documents listed below.

Refer to the Bylaws for the necessary qualifications and descriptions of the required supporting documents.

- Letters from the director of fellowship training program and the supervising qualified pancreas transplant physician verifying that the fellow has met the requirements.
- Recipient log(s) (Table 4C) that includes the date of transplant, and the patient's medical record and/or OPTN ID number. Each log must be signed by the director of the training program and/or primary transplant physician at that transplant program.

Date From To mm/dd/yy	Transplant Hospital	Program Director	# Pancreas Patients Followed			# Kidney/Pancreas Patients Followed		
			Pre	Peri	Post	Pre	Peri	Post

g) Transplant Experience (Post Fellowship Only): List the name of the transplant hospital(s), program director(s) name(s), applicable dates, and number of pancreas and/or kidney/pancreas transplant patients at the hospital for whom the physician accepted primary responsibility for substantive patient care (pre-, peri-, and post-operatively from the time of transplant). Refer to the Bylaws for the necessary qualifications and descriptions of the required supporting documents listed below.

- Supporting letter(s) from the qualified transplant physician and/or the pancreas transplant surgeon who has been directly involved with the individual.
- A recipient log(s) (Table 4C) that includes the date of transplant and the patient's medical record and/or OPTN ID number. Each log should be signed by the program director, division chief, or department chair from the program where the experience was gained.

Date From To mm/dd/yy	Transplant Hospital	Program Director	# Pancreas Patients Followed			# Kidney/Pancreas Patients Followed		
			Pre	Peri	Post	Pre	Peri	Post

h) Training/Experience. Describe how the physician fulfills the criteria for participating as an observer in 3 organ procurements and 3 pancreas transplants, as well as observing the evaluation of the donor and donor process, and management of at least 3 multiple organ donors that include the pancreas.

- Provide a log (Table 4D) of these cases that includes the date of procurement or transplant, medical record ID number and/or OPTN ID number and the location of the donor.
- If these criteria have not been met, submit a plan explaining how the individual will fulfill them.

Date From To mm/dd/yy	Transplant Hospital	# of PA Procurements Observed	# of PA Transplants Observed	# of PA Donors/ Donor Process	# of Multi-Organ Donors Observed Mgmt

i) Summarize how the Transplant Physician's experience fulfills the membership criteria. (Check all that apply)

Membership Criteria	Yes
1. On site	
2. M.D., D.O. or equivalent degree	
3. Certified by the American Board of Internal Medicine, Pediatrics or the foreign equivalent in:	
a. Nephrology	
b. Endocrinology	
c. Diabetology	
4. Achieved eligibility in:	
a. Nephrology	
b. Endocrinology	
c. Diabetology	
5. Direct involvement in pancreas transplant patient care within the last 2 years	
6. 12-month Transplant Medicine Fellowship:	
a. Involved in primary care of 8 or more pancreas transplant recipients for a minimum of 3 months from the time of their transplant	
b. Observed 3 procurements and 3 pancreas transplants	
c. Observed the evaluation of the donor and donor process, and management of at least 3 multiple organ donors which include the pancreas	
d. Didactic curriculum approved by the RRC-IM of the ACGME	
7. Experience in pancreas transplantation:	
a. 2-5 years experience on an active pancreas transplant service	
b. Involved in primary care of 15 or more pancreas transplant recipients for a minimum of 3 months from the time of their transplant	
c. Observed 3 procurements and 3 pancreas transplants	
d. Observed the evaluation of the donor and donor process, and management of at least 3 multiple organ donors which include the pancreas	
8. Pediatric Pathway:	
a. Program serves predominantly pediatric patients	
b. Individual has maintained current working knowledge in all aspects of pancreas transplantation and patient care within the last 2 years	
c. Transplant hospital has petitioned the Membership and Professional Standards Committee (MPSC) for approval under this pathway	
d. A preliminary interview before the MPSC shall be required	

Membership Criteria	Yes
9. 12-Month Conditional Pathway – ***Only available to Existing Programs:***	
a. Board certified in nephrology, endocrinology, or diabetology	
b. Involved in the primary care of 8 or more pancreas transplant recipients for a minimum of 3 months from the time of their transplant	
c. Has acquired experience equal to 12 months on an active pancreas transplant service over a maximum of 2 years	
d. Consulting relationship established with counterparts at another approved pancreas transplant hospital (include letter of support)	

j) Describe in detail the proposed primary transplant physician's involvement in the management of patients in this program and, if applicable, their plan for coverage of multiple transplant hospitals. Expand rows as necessary and use complete sentences (i.e. narrative descriptions) for each.

	Describe Involvement
Management of Patients with End Stage Pancreas Disease	
Candidate Evaluation Process	
Donor Selection	
Recipient Selection	
Histocompatibility and Tissue Typing	
Immediate Post-Operative Patient Care	
Post-Operative Immunosuppressive Therapy	
Differential Diagnosis of Pancreas Dysfunction in the Allograft Recipient	
Histologic Interpretation of Allograft Biopsies	
Interpretation of Ancillary Tests for Pancreas Dysfunction	

	Describe Involvement
Long-term Outpatient Follow-up	
Coverage of Multiple Transplant Hospitals (if applicable)	
Additional Information	

k) Describe the proposed primary physician's transplant training and experience in the areas listed below. Expand rows as necessary and use complete sentences (i.e. narrative descriptions) for each.

	Describe Training/Experience
Management of Patients with End Stage Pancreas Disease	
Candidate Evaluation Process	
Donor Selection	
Recipient Selection	
Histocompatibility and Tissue Typing	
Immediate Post-Operative Patient Care	
Post-Operative Immunosuppressive Therapy	
Differential Diagnosis of Pancreas Dysfunction in the Allograft Recipient	
Histologic Interpretation of Allograft Biopsies	

	Describe Training/Experience
Interpretation of Ancillary Tests for Pancreas Dysfunction	
Long-term Outpatient Follow-up	
Additional Information	

PART 3C, Section 2: Personnel – Additional/Other Physicians

Complete this section of the application to describe the involvement, training, and experience of other physicians associated with the program. **Physicians must be designated as Additional or Other as described below**.

All physicians must be listed in Table 1 (Certificate of Investigation) in this application.

The Bylaws provide the following definition of Additional Transplant Physician:

> *Additional Transplant Physicians must be credentialed by the institution to provide transplant services and be able to independently manage the care of transplant patients.*

Physicians that also support this program but who do not meet the definition of "primary" or "additional" should complete this section of the application. The type should be indicated as "other."

Duplicate pages as needed.

PART 3C, Section 2: Personnel – Additional/Other Physicians

2. Additional/Other Physicians (duplicate this section as needed). Provide the attachments listed below.

Check list	Question Reference	Required Supporting Documents
	3C, 2a	Current C.V.
	3C, 2b	A letter from the Credentialing Committee of the applicant hospital stating that the physician meets all requirements to be in good standing. Please provide an explanation of any status other than active/full.
	3C, 2c,e,f	A letter from the physician detailing his/her commitment to the program and level of involvement in substantive patient care.

a) Name: _____

For pancreas transplantation this individual is classified as ____ Additional Physician ___ Other Physician
(Check only one)

b) Date of employment at this hospital (MM/DD/YY): _____

Does individual have FULL privileges at this hospital?

_____ Yes Provide copy of hospital credentialing letter.

_____ No If the individual does **not** have full privileges, explain why and provide the date the individual will be considered for full privileges. Include an explanation that describes the scope of privileges.

c) Percentage of professional time spent on site: _____% = _____ hrs/week

d) Board certification type(s) or equivalent. If board certification is pending, indicate the date the exam has been scheduled. If individual has been recertified, please use that date.

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

e) Transplant Training (Fellowship): List the program(s) at which pancreas and/or kidney/pancreas transplant training was received. Include the name of the transplant hospital(s), program director(s) names, applicable dates, and the number of transplant patients followed for whom the physician provided substantive care (pre-, peri- and post-operatively from the time of transplant).

Date From To mm/dd/yy	Transplant Hospital	Program Director	# Pancreas Patients Followed			# Kidney/Pancreas Patients Followed		
			Pre	Peri	Post	Pre	Peri	Post

f) Transplant Experience (Post Fellowship Only): List the name of the transplant hospital(s), program director(s) name(s), applicable dates, and the number of pancreas and/or kidney/pancreas transplant patients for whom the physician accepted primary responsibility for substantive patient care (pre-, peri- and post-operatively from the time of transplant).

Date From To mm/dd/yy	Transplant Hospital	Program Director	# Pancreas Patients Followed			# Kidney/Pancreas Patients Followed		
			Pre	Peri	Post	Pre	Peri	Post

g) Describe in detail the physician's involvement in this pancreas transplant program. Expand rows as necessary and use complete sentences (i.e. narrative descriptions) for each.

	Describe Involvement
Management of Patients with End Stage Pancreas Disease	
Candidate Evaluation Process	
Donor Selection	
Recipient Selection	
Histocompatibility and Tissue Typing	
Immediate Post-Operative Patient Care	
Post-Operative Immunosuppressive Therapy	
Differential Diagnosis of Pancreas Dysfunction in the Allograft Recipient	
Histologic Interpretation of Allograft Biopsies	
Interpretation of Ancillary Tests for Pancreas Dysfunction	
Long-term Outpatient Follow-up	
Coverage of Multiple Transplant Hospitals (if applicable)	
Additional Information	

h) Describe the physician's transplant training and experience in the role of transplant patient management in the areas listed below. Expand rows as necessary and use complete sentences (i.e. narrative descriptions) for each.

	Describe Training/Experience
Management of Patients with End Stage Pancreas Disease	
Candidate Evaluation Process	

	Describe Training/Experience
Donor Selection	
Recipient Selection	
Histocompatibility and Tissue Typing	
Immediate Post-Operative Patient Care	
Post-Operative Immunosuppressive Therapy	
Differential Diagnosis of Pancreas Dysfunction in the Allograft Recipient	
Histologic Interpretation of Allograft Biopsies	
Interpretation of Ancillary Tests for Pancreas Dysfunction	
Long-term Outpatient Follow-up	
Additional Information	

Table 1: Certificate of Investigation

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

The Bylaws state that "***Each primary surgeon or primary physician**, listed on the application as a part of the plan for who shares coverage responsibility, shall submit an assessment, subject to medical peer review confidentiality requirements and which follows guidelines provided in the application and is satisfactory to the MPSC, of **all physicians and surgeons** participating in the program regarding their involvement in prior transgressions of UNOS requirements and plans to ensure that the improper conduct is not continued." (Emphasis Added)*

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

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:

* Expand rows as needed.

Table 2 - Program Coverage Plan

Please answer the questions below and provide a written copy of the current Program Coverage Plan. The plan must be signed by either:

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

In accordance with the Bylaws, the program director, in conjunction with the primary transplant surgeon and transplant physician, must submit a written Program Coverage Plan, which documents how 100% medical and surgical coverage is provided by individuals credentialed by the hospital to provide transplant service for the program. 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, during the year. The Program Coverage Plan must address the following requirements:

	Yes	**No**
Is this a single surgeon program?		
Is this a single physician program?		
If the answer to either one of the above questions is "Yes," explain the protocol for notifying patients.		
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 the "on call" surgeon/physician available within 30 miles of the hospital premises to address urgent patient issues?		
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 transplant 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:		

Table 3: OPTN Staffing Report

PANCREAS TRANSPLANT PROGRAM

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

Answer the questions below for this transplant program. Since this information will be used to update UNet[sm] and the Membership Directory, make sure to include the best (most accurate) telephone number and address for each person. Use additional pages as necessary. The surgeons and physicians named below should match those listed on the Certificate of Investigation.

