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

Table 1: OPTN Staffing Report

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

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

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

DEL	Name	L	D	Address	Phone	Fax	Email

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

DEL	Name	Open	Lap	D	Address	Phone	Fax	Email

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

DEL	Name	Open	Lap	D	Address	Phone	Fax	Email

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

DEL	Name	L	D	Address	Phone	Fax	Email

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

DEL	Name	L	D	Address	Phone	Fax	Email

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

DEL	Name	L	D	Address	Phone	Fax	Email
	*						

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

DEL	Name	L	D	Address	Phone	Fax	Email

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

DEL	Name	L	D	Address	Phone	Fax	Email
	*						

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

DEL	Name	L	D Address	Phone	Fax	Email]
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OMB No. 0915-0184 Expiration Date: 07/31/2020

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

DEL	Name	Address	Phone	Fax	Email

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

DEL	Name	L	D	Address	Phone	Fax	Email

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

DEL	Name	L	D	Address	Phone	Fax	Email

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

DEL	Name	L	D	Address	Phone	Fax	Email
	*						

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

DEL	Name	L	D	Address	Phone	Fax	Email

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

Department of Health and Human Services Health Resources and Services Administration

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DEL	Name	Title	L	D	Address	Phone	Fax	Email

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

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

Name	Date of Appointment	Primary Areas of Responsibility

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

1. Identify the primary transplant surgeon:

Name:

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

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

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

Primary Kidney Transplant Surgeon	
Living Donor Recovery Surgeon	

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

Yes	
No	

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

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

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

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

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

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

f) List the surgeon's current board certification(s) below. If board certification is pending, indicate the date the exam has been scheduled. If individual has been recertified, use that date, also provide a copy of certification(s). If the surgeon does not have current American or Canadian board certification, provide letters of recommendation requesting this exception and provide the plan for continuing education as described in the OPTN Bylaws.

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

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

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

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

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

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

Describe Level of Involvement in <u>this</u> Transplant Program	Describe Prior Training/Experience
	Iranspiant Program I Image: Ima

Table 2: Primary Surgeon - Transplant Log (Sample)

Complete a separate form for each transplant hospital.

Organ:	
Name of proposed primary surgeon:	
· · · · · · · · · · · · · · · · · · ·	
Name of hospital where transplants were	
• •	
norformod	
performed:	
performed: Date range of surgeon's appointment/training:	

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

		Medical Record/		or obcial occurry Namber.
#	Date of Transplant	OPTN ID #	Primary Surgeon	1 st Assistant
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
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26				
27				
28				
29				
30				

Director's Signature	Date
Print Name	

Table 3: Primary Surgeon - Procurement Log (Sample)

Organ:	
Name of proposed primary surgeon:	

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

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

Director's Signature	Date
Print Name	

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

Complete this section of the application to describe surgeons involved in the program that are not designated as primary, but are credentialed by the transplant hospital to provide transplant services and independently manage the care of transplant patients, including performing the transplant operations and organ procurement procedures. Duplicate this section as needed.

1. Identify the additional transplant surgeon: Name:

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

Date of employment at this hospital:

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

Kidney Transplant Surgeon	
Living Donor Kidney Recovery Surgeon	

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

Yes	
No	

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

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

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

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

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

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

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

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

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

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

Hospital Name	Location				

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

- 1. Identify the primary living donor kidney recovery surgeon:
 - Name:
 - a) This donor surgeon is being proposed as (check all that apply):

Primary Open Nephrectomy Donor Surgeon	
Primary Laparoscopic Nephrectomy Donor Surgeon	

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

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

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

Yes	
No	

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

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

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

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

e) Experience/Training:

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

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

[Insert response here, table will expand automatically.]

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

[Insert response here, table will expand automatically.]

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

Summary of Experience and Training for:	[Insert Name]
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The numbers entered should be validated on the donor recovery log on the next page. Insert additional rows as needed.

Training and Experience	ASTS Approved Program? Y/N	Dat (MM/DI Start	Transplant Hospital	Program Director	# Open Nephrectomies as Primary	# Open Nephrectomies as 1st Assistant	# Laparoscopic Nephrectomies as Primary	# Laparoscopic Nephrectomies as 1st Assistant
Fellowship Training								
Experience Post Fellowship								

nephrectomies were performed:

Table 5: Primary Donor Surgeon – Donor Recovery Log

Application Type: (Check all that apply)						
Open Nephrectomy						
Laparoscopic Nephrectomy						
Name of proposed primary						
Name of transplant center	where					

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

	Date of Procedure (Check Type)		Role in (Cheo	СРТ			
#	Nephrectomy	Donor ID #	Open	Lap	Primary	1 st Assistant	Code
1							
2							
3							
4							
5							
6							
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Part 3C: Section 2 - Living Donor Kidney Recoveries Personnel Additional Open and Laparoscopic Nephrectomy Donor Surgeon(s)

Complete this section to describe additional donor surgeons involved in the program that are not designated as primary, but are credentialed by the transplant hospital to provide transplant services and independently manage the care of transplant patients, including performing the transplant operations and organ procurement procedures. Duplicate this section as needed.

