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; or
   - 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 rooms	
b) Recovery room	
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		

Role and Responsibilities	Yes	No
authorizations.		
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 CV.

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 ___ 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 CV)			

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-, 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)			

Expand rows as needed.

8. **Staffing Resources – Planning:**
Using the chart below, show the expected transplant volume and staffing levels (FTE's) 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 TX 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/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); and
- 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; or**
- **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.