Identify the **transplant program Medical and/or Surgical Director(s)**:

Name	Address	Phone	Fax	Email

The **surgeons** who perform transplants are:

Name	Additional	Other	Address	Phone	Fax	Email

The **physicians** (internists) who participate in this transplant program are:

Name	Additional	Other	Address	Phone	Fax	Email

Identify the **hospital administrative director/manager** who will be involved with this program: **Use an * to indicate** which individual will serve as the primary transplant administrator if more than one is listed.

Name	Address	Phone	Fax	Email

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

Name	Address	Phone	Fax	Email

The **clinical transplant coordinators** who participate in this transplant program are:

Name	Address	Phone	Fax	Email

List the **data coordinators** for this transplant program below. **Use an * to indicate** which individual will serve as the primary data coordinator.

Name	Address	Phone	Fax	Email

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

Name	Address	Phone	Fax	Email

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

Name	Address	Phone	Fax	Email

Identify the **Director of Anesthesiology** who will be involved with this program:

Name	Address	Phone	Fax	Email

Table 4A - Primary Surgeon - Transplant Log (Sample)

Complete 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

#	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				

Extend lines on log as needed

Patient ID should <u>not</u> be name or Social Security Number.

Director's Signature: _____ **Date:** _____

Table 4B - Primary Surgeon - Procurement Log (Sample)

Complete separate form for each transplant hospital

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

#	Date of Procurement	Medical Record/ OPTN ID # of Donor	Location of Donor (hospital)	Comments (LRD/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				
31				
32				
33				
34				
35				

Extend lines on log as needed

Director's Signature: _____ **Date:** _____

Table 4C - Primary Physician - Recipient Log (Sample)

Complete 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.

List only those patients followed for 3 months from the time of transplant (including pre-, peri-, and post-operative management)

#	Date of Transplant	Medical Record/ OPTN ID #	Pre-Operative	Peri-Operative	Post-Operative (90-days follow-up care)	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						
26						
27						
28						
29						
30						

Extend lines on log as needed

Director's Signature: _____ **Date:** _____

Table 4D - Primary Physician – Observation Log (Sample)

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

In the tables below, document how the physician fulfills the requirements for participation as an observer in organ procurements and transplants, as well as observing the selection and management of at least 3 multiple organ donors that include the organ for which application is being submitted. *List cases in date order*.

Procurements Observed

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

Transplants Observed

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

Donor Selection and Management

#	Date of Procurement	Medical Record/ OPTN ID #	Location of Donor (Hospital)	Pancreas or Kidney/Pancreas or Multi-organ?
1				
2				
3				
4				
5				

Pancreas Islet Cell Transplant Program

Part 3: Facilities

This section must be completed when applying for a new program or reactivating an existing program.

1. Does this hospital presently have an OPTN approved pancreas transplant program?
   ___ Yes ___ No. If No, Part 7 of this application will need to be completed.

2. Year Islet Cell Transplant Program to Start (or started):_____

3. Provide the following required documents:

Check list	Required Supporting Documents
	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 (2 pages) 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

4. Islet Isolation – Pancreatic islets must be isolated in a facility with an FDA Investigational New Drug (IND) application in effect, with documented collaboration between the program and such facility. Provide a description of how this criterion is being met.

PART 4: Personnel

PART 4A: Personnel – Transplant Program Director(s)

1. Identify the Surgical and/or Medical Director(s) of the islet cell transplant program (include C.V.). Briefly describe the leadership responsibilities for each.

Check list	Question Reference	Required Supporting Documents
	4A, 1	Current C.V.

Name	Date of Appointment	Primary Areas of Responsibility

PART 4B, Section 1: Personnel – Surgical – Primary Surgeon

1. Primary Islet Cell Transplant Surgeon. Refer to the Bylaws for the necessary qualifications and more specific descriptions of the required supporting documents. Provide the attachments listed below.

Check list	Question Reference	Required Supporting Documents
	4B, 1a	Current C.V.
	4B, 1c	Letter from the Credentialing Committee of the applicant hospital stating that the surgeon meets all requirements to be in good standing. Please provide an explanation of any status other than active/full.
	4B, 1d,g,h	Letter from the surgeon detailing his/her commitment to the program and describing his/her transplant experience/training.
	4B, 1g	Formal Training: A letter from the training director verifying that the fellow has met the requirements.
	4B, 1g	Formal Training: A log (organized by date) of the transplant and procurement procedures.
	4B, 1h	Transplant Experience: A letter from the program director verifying that the individual has met the requirements.
	4B, 1h	Transplant Experience: A log (organized by date) of the transplant and procurement procedures.
		Other Letters of Recommendation (Reference)
	Table 1	Letter(s) of recommendation from person(s) named as primary surgeon and program director attesting to the individual's overall qualifications to act as primary surgeon and addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate.

a) Name: _____

b) Is this individual presently designated as the OPTN primary pancreas transplant surgeon for the pancreas transplant program? _____ Yes _____ No.

- If yes, supply the first 3 documents and the final document in the checklist above and answer question "i."
- If no, complete questions "c"-"k."

c) Date of employment at this hospital (MM/DD/YY): _____
Date assumed role of primary surgeon (MM/DD/YY): _____

Does individual have FULL privileges at this hospital?
_____ Yes Provide copy of hospital credentialing letter.
_____ No If the individual does **not** have full privileges, explain why, and provide the date the individual will be considered for full privileges. Include an explanation that describes the scope of privileges.

d) Percentage of professional time spent at this hospital: _____% = _____ hrs/week

e) List below the hospitals, health care facilities, and medical group practices and percentage of professional time this individual is on site at each:

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

f) Board certification type(s) or equivalent. If board certification is pending, indicate the date the exam has been scheduled. If individual has been recertified, please use that date.

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

g) Transplant Training (Fellowship): List the name of the transplant hospital(s) at which pancreas, kidney/pancreas, and/or islet cell transplant training (fellowship) was received. Include the program director(s) name(s), applicable dates, and the number of transplants and procurements performed. If the surgeon is qualifying as primary surgeon through fellowship training, also submit the supporting documents listed below. Refer to the Bylaws for the necessary qualifications and detailed descriptions of the required supporting documents:

- A letter from program director verifying that the fellow has met the requirements.
- Logs of the transplant and procurement procedures (Tables 4A and 4B). The logs should include a patient identifier/OPTN ID Number, transplant/procurement date, and the surgeon's role in the procedure (i.e., primary or 1st assistant). These logs must be signed by the director of the training program.

Date From – To MM/DD/YY	Transplant Hospital	Program Director	# Transplants as Primary Surgeon			# Transplants as 1st Assistant			# of Procurements as Primary Surgeon or 1st Assistant	
			PA	KP	IS	PA	KP	IS	PA	KP

h) Transplant Experience (Post Fellowship): List the name of the transplant hospital(s), the program director(s) name(s), applicable dates, and number of pancreas, kidney/pancreas, and/or islet cell transplants and procurements performed by the individual at each hospital. Refer to the Bylaws for the necessary qualifications and descriptions of the required supporting documents listed below.

- Letter(s) of reference from the program director(s) listed below.
- Logs of the transplant and procurement procedures (Tables 4A and 4B). The logs should include a patient identifier/OPTN ID Number, transplant/procurement date, and the surgeon's role in the procedure (i.e., primary or 1st assistant).
  Each transplant log should be signed by the program director, division chief, or department chair from the program where the experience was gained.

Date From – To MM/DD/YY	Transplant Hospital	Program Director	# Transplants as Primary Surgeon			# Transplants as 1st Assistant			# of Procurements as Primary Surgeon or 1st Assistant	
			PA	KP	IS	PA	KP	IS	PA	KP

i) Summarize how the surgeon's experience fulfills the membership criteria. (Check all that apply)

Membership Criteria	Yes
1. On site	
2. Certified by the American Board of Surgery, Urology, Osteopathic Surgery, or the foreign equivalent	
3. Two Year Transplant Fellowship	
a. Primary surgeon or 1st assistant on at least 15 pancreas transplants	
b. Primary surgeon or 1st assistant on at least 10 pancreas procurements	
c. Involved in all levels of pre-, peri-, and post-operative patient care within the last 2 years	
d. Training program approved by the Education Committee of the American Society of Transplant Surgeons or UNOS, or the foreign equivalent	
4. Experience (Post Fellowship)	
a. Primary surgeon or 1st assistant on 20 or more pancreas transplants over a minimum of 2 years and a maximum of 5 years	
b. Primary surgeon or 1st assistant on 10 or more pancreas procurements	
c. Involved in all levels of pre-, peri-, and post-operative patient care within the last 2 years	
5. Pediatric Pathway	
a. Program serves predominantly pediatric patients	
b. Individual has maintained current working knowledge in all aspects of pancreas transplantation and patient care within the last 2 years	
c. Transplant hospital has petitioned the Membership and Professional Standards Committee (MPSC) for approval under this pathway	
d. A preliminary interview before the MPSC shall be required	

j) Describe in detail the proposed primary surgeon's level of involvement in this transplant program, and if applicable, describe the surgeon's plan for coverage of transplant programs located in multiple transplant hospitals. Expand rows below as necessary and use complete sentences (i.e. narrative descriptions) for each.

	Describe Involvement
Management of Patients with Diabetes Mellitus	
Recipient Selection	
Donor Selection	
Histocompatibility and Tissue Typing	
Transplant Surgery	
Immediate Post-Operative and Continuing Inpatient Care	

	Describe Involvement
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	
Coverage of Multiple Transplant Hospitals (if applicable)	
Additional Information	

k) Describe the proposed primary surgeon's transplant training and experience in the areas listed below. (Expand rows below as necessary and use complete sentences (i.e. narrative descriptions) for each).

	Describe Training/Experience
Management of 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	
Additional Information	

PART 4B, Section 2: Personnel – Additional/Other Surgeons

Complete this section of the application to describe the involvement, training, and experience of any other surgeons participating in the program. **Surgeons must be designated as Additional or Other as described below**. All surgeons must be listed in Table 1 (Certificate of Investigation) in this application.

The Bylaws provide the following definition of Additional Transplant Surgeon:

> *Additional Transplant Surgeons must be credentialed by the institution to provide transplant services and be able to independently manage the care of transplant patients including performing the transplant operation and procurement procedures.*

Surgeons that also support this program but who do not meet the definition of "primary" or additional," should complete this section as well. The type should be indicated as "other."

Duplicate pages as needed.

