OMB No. 0915-0184
Expiration Date: XX/XX/XXXX

Part 1: Section A – Transplant Hospital

1. The OPTN Bylaws require that an applicant has in force medical liability insurance with a minimum of $1,000,000 coverage limit per occurrence. Coverage must be provided by an insurer that is either:
   - Licensed, 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 will suffice.

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

Yes	
No	

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

Fund Administrator	Amount of Self Insurance Fund	Describe Coverage

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

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

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

In accordance with the OPTN Bylaws, transplant hospitals must develop, and once developed must comply with, protocols to facilitate the recovery of organs from DCD donors. Transplant hospital DCD recovery protocols must address the model requirements set forth in OPTN Policies.

Certification Statement

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

Signature:
Date:
Name:

Part 2: Section A – Program Description

Duplicate this section for each organ application that is being submitted.

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

Application (Check)	Program Type	Application (Check)	Program Type
	Kidney		Pancreas
	Living Donor Kidney Recoveries		Pancreas Islet Cell
	Liver		Heart
	Living Donor Liver Recoveries		Lung
	VCA: Upper Limb		Intestine
	VCA: Head and Neck		VCA: Abdominal Wall
	VCA: Genitourinary Organs		VCA: Lower Limb
	VCA: Glands		VCA: Spleen
	VCA: Musculoskeletal Composite Graft Segment		

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

[Insert detailed response here. Table will expand automatically]

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

Yes	
No	

3. Is this a stand-alone pediatric hospital?

Yes	
No	
No, we are affiliated with:	

4. Is this program certified by Medicare?

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

CMS provider number:
Certification date:

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

Date Application Made	Application (Actual or Anticipated) Approval Date

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Part 2: Section B – Facilities

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

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

Part 2: Section C – Human Resources

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

   a) Patient to nurse ratio:

ICU	NON-ICU

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

[Insert detailed response here, table will expand automatically]

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

[Insert detailed response here, table will expand automatically]

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

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

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

Specialty Area	**In-House**	**Offsite**
Microbiology		
Clinical Chemistry		
Immunological Monitoring		
Blood Bank		
Hepatology		
Pediatrics		
Nephrology (with dialysis capability)		

Pulmonary Medicine (with respiratory therapy support)		

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

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

Yes	
No	

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

Yes	
No	

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

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

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

[Insert detailed response here. Table will expand automatically]

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

Yes	
No	

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

Phase of Patient Care			**If Requested**
See patients preoperatively			
Participate on the Selection Committee			
Consultation preoperatively with subspecialists (e.g. cardiologists, pulmonologists) as needed for specific cases			
Participate in M&M Conferences			
Other (describe)			

5. Staffing Resources – Planning:
   Using the chart below, show the expected transplant volume and staffing levels (FTEs) for year 1 through year 3 of the program. If the program is reactivating, address years 1-3 following reactivation approval.

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

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Part 2: Section D - Program Administration

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

[Insert detailed response here, table will expand automatically]

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

[Insert detailed response here, table will expand automatically]

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

[Insert detailed response here, table will expand automatically]

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

[Insert detailed response here, table will expand automatically]

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

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

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

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

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

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

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

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

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

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

[Insert detailed response here, table will expand automatically]

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

[Insert detailed response here, table will expand automatically]

Part 2: Section E –Protocols/Methods/Procedures

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

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

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

[Insert detailed response here, table will expand automatically]

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

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

[Insert detailed response here, table will expand automatically]

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

[Insert detailed response here, table will expand automatically]

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

Routine patient calls:
Outpatient emergencies:

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

[Insert detailed response here, table will expand automatically]

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

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

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

Transplant Clinic Oversight:
Transplant Clinic Participation:

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

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

   [Insert detailed response here, table will expand automatically]

   b) Are there formal exclusion criteria for acceptance?

   [Insert detailed response here, table will expand automatically]

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

Single Individual	
Committee of (list titles of participants):	

9. Immunosuppression: Answer the questions below regarding immunosuppression:

   a) Is there a standard immunosuppression protocol?

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

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

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

   Describe the interactions of team members in providing immunosuppression management.

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

[Insert detailed response here, table will expand automatically]

Part 2: Section F – Business/Implementation Plan

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

Verification of this plan is requested when:

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

Certification Statement
The undersigned, as the duly authorized Chief Executive Officer, hereby certifies after investigation that to the best of his or her knowledge, a Business/Implementation Plan has been developed, adopted and will be consulted regarding the institutional commitments being made and acknowledge in the this transplant program application.
Signature:
Date:
Name:

Part 2: Section G – Organ Procurement Arrangements

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

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

   [Insert detailed response here, table will expand automatically]

2. Describe any regional transplant agreements below.

   [Insert detailed response here, table will expand automatically]

Part 2: Section H – Histocompatibility Testing Arrangements

1. Each transplant program must have a written agreement with a histocompatibility laboratory(ies) that will be providing testing services. Select the statement below that best describes how this transplant program will meet this requirement and submit a written agreement that includes all of the elements required in the OPTN Bylaws.

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

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

Histocompatibility Laboratory Name	Address	Functions Performed