PART 4B, Section 2: Personnel – Additional/Other Surgeons

2. Additional/Other Surgeons (duplicate this section as needed). Provide the attachments listed below:

Check list	Question Reference	Required Supporting Documents
	4B, 2a	Current C.V.
	4B, 2b	A letter from the Credentialing Committee of the applicant hospital stating that the surgeon meets all requirements to be in good standing. Please provide an explanation of any status other than active/full.
	4B, 2c,e,f	A letter from the Surgeon detailing his/her commitment to the program and level of involvement in substantive patient care.

a) Name: _____

For Pancreas Islet Cell transplantation this individual is classified as (Check only one)
___ Additional Surgeon
___ Other Surgeon

b) Date of employment at this hospital (MM/DD/YY): _____

Does individual have FULL privileges at this hospital?
_____ Yes Provide copy of hospital credentialing letter.
_____ No If the individual does **not** have full privileges, explain why, and provide the date the individual will be considered for full privileges. Include an explanation that describes the scope of privileges.

c) Percentage of professional time spent at this hospital: _____% = _____ hrs/week

d) Board certification type(s) or equivalent. If board certification is pending, indicate the date the exam has been scheduled. If individual has been recertified, please use that date.

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

e) Transplant Training (Fellowship): List the name of the transplant hospital(s) at which pancreas, kidney/pancreas, and/or islet cell transplant training (fellowship) was received. Include the program director(s) name(s), applicable dates, and the number of transplants and procurements the individual performed.

Date From – To MM/DD/YY	Transplant Hospital	Program Director	# Transplants as Primary Surgeon			# Transplants as 1st Assistant			# of Procurements as Primary Surgeon or 1st Assistant	
			PA	KP	IS	PA	KP	IS	PA	KP

f) Transplant Experience (Post fellowship): List the name of the transplant hospital(s), the program director(s) name(s), applicable dates, and number of pancreas, kidney/pancreas, and/or islet cell transplants and procurements performed by the individual at each hospital.

Date From – To MM/DD/YY	Transplant Hospital	Program Director	# Transplants as Primary Surgeon			# Transplants as 1st Assistant			# of Procurements as Primary or 1st Assistant	
			PA	KP	IS	PA	KP	IS	PA	KP

g) Describe in detail the surgeon's level of involvement in this pancreas islet transplant program in the areas listed below. Expand rows as necessary and use complete sentences (i.e. narrative descriptions) for each.

	Describe Involvement
Management of 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	
Coverage of Multiple Transplant Hospitals (if applicable)	
Additional Information	

h) Describe the surgeon's pancreas and pancreas islet transplant training and experience in the areas listed below. Expand rows as necessary and use complete sentences (i.e. narrative descriptions) for each.

	Describe Training/Experience
Management of 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	
Additional Information:	

PART 4C, Section 1: Personnel – Medical – Primary Physician

1. **Primary Islet Cell Transplant Physician.** Refer to the Bylaws for necessary qualifications. Provide the attachments listed below.

Check list	Question Reference	Required Supporting Documents
	4C, 1a	Current C.V.
	4C, 1c	Letter from the Credentialing Committee of the applicant hospital stating that the physician meets all requirements to be in good standing. Please provide an explanation of any status other than active/full.
	4C, 1d,g,h	Letter from the Physician detailing his/her commitment to the program; level of involvement with substantive patient care; and summarizing his/her previous transplant experience.
	4C, 1g	Formal Training: A letter from training director verifying that the fellow has met the requirements
	4C, 1g	Formal Training: A letter from supervising qualified pancreas transplant physician verifying that the fellow has met the requirements
	4C, 1g	Formal Training: Log(s) (organized by date of transplant) of the transplant recipients followed.
	4C, 1h	Transplant Experience: A letter from qualified transplant physician and/or pancreas transplant surgeon directly involved with the individual verifying that the individual has met the requirements
	4C, 1h	Transplant Experience: Logs (organized by date of transplant) of the transplant recipients followed.
		Other Letters of Recommendation (Reference)
	Table 1	Letter(s) of recommendation from person(s) named as primary physician and program director attesting to the individual's overall qualifications to act as primary physician and addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate

a) Name:_____

b) Is this individual presently designated as the OPTN primary pancreas transplant physician for the pancreas transplant program? _____ Yes _____ No.
- If yes, supply the first 3 documents and the final document in the checklist above and answer question "j."
- If no, complete questions "c" – "l."

c) Date of employment at this hospital (MM/DD/YY): _____
Date assumed role of primary physician (MM/DD/YY): _____

Does individual have FULL privileges at this hospital?
_____ Yes Provide copy of hospital credentialing letter.
_____ No If the individual does **not** have full privileges, explain why, and provide the date the individual will be considered for full privileges. Include an explanation that describes the scope of privileges.

d) Percentage of professional time spent at this hospital: _____% = _____ hrs/week

e) List below other hospitals, health care facilities, and medical group practices and percentage of professional time this individual is on site at each:

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

f) Board certification type (s) or equivalent. If board certification is pending, indicate the date the exam has been scheduled. If individual has been recertified, please use that date.

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

g) Transplant Training (Fellowship): List the program(s) at which pancreas, kidney/pancreas, and/or islet cell transplant training was received. Include the name of the transplant hospital(s), program director(s) name(s), applicable dates, and the number of transplant patients for whom the physician provided substantive patient care (pre-, peri- and post-operatively from the time of transplant). If the physician is qualifying as the primary physician through fellowship training, also submit the supporting documents listed below.

Refer to the Bylaws for the necessary qualifications and descriptions of the required supporting documents.

- Letters from the director of fellowship training program and the supervising qualified pancreas transplant physician verifying that the fellow has met the requirements.
- Recipient log(s) (Table 4C) that includes the date of transplant and the patient's medical record and/or OPTN ID number. Each log must be signed by the director of the training program and/or primary transplant physician at that transplant program.

Date From To mm/dd/yy	Transplant Hospital	Program Director	# Pancreas Patients Followed			# Kidney/Pancreas Patients Followed			# Islet Patients Followed		
			Pre	Peri	Post	Pre	Peri	Post	Pre	Peri	Post

h) Transplant Experience (Post Fellowship Only): List the name of the transplant hospital(s), program director(s) name(s), applicable dates, and number of pancreas, kidney/pancreas, and/or islet cell transplant patients for whom the physician accepted primary responsibility for substantive patient care (pre-, peri-, and post-operatively from the time of transplant). Refer to the Bylaws for the necessary qualifications and descriptions of the required supporting documents listed below.

- Supporting letter(s) from the qualified transplant physician and/or the pancreas transplant surgeon who has been directly involved with the individual.
- Recipient log(s) (Table 4C) that includes the date of transplant and the patient's medical record and/or OPTN ID number. Each log should be signed by the program director, division chief, or department chair from the program where the experience was gained.

Date From To mm/dd/yy	Transplant Hospital	Program Director	# Pancreas Patients Followed			# Kidney/Pancreas Patients Followed			# Islet Patients Followed		
			Pre	Peri	Post	Pre	Peri	Post	Pre	Peri	Post

i) Training/Experience: Describe how the physician fulfills the criteria for participating as an observer in 3 organ procurements and 3 pancreas transplants, as well as observing the evaluation of the donor and donor process, and management of at least 3 multiple organ donors that include the pancreas.

- Provide a log (Table 4D) of these cases that includes the date of procurement or transplant, medical record ID number and/or OPTN ID number, and the location of the donor.
- If these criteria have not been met, submit a plan explaining how the individual will fulfill them.

Date From To mm/dd/yy	Transplant Hospital	# of PA Procurements Observed	# of PA Transplants Observed	# of PA Donors/ Donor Process	# of Multi-Organ Donors Observed Mgmt.

j) Summarize how the Transplant Physician's experience fulfills the membership criteria. (Check all that apply)

Membership Criteria	Yes
1. On site	
2. M.D., D.O. or equivalent degree	
3. Certified by the American Board of Internal Medicine, Pediatrics or the foreign equivalent in:	
a. Nephrology	
b. Endocrinology	
c. Diabetology	
4. Achieved eligibility in:	
a. Nephrology	
b. Endocrinology	
c. Diabetology	
5. Direct involvement in pancreas transplant patient care within the last 2 years	
6. 12-month Transplant Medicine Fellowship:	
a. Involved in primary care of 8 or more pancreas transplant recipients for a minimum of 3 months from the time of their transplant	
b. Observed 3 procurements and 3 pancreas transplants	
c. Observed the evaluation of the donor and donor process, and management of at least 3 multiple organ donors which include the pancreas	
d. Didactic curriculum approved by the RRC-IM of the ACGME	
7. Experience in pancreas transplantation:	
a. 2-5 years experience on an active pancreas transplant service	
b. Involved in primary care of 15 or more pancreas transplant recipients for a minimum of 3 months from the time of their transplant	
c. Observed 3 procurements and 3 pancreas transplants	
d. Observed the evaluation of the donor and donor process, and management of at least 3 multiple organ donors which include the pancreas	
8. Pediatric Pathway:	
a. Program serves predominantly pediatric patients	
b. Individual has maintained current working knowledge in all aspects of pancreas transplantation and patient care within the last 2 years	
c. Transplant hospital has petitioned the Membership and Professional Standards Committee (MPSC)for approval under this pathway	
d. A preliminary interview before the MPSC shall be required	

Membership Criteria	Yes
9. 12-Month Conditional Pathway – ***Only available to Existing Programs***	
a. Board certified in nephrology, endocrinology, or diabetology	
b. Involved in the primary care of 8 or more pancreas transplant recipients for a minimum of 3 months from the time of their transplant	
c. Has acquired experience equal to 12 months on an active pancreas transplant service over a maximum of 2 years	
d. Consulting relationship established with counterparts at another approved pancreas transplant hospital (include letter of support)	

k) Describe in detail the proposed primary transplant physician's involvement in the management of patients in this program and, if applicable, their plan for coverage of multiple transplant hospitals. Expand rows as necessary and use complete sentences (i.e. narrative descriptions) for each.

	Describe Involvement
Management of Patients with End Stage Pancreas Disease	
Candidate Evaluation Process	
Donor Selection	
Recipient Selection	
Histocompatibility and Tissue Typing	
Immediate Post-Operative Patient Care	
Post-Operative Immunosuppressive Therapy	
Differential Diagnosis of Pancreas Dysfunction in the Allograft Recipient	
Histologic Interpretation of Allograft Biopsies	
Interpretation of Ancillary Tests for Pancreas Dysfunction	
Long-term Outpatient Follow-up	
Coverage of Multiple Transplant Hospitals	
Additional Information	

l) Describe the proposed primary physician's transplant training and experience in the areas listed below. Expand rows as necessary and use complete sentences (i.e. narrative descriptions) for each.

	Describe Training/Experience
Management of Patients with End Stage Pancreas Disease	
Candidate Evaluation Process	
Donor Selection	
Recipient Selection	
Histocompatibility and Tissue Typing	
Immediate Post-Operative Patient Care	
Post-Operative Immunosuppressive Therapy	
Differential Diagnosis of Pancreas Dysfunction in the Allograft Recipient	
Histologic Interpretation of Allograft Biopsies	
Interpretation of Ancillary Tests for Pancreas Dysfunction	
Long-term Outpatient Follow-up	
Additional Information	

PART 4C, Section 2: Personnel – Additional/Other Physicians

Complete this section of the application to describe the involvement, training, and experience of other physicians associated with the program. **Physicians must be designated as Additional or Other as described below**.

All physicians must be listed in Table 1 (Certificate of Investigation) in this application.

The Bylaws provide the following definition of Additional Transplant Physician:

> *Additional Transplant Physicians must be credentialed by the institution to provide transplant services and be able to independently manage the care of transplant patients.*

Physicians that also support this program but who do not meet the definition of "primary" or "additional," should complete this section of the application. The type should be indicated as "other."

Duplicate pages as needed.

PART 4C, Section 2: Personnel – Additional/Other Physicians

2. Additional/Other Physicians (Duplicate this section as needed). Refer to the Bylaws for the necessary qualifications and descriptions of the required supporting documents listed below.

Check list	Question Reference	Required Supporting Documents
	4C, 2a	Current C.V.
	4C, 2b	A letter from the Credentialing Committee of the applicant hospital stating that the physician meets all requirements to be in good standing. Please provide an explanation of any status other than active/full.
	4C, 2c,e,f	A letter from the Physician detailing his/her commitment to the program and level of involvement in substantive patient care.

a) Name: _____

For Pancreas Islet Cell transplantation this individual is classified as (Check only one)
___ Additional Physician
___ Other Physician

b) Date of employment at this hospital (MM/DD/YY): _____

Does individual have FULL privileges at this hospital?
_____ Yes Provide copy of hospital credentialing letter.
_____ No If the individual does **not** have full privileges, explain why, and provide the date the individual will be considered for full privileges. Include an explanation that describes the scope of privileges.

c) Percentage of professional time spent on site: _____% = _____ hrs/week

d) Board certification type(s) or equivalent. If board certification is pending, indicate the date the exam has been scheduled. If individual has been recertified, please use that date.

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

e) Transplant Training (Fellowship): List the program(s) at which pancreas, kidney/pancreas, and/or islet cell transplant training was received. Include the name of the transplant hospital(s), program director(s) name(s), applicable dates, and the number of transplant patients for whom the physician provided substantive care (pre-, peri- and post-operatively from the time of transplant).

Date From To mm/dd/yy	Transplant Hospital	Program Director	# Pancreas Patients Followed			# Kidney/Pancreas Patients Followed			# Islet Patients Followed		
			Pre	Peri	Post	Pre	Peri	Post	Pre	Peri	Post

f) Transplant Experience (Post Fellowship Only): List the name of the transplant hospital(s), program director(s) name(s), applicable dates, and number of pancreas, kidney/pancreas, and/or islet cell transplant patients for whom the physician accepted primary responsibility for substantive patient care (pre-, peri-, and post-operatively from the time of transplant).

Date From To mm/dd/yy	Transplant Hospital	Program Director	# Pancreas Patients Followed			# Kidney/Pancreas Patients Followed			# Islet Patients Followed		
			Pre	Peri	Post	Pre	Peri	Post	Pre	Peri	Post

g) Describe in detail the physician's involvement in this islet cell transplant program. Expand rows as necessary and use complete sentences (i.e. narrative descriptions) for each.

	Describe Involvement
Management of Patients with End Stage Pancreas Disease	
Candidate Evaluation Process	
Donor Selection	
Recipient Selection	
Histocompatibility and Tissue Typing	
Immediate Post-Operative Patient Care	
Post-Operative Immunosuppressive Therapy	
Differential Diagnosis of Pancreas Dysfunction in the Allograft Recipient	
Histologic Interpretation of Allograft Biopsies	
Interpretation of Ancillary Tests for Pancreas Dysfunction	
Long-term Outpatient Follow-up	
Coverage of Multiple Transplant Hospitals (if applicable)	
Additional Information	

h) Describe the physician's transplant training and experience in the role of transplant patient management in the areas listed below. Expand rows as necessary and use complete sentences (i.e. narrative descriptions) for each.

	Describe Training/Experience
Management of Patients with End Stage Pancreas Disease	
Candidate Evaluation Process	
Donor Selection	
Recipient Selection	
Histocompatibility and Tissue Typing	
Immediate Post-Operative Patient Care	
Post-Operative Immunosuppressive Therapy	
Differential Diagnosis of Pancreas Dysfunction in the Allograft Recipient	
Histologic Interpretation of Allograft Biopsies	
Interpretation of Ancillary Tests for Pancreas Dysfunction	
Long-term Outpatient Follow-up	
Additional Information	

Part 5: Supporting Personnel

1. Provide documentation that verifies that the program has a collaborative relationship with a physician qualified to cannulate the portal system under direction of the transplant surgeon.

   Name of designated physician: _____

   Provide the following supporting documentation:

Check list	Required Supporting Documents
	Current C.V.
	A letter from the Credentialing Committee of the applicant hospital that states that the physician is qualified to perform this procedure and has privileges to practice in this hospital. Please provide an explanation of any status other than active/full.
	A letter from the physician detailing his/her level of commitment to the program.

2. Describe the program's access to the personnel listed below. Include the individual's name, and if they are on site or not. (Adequate access is defined by an agreement of affiliation with counterparts at another transplant hospital who employ individuals with the expertise described below). Provide a letter of commitment/support from each individual listed.

   a) Board-certified endocrinologist

   Name: _____

   Percentage of time on site: _____

   Provide the following supporting documentation:

Check list	Required Supporting Documents
	Current C.V.
	A letter from the Credentialing Committee of the applicant hospital that indicates if the physician has privileges to practice in this hospital. Please provide an explanation of any status other than active/full.
	A letter from the physician detailing his/her level of commitment to the program and involvement with substantive patient care.

   b) A physician, administrator, or technician with experience in compliance with FDA regulations.

   Name: _____

   Percentage of time on site: _____

   Provide the following supporting documentation:

Check list	Required Supporting Documents
	Current C.V.
	A letter from the physician detailing his/her level of commitment and experience.

c) A laboratory-based researcher with experience in pancreatic islet isolation and transplantation.

Name: _____

Percentage of time on site: _____

Provide the following supporting documentation:

Check list	Required Supporting Documents
	Current C.V.
	A letter from the physician detailing his/her level of commitment and experience.

Part 6: Programs Not Located at an Approved Pancreas Transplant Hospital

A program that meets all requirements for a pancreatic islet transplant program set forth in the Bylaws, including, without limitation, requirements applicable generally for membership and without regard to organ specificity, with the sole exception that the program is not located at a transplant hospital approved under the Bylaws to perform whole pancreas transplantation, may nevertheless qualify as a pancreatic islet transplant program.

A preliminary interview with the Membership and Professional Standards Committee is required for programs seeking approval under this pathway.

Please provide the following additional documentation to demonstrate that this program can qualify for approval under this pathway.

1. Provide documentation of an affiliation relationship with an OPTN approved pancreas transplant program, including on site admitting privileges at this applicant hospital for the primary whole pancreas transplant surgeon and physician.

   a) Name of Affiliated transplant hospital: _____

   b) Name of designated surgeon: _____

   Percentage of time on site: _____

   Provide the following supporting documentation for this surgeon:

Check list	Required Supporting Documents
	Current C.V.
	A letter from the Credentialing Committee of the applicant hospital that states that the surgeon has on site admitting privileges. Please provide an explanation of any status other than active/full.
	A letter from the surgeon detailing his/her level of commitment to the program and involvement with substantive patient care.

   c) Name of designated physician: _____

   Percentage of time on site: _____

   Provide the following supporting documentation:

Check list	Required Supporting Documents
	Current C.V.
	A letter from the Credentialing Committee of the applicant hospital that states that the physician has on site admitting privileges. Please provide an explanation of any status other than active/full.
	A letter from the physician detailing his/her level of commitment to the program and involvement with substantive patient care.

2. Provide documentation that demonstrates the availability of qualified personnel to address pre-, peri-, and post-operative care issues regardless of the treatment option ultimately selected.

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.

Table 1: Certificate of Investigation

List all transplant surgeons and physicians currently involved in the program,

The Bylaws state that "***Each primary surgeon or primary physician*** *listed on the application as a part of the plan for* ***who shares coverage responsibility*** *shall submit an assessment, subject to medical peer review confidentiality requirements and which follows guidelines provided in the application and is satisfactory to the MPSC, of* ***all physicians and surgeons*** *participating in the program regarding their involvement in prior transgressions of UNOS requirements and plans* ***to ensure that the improper conduct is not continued."*** *(Emphasis added)*

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

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:

* Expand rows as needed.

Table 2 - Program Coverage Plan

Please answer the questions below and provide a written copy of the current Program Coverage Plan. The plan must be signed by either:

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

In accordance with the Bylaws, the program director, in conjunction with the primary transplant surgeon and transplant physician must submit to UNOS a written Program Coverage Plan, which documents how 100% medical and surgical coverage is provided by individuals credentialed by the transplant hospital to provide transplant service for the program. 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, during the year. The Program Coverage Plan must address the following requirements:

	Yes	**No**
Is this a single surgeon program?		
Is this a single physician program?		
If the answer to either one of the above questions is "Yes," explain the protocol for notifying patients.		
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 the "on call" surgeon/physician available within 30 miles of the hospital premises to address urgent patient issues?		
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 transplant 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:		

Table 3: OPTN Staffing Report

PANCREAS ISLET TRANSPLANT PROGRAM

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

Answer the questions below for this transplant program. Since this information will be used to update UNet[sm] and the Membership Directory, make sure to include the best (most accurate) telephone number and address for each person. Use additional pages as necessary. The surgeons and physicians named below should match those listed on the Certificate of Investigation.

Identify the **transplant program Medical and/or Surgical Director(s)**:

Name	**Address**	**Phone**	**Fax**	**Email**

The **surgeons** who perform transplants are:

Name	**Additional**	**Other**	**Address**	**Phone**	**Fax**	**Email**

The **physicians** (internists) who participate in this transplant program are:

Name	Additional	Other	Address	Phone	Fax	Email

Identify the **hospital administrative director/manager** who will be involved with this program: **Use an * to indicate** which individual will serve as the primary transplant administrator if more than one is listed.

Name	Address	Phone	Fax	Email

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

Name	Address	Phone	Fax	Email

The **clinical transplant coordinators** who participate in this transplant program are:

Name	Address	Phone	Fax	Email

List the **data coordinators** for this transplant program below. **Use an * to indicate** which individual will serve as the primary data coordinator.

Name	Address	Phone	Fax	Email

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

Name	Address	Phone	Fax	Email

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

Name	Address	Phone	Fax	Email

Identify the **Director of Anesthesiology** who will be involved with this program:

Name	Address	Phone	Fax	Email

Identify the **designated FDA regulations expert(s)** who will be involved with this program

Name	Address	Phone	Fax	Email

Identify the **designated laboratory-based researcher** who will be involved with this program:

Name	Address	Phone	Fax	Email

Table 4A – Primary Surgeon - Transplant Log (Sample)

Complete a separate form for each transplant hospital

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

List cases in date order

#	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				

Extend lines on log as needed

Patient ID should not be name or Social Security Number.

Director's Signature: _____ **Date:** _____

Table 4B – Primary Surgeon - Procurement Log (Sample)

Complete a separate form for each transplant hospital

Organ	
Name of proposed primary surgeon	
Name of transplant 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

#	Date of Procurement	Medical Record/ OPTN ID # of Donor	Location of Donor (hospital)	Comments (LRD/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				
31				
32				
33				
34				
35				

Extend lines on log as needed

Director's Signature: _____ **Date:** _____

Table 4C – Primary Physician - Recipient Log (Sample)

Complete a separate form for each transplant hospital

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.

List only those patients followed for 3 months from the time of transplant (including pre-, peri-, and post-operative management)

#	Date of Transplant	Medical Record/ OPTN ID #	Pre-Operative	Peri-Operative	Post-Operative (90-days follow-up care)	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						
26						
27						
28						
29						
30						
31						
32						
33						
34						
35						

Extend lines on log as needed

Director's Signature: _____ Date: _____

Table 4D - Primary Physician – Observation Log (Sample)

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

In the tables below, document how the physician fulfills the requirements for participation as an observer in organ procurements and transplants, as well as observing the selection and management of at least 3 multiple organ donors that include the organ for which application is being submitted. *List cases in date order*.

Procurements Observed

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

Transplants Observed

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

Donor Selection and Management

#	Date of Procurement	Medical Record/ OPTN ID #	Location of Donor (Hospital)	Specify Organ specific or Multi-organ?
1				
2				
3				
4				
5				

Table 4E - Reporting: Islet Cell Transplants Performed by Transplant Hospital Center Code _____

Once approved, the program must submit data to UNOS through use of standardized forms. Data requirements include submission of information on all deceased and living donors, potential transplant recipients, and actual transplant recipients. Pending development of standardized data forms for pancreatic islet transplantation, the program must provide patient logs to UNOS every six months and on an annual basis, reporting transplants performed, by patient name, social security number, date of birth, and donor identification number, as well as whether patient is alive or dead, and whether the pancreas was allocated for islet or whole organ transplantation. The logs shall be cumulative.

Islet Cell Transplants Performed by Transplant Hospital (to date) – sort by Patient ID, then by transplant date.

#	Date of Transplant	Pt. Name	SSN	Date of Birth	Donor ID Number(s)	Pt. Status Alive/Deceased	Pancreas Allocated for Islet or Whole Organ
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							
13							
14							
15							
16							
17							
18							
19							
20							

Table 4F - Reporting: Pancreas Allocation Center Code: _____

For each donor pancreas allocated to the program for islet transplantation, the program must report to UNOS whether the islets were used for clinical islet transplantation and, if not, why and their ultimate disposition, together with such other information as requested on the Pancreatic Islet Donor Form.

(*List in date order)*

#	Date Pancreas Allocated	Islets Used for Clinical Islet TX (Y/N)	If No, Explain	Disposition
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				

Part 5: Organ Procurement

1. Do you work with an organ procurement organization (OPO) which either:

   (1) is itself a member of the OPTN (or is currently applying for membership), or
   (2) is controlled by another clinical transplant hospital that is an OPTN member (or currently applying for membership), to serve your organ procurement needs?

   Yes ____ No ____

- If yes, answer the questions in Section A below
- If no, proceed to Section B

SECTION A – Organ Procurement Organization (OPO) Arrangements – Contracted

1. Provide name, mailing address, and primary phone numbers for the organ procurement organization (OPO).

Name	Address /Phone

2. Attach a copy of the current contract or letter of agreement with the OPO.

SECTION B- Application for Hospital Based Organ Procurement Organization (OPO)

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

   a) OPO Name: _____
   Address: _____
   _____

   b) CMS Provider Number: _____

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

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

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

4. If applicable, list below the names and addresses of clinical transplant hospitals this OPO will serve, and the type of programs that it will serve for each transplant hospital (i.e. kidney, heart, heart/lung, lung, liver, pancreas, pancreas islet cell): (Expand rows as needed)

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

Name & Address	Type of Program(s)	Regional Transplant Agreements

5. Outline the purposes and the goals of this organization as stipulated in the charter and bylaws. Attach copies of charter and bylaws.

6. Attach a list of names and positions of the Board of Directors and/or Advisory Board.

7. Attach a copy of non-profit status notification from federal and state offices.

8. Is this OPO 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 your current insurance coverage.
- If "no" and it has a funded self-insurance program, give the name of the fund administrator and the amount of the self-insurance fund, and describe the coverage available to this institution from the fund.

9. Name below and provide a copy of an agreement that documents arrangements with a CLIA certified laboratory (or certified laboratories), in the appropriate specialty or subspecialty or service, that will provide donor infectious disease screening including acquired immune deficiency virus, consistent with OPTN standards.

10. Provide the name of OPTN approved histocompatibility laboratory(ies) with which the OPO will be affiliated.

- Attach copies of the agreement(s).

11. Describe the defined service area in terms of geographic region (counties served), population base, and hospital allocation catchment area.

- Indicate to what extent the defined service area is exclusive and for any non-exclusive service areas served, what other OPO's are involved.
- Include a map diagramming the area.

12. Attach a list of donor hospitals served and provide a current copy of each agreement.

13. Communication of Information for Organ Distribution: The OPO is responsible for equitable organ allocation within its service area according to OPTN policies and must be able to communicate in a timely manner appropriate information necessary to facilitate equitable organ distribution as well as perform other functions necessary to discharge this responsibility.

- Describe how this OPO will fulfill this requirement including the arrangements for recovery and distribution of renal and non-renal organs and tissues, and the arrangement for recovery and distribution of tissue (eye, bone, skin, etc).
- Attach agreements with tissue and eye banks within area.

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

15. 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

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

Name	Position

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

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

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

Certification Statement

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

Chief Executive Officer **Date**

_____ _____

PART 6: Histocompatibility Testing

PART 6, SECTION A: Histocompatibility Testing Arrangements

1. Will you engage one or more laboratories to serve your histocompatibility testing needs that are either

   a) members of the OPTN (or currently applying for membership); or
   b) controlled by another clinical transplant hospital that is an OPTN member (or is currently applying for membership)?

   Yes: _____ **No**: _____

2. If **Yes**, give name and address of each such histocompatibility laboratory, the contact person, and the functions performed by each laboratory.

   - Include a copy of each agreement your transplant hospital has with a Histocompatibility Laboratory.

   Do not complete Section B & C unless your own laboratory performs one or more histocompatibility testing functions.

Laboratory Name (1)	
Address	
Contact Person	
Functions Performed	

Laboratory Name (2)	
Address	
Contact Person	
Functions Performed	

PART 6, SECTION B: Application for Hospital Based Histocompatibility Laboratory

Complete this section if the answer to Question 1 in Part 6, Section A is **No.**

Name of Applicant Laboratory: _____

CMS #: _____ CLIA #: _____

1. In order to qualify for OPTN Institutional Membership as a clinical transplant hospital, each transplant program of the transplant hospital must utilize one or more histocompatibility laboratories that meet the applicable OPTN standards. All histocompatibility laboratories must be accredited in Solid Organ Transplantation: Deceased Donor. If the transplant hospital performs living donor organ transplants, the laboratory must be accredited for Solid Organ Transplantation: Living Donor. Does this transplant hospital perform living donor organ transplants?

   Yes___ No ___

2. Upon receipt your application will be forwarded to the American Association for Histocompatibility and Immunogenetics (ASHI) or the College of American Pathologists (CAP), which have been granted deemed status to perform histocompatibility laboratory inspections.

   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.

   a) Has your laboratory been accredited by ASHI or CAP within the last three years?

	ID #	**Yes**	**No**	**Last Accreditation Date**
ASHI Accredited				
CAP Accredited				

   b) If the answer to item "a" above is **Yes**, indicate the categories for which the laboratory was accredited.

Categories	Yes	No
Solid Organ Transplantation: Deceased Donor		
Solid Organ Transplantation: Living Donor		
Islet Cell Transplantation		

3. Identify the laboratory director(s), clinical consultant(s), technical supervisor, and general supervisor.

Position	**Name**
Primary Laboratory Director	
Other Laboratory Director(s)	
Clinical Consultant	
Technical Supervisor (if other than the laboratory director)	
General Supervisor (if other than the laboratory director)	

4. Describe the plan for coverage if the laboratory director is not full time at this laboratory or also serves as a director at another laboratory.

5. 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.

   b) List any regional, national, or international transplant registries to which you are now submitting data. Also, list any registry to which you had previously submitted data, giving the years of such submission.

   c) Describe the methods to be used to collect, verify, and submit data on a timely basis. Identify the current status of local data collection and compilation by hard copy and computer. Identify the hardware and software used for any computer files.

6. List the name and address of other transplant hospitals for which you will provide histocompatibility testing services. Attach a copy of your agreement(s).

7. If your histocompatibility laboratory is not presently accredited by ASHI or CAP, do you wish to apply for ASHI or CAP accreditation?

   ASHI: **Yes ____ No ____**
   CAP: **Yes ____ No ____**

If your histocompatibility laboratory is currently accredited or is in the process of being accredited by ASHI or CAP, please stop here.

Attach a copy of the ASHI/CAP application. When available, proof of certification must be provided.

PART 6, SECTION C (1): OPTN Accreditation Program - Application Instructions

This application form is for use by laboratories not currently accredited by ASHI or CAP.

TABLE OF CONTENTS

GLOSSARY OF ABBREVIATIONS

ABB	American Board of Bioanalysis
ABCC	American Board of Clinical Chemistry
ABHI	American Board of Histocompatibility and Immunogenetics
ABMLI	American Board of Medical Laboratory Immunology
ABMM	American Board of Medical Microbiology
ASHI	American Society for Histocompatibility and Immunogenetics
Ab	antibody
Ag	antigen
AHG	antihuman globulin
AP	Accreditation Program
ARB	Accreditation Review Board
CAP	College of American Pathologists
CDC	complement-dependent cytotoxicity
CE	continuing education
CFR	Code of Federal Regulation
CLIA	Clinical Laboratory Improvement Act (Amendments)
DHHS	Department of Health and Human Services
DNA	deoxyribonucleic acid
ELISA	enzyme-linked immuno-sorbent assay
FTE	full time equivalent
HCFA	Health Care Financing Administration
HHT	human histocompatibility testing
HLA	human leukocyte antigen
JC	Joint Commission
MLC	mixed lymphocyte culture
OPTN	Organ Procurement and Transplantation Network
PCR	polymerase chain reaction
PRA	panel reactive antibody
SEOPF	South-Eastern Organ Procurement Foundation
SSOP	sequence specific oligonucleotide probe
SSP	sequence specific primer
TAT	turn around time
TX	transplant
UNOS	United Network for Organ Sharing
XM	crossmatch

GENERAL INSTRUCTIONS

1. **IMMEDIATELY UPON RECEIPT**, record the date of receipt of this application on the Processing Record Form.

2. Before completing the application, read all instructions carefully.

3. All documentation must be in English and typed.

4. Your CLIA provider number, OPTN number (if applicable), and application date must be at the top of each page of the application and at the top of all additional documents submitted (i.e. proficiency reports, etc.).

5. Accreditation in Deceased Donor Solid Organ Transplantation requires that the laboratory provide 24-hour on call coverage.

6. CFR Sec. 493.51 requires that DHHS or its designee be notified within 30 days of any change in ownership, name, location, director, or technical supervisor.

7. The American Society for Histocompatibility and Immunogenetics and the College of American Pathologists have been granted deemed status to carry out its inspections and accreditation process.

1. SUBMISSION OF THE APPLICATION

When your application is complete and ready for submission, record the date it is being sent on the Processing Record Form. Return the original application and one (1) complete copy.

Express Mail:
UNOS
Membership Services
700 North 4th Street
Richmond, VA 23219

US Mail:
UNOS
Membership Services
PO Box 2484
Richmond, VA 23218

Main Phone: (804) 782-4800

Processing of the application will not begin if the ASHI or CAP Executive Office has not received payment of the laboratory's accreditation fees.

Retain these instructions, an entire copy of your submission and the Inspector's Checklist to help you prepare for the inspection.

The accreditation manager will perform an initial review of the application.

Incomplete applications will not be processed further until they are complete and deadlines cannot be extended.

INSPECTION

Inspectors are appointed on the basis of their expertise, objectivity, integrity, experience, and to minimize expenses born by the applicant, geographical location. If you believe an appointed inspector has a conflict of interest that will interfere with his/her objectivity, please petition in writing for a different inspector. You will have one right of refusal. The commissioner will evaluate the situation and take appropriate action.

The inspection may take one or more days, depending upon the areas in which accreditation is sought and size of the laboratory. To facilitate a thorough evaluation, have all records readily available and, if possible, designate at least one individual to assist the inspector in accessing the necessary information. The manual, or a separate protocol manual, should provide instructions for the appropriate use of each technique and specify testing for the various clinical applications.

At the end of the inspection, an exit interview will be conducted and the inspector will inform you if deficiencies were found. The inspection is only one part of an extensive evaluation process and any comments made by the inspector must not be construed as judgment for or against approval of the laboratory. After the inspection has been performed, complete the inspection questionnaire form that the inspector will leave with you and return it promptly to your commissioner.

RESPONSE TO DEFICIENCIES

Following the inspection, responses to the deficiencies, cited by the inspector and any other deficiencies identified by the commissioner, must be submitted within 30 days of the notification of the deficiency. Responses must include supporting documentation.

2. COVER PAGE

Provide the names of the laboratory, director(s), and department, as they should appear on the accreditation certificate (+).

CFR 493 requires that the laboratory have a director (493.1441), technical specialist (493.1447), clinical consultant, (493.1453) and general supervisor (493.1459). Provide the appropriate name(s) for each position.

**There must be a name entered for all positions listed, if left blank, the packet will be returned.

Check all areas of accreditation in which you wish to be evaluated for accreditation and record **"NEW"** for those in which your lab is not currently accredited.

A. PERSONNEL: DIRECTOR/TECHNICAL SUPERVISOR QUALIFICATIONS (STANDARD B1.000)

The individual identified as director/technical supervisor must complete this section. If two or more individuals share the director/technical supervisor's responsibilities, use a copy of the forms for each individual. Complete all sections and submit a copy of the curriculum vitae, current certification, and current licensure if a state requirement.

A laboratory director must have sufficient training and experience in each specialty, subspeciality, analyte, test, or procedure for which the laboratory is accredited to provide adequate management and direction of the laboratory personnel and activities.

> *(CFR 493.1443) For lab directors, MDs must be licensed to practice medicine in the state in which the lab is located or deemed qualified as of 2-28-92. If not an MD, they must have an earned doctoral degree (not an MD degree) in a biological, chemical, or physical science and, by 12-31-00, be certified by ABHI, ABB, ABCC, ABMLI, ABMM or other board approved by HHS.*

The laboratory technical supervisor must be qualified by education, training, and experience to provide technical supervision for each speciality, subspeciality, analyte, test, or procedure for which the laboratory is accredited.

> *(CFR 493.1449) Technical supervisors must be either an MD licensed to practice medicine in the state in which the lab is located (no grandfather clause) or a PhD (as above) and (for either degree) have 4 years post doctoral training and/or experience in histocompatibility or 2 years training and/or experience in the laboratory specialty of general immunology plus 2 years training and/or experience in histocompatibility.*

In most cases, one person fills both positions.

For director/technical supervisors that were previously approved, submit an abridged publication list limited to the last two years, include any updated information on these pages (i.e. additional lab training/experience as required with changing lab activities, change in responsibility, etc.) and a copy of current licensure if a state requirement (required for all MDs).

B. PERSONNEL: CLINICAL CONSULTANT QUALIFICATIONS

If the clinical consultant is not the director or technical supervisor, submit a copy of the current certification and current licensure if a state requirement. The clinical consultant must have sufficient training and experience in areas of the laboratory's accreditation to be qualified to consult with and render opinions to the laboratory's clients concerning the appropriateness of human immunogenetics, histocompatibility, and /or transplantation immunology testing and the interpretation of these test results in relation to diagnosis, treatment, and management of patient care.

> *(CFR Sec. 493.1455) The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must (a) be qualified as a laboratory director under Sec. 493.1443(b)(1), (2), or (3)(i) or, for the subspecialty of oral pathology, Sec. 493.1443(b)(6); or (b) be a doctor of medicine, doctor of osteopathy, doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the state in which the laboratory is located.*

If the director/technical supervisor serves as the clinical consultant, it must be stated on this form.

C. PERSONNEL: GENERAL SUPERVISOR QUALIFICATIONS

This section should be completed by all personnel with authority to sign out reports and/or function as a general supervisor. Submit curriculum vitae for each person. If the director serves as general supervisor, indicate this on the cover page and leave the remainder of this section blank. The general supervisor must have training and experience under the direction of the laboratory director and supervision of the technical supervisor to provide day-to-day supervision of testing personnel and reporting of test results. In the absence of the director and technical supervisor, the general supervisor must be responsible for the proper performance of all laboratory procedures and reporting of test results.

D. PERSONNEL LIST

List all personnel who perform work related to histocompatibility and immunogenetics activities of the laboratory, including the director(s), co-director(s), associate director(s), scientist(s), fellow(s), supervisor(s), technologist(s), technician(s), lab aide(s) and assistant(s), support staff (clerical, secretarial), administrative personnel (computer, business manager, etc.). Supply the following information either in the following format or on the Personnel List:

- Start date in this laboratory
- Name
- Positions
- Degrees
- Certifications
- Years of working experience in human histocompatibility testing (HHT)
- % FTE in clinical HHT

- Personnel on-call for deceased donor testing
- For non-degreed technical personnel not previously reviewed by the ASHI Accreditation Program, indicate those qualified to work unsupervised, whether or not they take deceased donor call and under which specific standards of CFR 493.1489 and 1491 they qualify
- Copy of the state license for each person required to hold a license
- Copy of the competency quality assurance summary for each of the technical personnel

E. CONTINUING EDUCATION SUMMARY

For the lab director and each member of the technical staff, submit a summary of participation in continuing education during the previous year (calendar year or fiscal year). Note programs which are HHT related ASHI approved. Briefly describe the program content. Include safety training, technical meetings, clinical meetings, technical competency assessment, and review of proficiency testing, quality control and lab manuals. Note the number of hours of actual participation and the level of participation (lecturer, presenter, participant, or attendee).

The minimum hours of continuing education will be met if the individual is ABHI certified and has maintained continued certification. For directors/technical supervisors not maintaining continued certification, a minimum of 50 hours/year is required. For general supervisors not maintaining continued certification, a minimum of 27 hours/year is required. For those testing personnel not maintaining continued certification, a minimum of 12 hours/year is required.

Supply the following information either in the following format or on the Continuing Education Summary Form:

- Name
- Position
- Brief job description (i.e. supervises serologic testing and performs molecular testing)
- Program
- Participation hours
- Participation level
- Approved by ABHI
- Content
- Summary of contact hours by type and total

F. LABORATORY ACTIVITIES

In the last year (calendar or fiscal), indicate the approximate percent of the lab's total clinical effort for each area of accreditation, the number of cases for each clinical activity listed, and the number of tests performed.

G. PROFICIENCY TEST RESULTS

Laboratory accreditation requires successful participation in approved external proficiency testing programs, when available, for all clinical tests performed by the laboratory in the categories being evaluated. Laboratories may use more than one proficiency testing survey provider. Performance of the tests must be rotated among all technologists performing the tests and be processed and tested in the same manner as patient specimens. Satisfactory performance requires at least an 80% success rate for each challenge (send out), of each analyte (CFR 493, subpart H). For a survey report of 5 samples for phenotyping (analyte), a satisfactory performance would be an error of no more than 1 of the 5 phenotypes. Tabulate the results on the Proficiency Result Summary Form, including only those results that reached consensus and submit a copy of corrective actions for any errors in any category submitted. If proficiency testing is not available for a test your laboratory performs, validate accuracy and reproducibility of the test at least twice each year and submit a summary of these results.

Unsuccessful participation in a proficiency testing: failure to attain minimum satisfactory score.

Unsuccessful participation in proficiency testing requires remedial action as detailed in CFR 493.1701. Failure to take remedial action can result in CMS imposed sanctions as specified in CFR 493, subpart R.

HLA Class I and II Antigen Typing

Results submitted for any proficiency testing survey provider for each analyte must include all results for a one-year period. Submit the full year's results from the cells/specimens typed for the major A, B and DR antigens, from the twelve (12) month (calendar or fiscal year) period preceding the application date.

Laboratories required to meet the OPTN Standards must be able to type for the World Health Organization (WHO) recognized antigens for which reagents are readily available.

HLA Class I Allele Typing

Results submitted for any proficiency testing survey provider for each analyte must include all results for a one-year period. Submit the full year's results from the cells/specimens typed for HLA Class I alleles, from the twelve (12) month (calendar or fiscal year) period preceding the application date.

HLA Class II Allele Typing

Results submitted for any proficiency testing survey provider for each analyte must include all results for a one-year period. Submit the full year's results from the cells/specimens typed for HLA Class II alleles, from the twelve (12) month (calendar or fiscal year) period preceding the application date.

Antibody Screen Tests and Antibody Identification

Results submitted for any proficiency testing survey provider for each analyte must include all results for a one-year period. Submit the full year's results from the antibody screen tests from the twelve (12) month (calendar or fiscal year) period preceding the application date.

Crossmatch Testing by Cytotoxicity

Results submitted for any proficiency testing survey provider for each analyte must include all results for a one-year period. Submit the full year's results from the crossmatch testing by cytotoxicity from the twelve (12) month (calendar or fiscal year) period preceding the application date.

Crossmatch Testing by Flow Cytometric Methods

Results submitted for any proficiency testing survey provider for each analyte must include all results for a one-year period. Submit the full year's results from the crossmatch testing by flow cytometric methods from the twelve (12) month (calendar or fiscal year) period preceding the application date.

H. VALIDATION REQUIREMENTS FOR USING A NEW PROCEDURE OR TEST

Among the most critical aspects of laboratory evaluation are the assessment of test performance and outcome. This evaluation process includes a review of results of not only proficiency test surveys but also of tests performed during the various situations found in the laboratory and of internal proficiency tests. These situations include the tests performed on subjects in varying states of health and tests performed using various types of material (blood, lymph nodes, spleen, etc.). The purpose of these guidelines is to describe the minimum data that must be submitted by all laboratories.

Prior to reporting test results of a new procedure or test, the laboratory must establish performance specifications and

demonstrate that it can obtain these performance specifications or, for FDA-approved kits, the specifications of the manufacturer. Performance specifications include accuracy, precision, analytical sensitivity and analytical specificity to include interfering substances, reportable range of patient test results, reference range(s) (normal values) and any other performance characteristics required for test performance. Calibration and calibration verification procedures must be performed and documented. Control and quality assurance procedures must be routinely performed. Personnel must be trained, qualified and have appropriate technical supervision available. For further information, refer to CFR 493.1201b, 493.1205a, 493.1205c, 493.1213, 493.1217, 493.1218, 493.1701, 493.1705, and 493.1709.

Minimally, these sections require the lab to do the following:

1. Establish specification requirements for test performance

2. Evaluate the test system to assure that it meets the specification requirements

3. Identify and establish ongoing quality control measures

4. Train personnel and take measures to evaluate and ensure their ongoing competency

Documentation for accreditation should include the following:

1. Protocol and example of a case file. This should include an explanation of how and when the test will be used.

2. Step by step procedure. Include whether this replaces previously used technologies or is an adjunct to technologies in use.

3. Performance requirements. This may be included in the procedure or in a quality control manual. If new equipment is employed, include documentation of validation of the new equipment.

4. Validation summary data, analysis, and conclusions.

5. Limitations and shortcomings, how these will be handled, general troubleshooting. This may be included in the quality control section of the procedure.

6. Training guidelines and documentation of testing personnel competency (for personnel currently authorized to perform this test).

I. SUPPLEMENTARY DOCUMENTATION OF DIRECTOR(S)/TECHNICAL SUPERVISOR(S) QUALIFICATION

Some applicants may fulfill the training/experience requirements for a director of a histocompatibility laboratory, but lack sufficient documentation of professional competence as delineated in Standard B1.000 ("by external measures such as national proficiency testing, participation in national or international workshops or publications in peer-reviewed journals"). In such cases, the applicant is required to submit the following supplementary documentation to UNOS:

Portfolio of Case Files

The purpose of this portfolio is to provide the OPTN with documentation of the applicant's ability to review and interpret test results obtained in various clinical situations; to provide insight into probable causes of and appropriate solutions for test failure; to recommend additional follow-up tests as needed; and to provide appropriate commentary for use by clinicians. The files, therefore, must include evidence of interpretive comments and review by the applicant. The submitted case files should be consecutive. For example, an applicant wishing to qualify in another area of expertise could visit another accredited lab for specific training and to compile the needed number of cases. The files should include relevant, but anonymous patient information (e.g. race/ethnicity, parity, underlying disease, etc.).

These case files need to reflect the applicant's expertise in three major areas:

Technology

The applicant must have sufficient experience with the technologies employed to know their strengths and limitations. This is necessary in order to be able to select technologies appropriate for each situation, interpret test results, and establish a quality assurance program.

Test Selection

The applicant must be capable of determining what tests are necessary for various clinical applications and of developing new tests and test strategies as dictated by changes in individual patient status.

Interpretation/Consultation

The applicant must have adequate expertise to know what information is needed to evaluate individual clinical cases and be capable of utilizing the collective body of information to assess risk level, identify possible clinical strategies, and make scientific evaluations of the immune state of the patient. Further, the applicant should be capable of supporting clinical studies and of using clinical data in the ongoing development of test strategies.

The most effective way to acquire a case portfolio is through training and experience under the guidance of an ASHI or CAP approved director/technical supervisor. If an individual no longer has access to case files reviewed, it may be possible to visit another laboratory and review files. In this case, the director/technical supervisor must serve as an advisor. The advisor will be required to submit an evaluation of the applicant's expertise in each area in which accreditation is sought. If various test methods are used, the cases submitted should have sufficient numbers of each test method to validate the applicant's expertise/qualifications (e.g. CDC, ELISA, and flow cytometry antibody analysis). The case files must be submitted as described below:

1. Fifty (50) family work-ups for living related solid organ transplantation. For renal, living related transplantation, the files must include the recipient's serum screen results. Full HLA phenotypes for all available family members must be included.

2. Fifty (50) recipient work-ups for deceased donor renal and/or non-renal transplantation. This portfolio must include complete HLA phenotypes and serum screens.

3. Fifty (50) deceased donor work-ups. This portfolio must include full HLA phenotypes and other test results as applicable (e.g. ABO if performed in the laboratory).

Continuing Education

Documentation of continuing education during the past 5 years in the areas relevant to their application must be submitted. For non-ASHI or non-CAP approved meetings, information about the program should be submitted in order for the committee to assess the relevance to histocompatibility and immunogenetics.

In addition, the applicant may submit letters from ASHI or CAP accredited directors if they might help verify training, experience, or involvement in the field. In cases of collaborative research or papers, the letter should identify the exact role of the applicant in the project; i.e. did the applicant actually perform or assist with the portions of the project relative to histocompatibility and immunogenetics.

J. PROCEDURES

Submit a copy of the laboratory procedure manual.

Submit copies of reading/scoring sheets for all tests in use.

HLA Class I and II Antigen Typing

List all HLA antigens your laboratory can identify.

HLA Class I and II Allele Typing

List all HLA alleles for which your laboratory can test and can identify.

Submit a list of probes and primers in use for various tests.

For molecular testing labs, briefly describe or submit protocols for preventing pre-PCR contamination, including description of physical layout.

CFR 493.51 requires that DHHS or the accrediting organization be notified no later than 6 months after any deletions or changes in test methodologies for any test.

K. ANTIBODY SCREENING/ANTIBODY CHARACTERIZATION

Briefly describe or submit your serum screening protocol indicating what serum samples are screened, when, by what technique, etc.

Submit panel phenotypes. If the panel is not the same all the time, submit the phenotypes of the first and last panel of the previous year (calendar or fiscal).

L. QUALITY ASSURANCE

Submit an example of training documentation for new technical personnel.

Submit training documentation for all technical personnel.

List laboratories subcontracted and evidence of their certification.

M. ADDITIONAL DOCUMENTATION, FOR LABORATORIES NOT CURRENTLY ASHI ACCREDITED

Submit a list of all reagents used in clinical tests.

Submit a brief description of quality control testing and monitoring for all reagents.

Submit a floor plan and total square footage for the laboratory.

Submit a list of all laboratory equipment used clinically.

Submit a brief description of the equipment function verification and preventative maintenance procedure.

List the records that are maintained, for how long and what format (paper, electronic). Include worksheets, reports, QC records, etc.

Submit a brief description of the computer validation and back-up system.

3. TEST PROCEDURES AND PROTOCOLS

For each area in which you are seeking accreditation, submit a one-page summary of the testing. Submit a complete case file from the last month for each clinical application.

A case file consists of - a requisition of the orders and a report.

For the application of Solid Organ Transplantation: Deceased Donor, describe the testing process including the procedures (tests) used in the initial patient work-up (typing, antibody screening, auto crossmatching, etc.), deceased donor work-up, pre-TX work-up, specimen selection criteria (i.e. sera used in crossmatch), requirements for specific testing (i.e. flow crossmatch testing on regraft patients), etc.. Accreditation in this area requires that the laboratory provide 24-hour on call coverage and meets the requirements of the OPTN Standards.

For the application of Solid Organ Transplantation: Live Donor, describe the testing process, including the procedures (tests) used in the initial patient work-up (typing, antibody screening, auto crossmatching, etc.), initial donor work-up, all additional pre-TX testing, specimen selection criteria (i.e. sera used in crossmatch), requirements for specific testing (i.e. flow crossmatch testing on regraft patients), etc. Include variations for different organ types. Accreditation in this area requires that the laboratory meet the requirements of the OPTN Standards.

For the application of Islet Cell Transplantation, describe the testing process, including the procedures (tests) used in the initial patient work-up (typing, antibody screening, auto crossmatching, etc.), initial donor work-up, all additional pre-TX testing, specimen selection criteria (i.e. sera used in crossmatch), requirements for specific testing (i.e. flow crossmatch testing on regraft patients), etc.. Accreditation in this area requires that the laboratory meet the requirements of the OPTN Standards.

4. CHECKLIST OF REQUESTED DOCUMENTS

- ❑ Processing Record Form with date of receipt and date of submission (original)
  FIVE copies, each in an accordion file (included):

- ❑ Cover page
- ❑ Director/Technical Supervisor(s) qualifications
- ❑ Director/Technical Supervisor(s) CVs
- ❑ Director/Technical Supervisor(s) certification(s)
- ❑ Director/Technical Supervisor(s) current state license, if applicable
- ❑ Clinical Consultant(s) qualifications
- ❑ Clinical Consultant(s) current state license, if applicable
- ❑ General Supervisor(s) qualifications
- ❑ General Supervisor(s) CVs
- ❑ Personnel List
- ❑ Copy of state license for each of the technical personnel, if applicable
- ❑ Copy of the competency quality assurance summary for each of the technical personnel
- ❑ Continuing Education Summary Form for each member of the technical staff
- ❑ Laboratory activities
- ❑ Proficiency testing reports
- ❑ Proficiency Result Summary Form
- ❑ Proficiency testing corrective actions, if applicable
- ❑ Validation documentation for new procedures or tests
- ❑ Protocol and example of a case file
- ❑ Step by step procedure
- ❑ Performance requirements
- ❑ Validation summary data, analysis, and conclusions
- ❑ Limitations and shortcomings, how these will be handled, general troubleshooting
- ❑ Training guidelines and documentation of testing personnel competency
- ❑ Supplemental documentation of director/technical supervisor qualifications
- ❑ Copy of the laboratory procedure manual
- ❑ Reading/scoring sheets for all test systems
- ❑ List of all HLA antigens your lab can identify
- ❑ List of all HLA alleles for which your lab can test and can identify
- ❑ List of probes and primers in use for various tests
- ❑ Protocol for preventing pre-PCR contamination
- ❑ Serum screening protocol
- ❑ Panel phenotypes
- ❑ Copy of training documentation for all technical personnel
- ❑ Performance improvement programs initiated
- ❑ List of labs subcontracted and certificates
- ❑ Description of testing process and a complete case file for appropriate application(s):
- ❑ Solid Organ Transplantation: Deceased Donor
- ❑ Solid Organ Transplantation: Live Donor
- ❑ Islet Cell transplantation
- ❑ List of all reagents
- ❑ Description of quality control testing and monitoring for all reagents
- ❑ Floor plan and total square footage of lab
- ❑ List of all laboratory equipment
- ❑ Description of equipment function verification and preventative maintenance procedure
- ❑ List of records maintained
- ❑ Description of computer validation and back-up system

CLIA #_____
OPTN # _____
Date _____

PART 6, SECTION C (2): OPTN Accreditation Program Accreditation Application

A. COVER PAGE

Provide the names of the laboratory, director(s), department, and institution, as they should appear on the accreditation certificate (+).

Position	Name
+Primary Lab Director	
Other Lab Director(s)	
Technical Supervisor*	
Clinical Consultant*	
General Supervisor*	
+Laboratory or Department Name	
+Institution	
Street Address	
City, State, Zip	
Contact Person	
Telephone	
Fax	
E-Mail Address	
Website Address	

**As Defined in CFR 493.1441-1467*

AREAS OF ACCREDITATION

Check all areas in which you wish to be evaluated for accreditation, and indicate "NEW" for those in which your lab is not currently accredited.

Areas of Accreditation	To be Evaluated	New
Solid Organ Transplantation: Deceased Donor		
Solid Organ Transplantation: Live Donor		
Islet Cell Transplantation		

Other accreditation/certification held by laboratory (specify):_____

(Print name of director or other authorized individual) _____ does hereby apply for laboratory accreditation in the area(s) of accreditation designated above. I understand that granting of accreditation is dependent on complete compliance with all applicable standards. I certify that all information provided is truthful and accurate.

Signature of authorized individual: _____

Date: _____

CLIA #_____
OPTN # _____
Date _____

B. PERSONNEL QUALIFICATIONS

DIRECTOR/TECHNICAL SUPERVISOR QUALIFICATIONS (Standard B1.000)

The individual identified as director/technical supervisor must complete this section. If two or more individuals share the director/technical supervisor's responsibilities, use a copy of the forms for each individual. Complete all sections and submit a copy of the curriculum vitae, current certification, and current licensure if a state requirement.

(CFR 493.1443) For lab directors, MDs must be licensed to practice medicine in the state in which the lab is located or deemed qualified as of 2-28-92. If not an MD, they must have an earned doctoral degree (not an MD degree) in a biological, chemical, or physical science and, by 12-31-00, be certified by ABHI, ABB, ABCC, ABMLI, ABMM or other board approved by HHS.

(CFR 493.1449) Technical supervisors must be either an MD licensed to practice medicine in the state in which the lab is located (no grandfather clause) or a PhD (as above) and (for either degree) have 4 years post doctoral training and/or experience in histocompatibility; or 2 years training and/or experience in the laboratory specialty of general immunology, plus 2 years training and/or experience in histocompatibility.

In most cases, one person fills both positions.

For directors/technical supervisors that were previously approved:

- submit an abridged publication list limited to the last two years, include any updated information on these pages (i.e. additional lab training/experience as required with changing lab activities, change in responsibility, etc.); and
- a copy of current licensure if a state requirement (required for all MDs).

Name	
Discipline(s)	
State Licensure (provide copy of current, if applicable)	
City Licensure (provide copy of current, if applicable)	

List all professional positions at any institutions (director, supervisor, consultant, teacher) held by the director/technical supervisor(s) and estimated time commitment of each (hours/week):

Professional Position	**Estimated Time Commitment (hours/week)**

CLIA #_____
OPTN # _____
Date _____

Post-Doctoral Training in Areas of Biology Other Than Human Histocompatibility Testing

List all laboratory specialties in which post-doctoral training was received including exact dates and specific training received for each. Submit a letter from instructor, if possible.

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	

Institution Name	
Laboratory Name	
Laboratory Specialty	
Instructor Name	
Dates	
Specific Training	
Hours/week	

Experience in Areas of Biology Other than Human Histocompatibility Testing

Institution Name	
Name of Director	
Your Title	
Dates	
Hours/week	
Description of Duties	

Institution Name	
Name of Director	
Your Title	
Dates	
Hours/week	
Description of Duties	

Institution Name	
Name of Director	
Your Title	
Dates	
Hours/week	
Description of Duties	

CLIA #_____
OPTN # _____
Date _____

Post-Doctoral Training in Human Histocompatibility Testing

List all laboratory specialties in which post-doctoral training was received including exact dates and specific training received for each. Submit a letter from instructor, if possible.

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	

Laboratory Involvement

Is emergency consultation available during your absence? _____

- Detail the report review process for each laboratory report including the director/technical supervisor's role.
- If the director/technical supervisor does not review all reports, include the percentage that are reviewed and how they are selected.

Indicate the approximate number of cases up to 500 (after that just indicate >500) that you have reviewed in each of the following categories:

Category	# of Cases
Renal transplantation, deceased donor typing and crossmatch	
Renal transplantation, living donor, typing and crossmatch	
Non-renal deceased donor typing and crossmatch	
Islet Cell transplantation	
Allele level typing	
HLA antibody screening	
HLA antibody characterization	
Flow cytometry crossmatch	

CLIA #_____
OPTN # _____
Date _____

In the space below, describe your role in the laboratory, including the:

- extent to which you participate in the review, interpretation and reporting of test results,
- development and performance or supervision of test procedures,
- training and evaluation of staff and fellows, and
- establishment of laboratory policy.

If there is more than one director, indicate all areas in which you are involved and, if appropriate, in which area you have primary responsibility.

CLIA #_____
OPTN # _____
Date _____

Expertise (new director/technical supervisor or when director/technical supervisor add new testing)

Provide below a description of your professional activities which provide evidence of your expertise in human histocompatibility testing and immunogenetics. Include the following:

- participation in relevant national and international scientific societies,
- participation in workshops in human histocompatibility testing,
- formal teaching responsibilities, and
- all other activities that will be helpful in evaluating your qualifications.

Note, if documentation of expertise is not available, this requirement may be met by submitting a portfolio of cases you have analyzed. Please contact your commissioner for further information.

CLIA #_____
OPTN # _____
Date _____

C. PERSONNEL QUALIFICATIONS
CLINICAL CONSULTANT QUALIFICATIONS

If the clinical consultant is not the director or technical supervisor, submit a copy of the current certification and current licensure if a state requirement.

(CFR Sec. 493.1455) The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must (a) be qualified as a laboratory director under Sec. 493.1443(b)(1), (2), or (3)(i) or, for the subspecialty of oral pathology, Sec. 493.1443(b)(6); or (b) be a doctor of medicine, doctor of osteopathy, doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the state in which the laboratory is located.

D. PERSONNEL QUALIFICATIONS

GENERAL SUPERVISOR QUALIFICATIONS

This section should be completed by all personnel with authority to sign out reports and/or function as a general supervisor. Submit curriculum vitae for each person. If the director serves as general supervisor, indicate this on the cover page and leave the remainder of this section blank.

If previously submitted, submit an abridged publication list limited to the last two years and include any updated information on these pages.

Name	
Position	
State Licensure (provide copy of current, if applicable)	
City Licensure (provide copy of current, if applicable)	
Provide description of duties in your present position	

CLIA # ________________
OPTN # ________________
Date ________________

Training

List all laboratory training received, beginning with the most recent.

Institution Name	
Laboratory Name	
Instructor Name	
Dates	
Specific Training	

Institution Name	
Laboratory Name	
Instructor Name	
Dates	
Specific Training	

Institution Name	
Laboratory Name	
Instructor Name	
Dates	
Specific Training	

Institution Name	
Laboratory Name	
Instructor Name	
Dates	
Specific Training	

Institution Name	
Laboratory Name	
Instructor Name	
Dates	
Specific Training	

Institution Name	
Laboratory Name	
Instructor Name	
Dates	
Specific Training	

CLIA #__________________
OPTN # ___________________
Date ___________________

Experience

List all laboratory working experience, beginning with the most recent prior to your present position.

Institution Name	
Name of Director	
Your Title	
Dates	
Hours/Week	
Description of Duties	

Institution Name	
Name of Director	
Your Title	
Dates	
Hours/Week	
Description of Duties	

Institution Name	
Name of Director	
Your Title	
Dates	
Hours/Week	
Description of Duties	

Institution Name	
Name of Director	
Your Title	
Dates	
Hours/Week	
Description of Duties	

Institution Name	
Name of Director	
Your Title	
Dates	
Hours/Week	
Description of Duties	

CLIA #_____
OPTN # _____
Date _____

E. PERSONNEL LIST

Start Date M/YY	Name	Position	Degrees	Certifications	Yrs HHT	% FTE Clinical HHT	On-Call	Total CE Hours

CLIA #_____
OPTN # _____
Date _____

E. PERSONNEL LIST (continued)

Start Date M/YY	Name	Position	Degrees	Certifications	Yrs HHT	% FTE Clinical HHT	On-Call	Total CE Hours

CLIA #_____
OPTN # _____
Date _____

E. PERSONNEL LIST (continued)

Start Date M/YY	Name	Position	Degrees	Certifications	Yrs HHT	% FTE Clinical HHT	On-Call	Total CE Hours

CLIA #_____
OPTN # _____
Date _____

F. CONTINUING EDUCATION SUMMARY FORM

The minimum hours of continuing education will be met if the individual is ABHI certified and has maintained continued certification. For directors/technical supervisors not maintaining continued certification, a minimum of 50 hours/year is required. For general supervisors not maintaining continued certification, a minimum of 27 hours/year is required. For those testing personnel not maintaining continued certification, a minimum of 12 hours/year is required.

Name	
Position	
Brief job description	
Period (12 month period preceding the application date)	

Name	
Position	
Brief job description	
Period (12 month period preceding the application date)	

Name	
Position	
Brief job description	
Period (12 month period preceding the application date)	

Name	
Position	
Brief job description	
Period (12 month period preceding the application date)	

Summary of Contact Hours by Type	Hours
Lecturer	
Presenter	
Participant	
Attendant	
Total	

CLIA #_____
OPTN # _____
Date _____

G. LABORATORY ACTIVITIES

Period (twelve [12] month period preceding the application date)_____ to _____

In the past twelve (12) month period preceding the application date, indicate the approximate percent of the lab's total clinical effort for each area of accreditation:

Area of Accreditation	%
Solid Organ TX: Deceased Donor	
Solid Organ TX: Living Donor	
Islet Cell Transplantation	
All Other (e.g., HSC/BMT)	

In the past twelve (12) month period preceding the application date, complete the following indicating the number of cases for which your laboratory provided services:

	# of Cases
Deceased donor renal transplants	
Deceased donors: local	
Deceased donors: imports	
Average number of patients on the deceased donor renal waiting list	
Non-renal solid organ transplants	
Living donor transplants	
Islet Cell transplantation	

In the past twelve (12) month period preceding the application date, indicate the number of tests performed:

	# of Tests Performed
Class I serologic	
Class I SSP	
Class I SSOP	
Class I sequencing	
Class II serologic	
Class II SSP	
Class II SSOP	
Class II sequencing	
Single Ag	
PRA-CDC	
PRA-ELISA	
PRA-Flow Cytometry	
Ab-CDC	
Ab-ELISA	
Ab-Flow Cytometry	
XM-CDC	
XM-ELISA	
XM-Flow Cytometry	
MLC	
Others	

CLIA #_____
OPTN #_____
Date_____

H. PROFICIENCY RESULTS SUMMARY FORM

Period (twelve [12] month period preceding the application date)_____
_____

Typing Survey	Technology	No. of specimens with errors	No. specimens tested	Concordance(%)	Successful	Unsuccessful
	Class I Serologic					
	Class I DNA-Low Resolution					
	Class I DNA-High Resolution					
	Class II Serologic					
	Class II DNA-Low Resolution					
	Class II DNA-High Resolution					
	ABO/Rh Typing					

Crossmatch Survey	Technology	No. of specimens with errors	No. specimens tested	Concordance(%)	Successful	Unsuccessful
	T Cell CDC					
	T Cell AHG					
	T Cell Flow					
	B Cell CDC					
	B Cell AHG					
	B Cell Flow					

Ab Screen Survey	Technology	No. of specimens with errors	No. specimens tested	Concordance(%)	Successful	Unsuccessful
	Class I CDC					
	Class I AHG					
	Class I ELISA					
	Class I Flow					
	Class II CDC					
	Class II AHG					
	Class II ELISA					
	Class II Flow					

Include corrective action documentation for each error