- 1. Identify the additional donor recovery surgeon: Name:
 - a) This donor surgeon is being proposed as (check all that apply):

Open Nephrectomy Donor Surgeon	
Laparoscopic Nephrectomy Donor Surgeon	

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

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

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

Yes	
No	

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

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

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

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

e) Experience/Training:

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

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

[Insert response here, table will expand automatically]

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

1. Identify the primary transplant physician:

Name:

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

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

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

Yes	
No	

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

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

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

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

e) List the physician's current board certification(s) below. If board certification is pending, indicate the date the exam has been scheduled. If the physician has been recertified, use that date, also provide a copy of the certifications(s). If the physician does not have current American or Canadian board certification, provide letters of recommendation requesting this exception and provide the plan for continuing education as described in the OPTN Bylaws as described in the OPTN Bylaws.

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

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

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

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

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

h) Training/Experience. List how the physician fulfills the criteria for participating as an observer of deceased and living donor kidney transplants and kidney procurements. For procurements, the physician must have observed the evaluation, donation process, and management of the donors.

Date From - To (MM/DD/YY)	Transplant Hospital	# of KI Procurements Observed	# of KI Transplants Observed

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

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

Table 6: Primary Physician – Recipient Log (Sample)

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

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

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

Table 7: Primary Physician – Evaluation Logs (Sample)

Only complete these tables if you are applying through The Transplant Nephrology Fellowship, Clinical Experience, or Conditional Approval Pathways (OPTN Bylaws, Appendix E.3.A, E.3.B, or E.3.C). If you are applying through any pediatric pathway, you do NOT need to complete these logs.

Organ:	
Name of proposed primary physician:	

In the tables below, document the physician's participation in the evaluation of potential kidney recipients as well as potential living donors.

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

Potential Recipients Evaluated

	Date of	Medical Record/ OPTN	
#	Evaluation	ID #	Hospital
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			
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19			
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21			
22			
23			
24			
25			

Potential Living Donors Evaluated

#	Date of Evaluation	Medical Record/ OPTN ID #
#	Evaluation	OPTNTD #
1		
2		
3		
4		
5		
6		

#	Date of Evaluation	Medical Record/ OPTN ID #
7		
8		
9		
10		

Table 8: Primary Physician – Observation Log (Sample)

Organ:	
Name of proposed primary physician:	

In the tables below, document the physician's participation as an observer in kidney transplants and kidney procurements. For procurements, the physician must have observed the evaluation, donation process, and management of the donors.

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

Transplants Observed

#	Date of Transplant	Medical Record/ OPTN ID #	Living Donor or Deceased	Recipient Age	Hospital
1					
2					
3					
4					
5					

Procurements Observed

#	Date of Procurement	Medical Record/ OPTN ID #	Living Donor or Deceased
1			
2			
3			
4			
5			

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

Complete this section of the application to describe physicians involved in the program that are not designated as primary, but are credentialed by the transplant hospital to provide transplant services and be able to independently manage the care of transplant patients. Duplicate this section as needed.

1. Identify the additional transplant physician:

Name:

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

Date of employment at this hospital:

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

Yes	
No	

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

Date full privileges to be granted (MM/DD/YY):

Explain the physician's current credentialing status, including any limitations on practice:

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

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

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

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

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

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

Table 9: Certificate of Investigation

- 1. List all transplant surgeons and physicians currently involved in the program.
 - a) This hospital has conducted its own peer review of all surgeons and physicians listed below to ensure compliance with applicable OPTN Bylaws. Expand rows as needed.

Names of Surgeons		

Names of Physicians			

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

Yes	
No	
Not Applicable	

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

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

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

Table 10: Program Coverage Plan

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

a. OPTN/UNOS Representative; or

b. Program Director(s); or

c. Primary Surgeon and Primary Physician.

	Yes	No
Is this a single surgeon program?		
Is this a single physician program?		
If single surgeon or single physician, submit a copy of the patient notice	e or the pr	otocol
for providing patient notification.		
Does this transplant program have transplant surgeon(s) and		
physician(s) available 365 days a year, 24 hours a day, 7 days a		
week to provide program coverage?		
If the answer to the above question is "No," an explanation must be pro-	ovided tha	t
justifies why the current level of coverage should be acceptable to the l	MPSC. Plea	ise
use the additional information section below.		
Transplant programs shall provide patients with a written summary		
of the Program Coverage Plan at the time of listing and when there		
are any substantial changes in program or personnel. Has this		
program developed a plan for notification?		
Is a surgeon/physician available and able to be on the hospital		
premises to address urgent patient issues?		
Is a transplant surgeon readily available in a timely manner to		
facilitate organ acceptance, procurement, and implantation?		
A transplant surgeon or transplant physician may not be on call		
simultaneously for two transplant programs more than 30 miles		
apart unless circumstances have been reviewed and approved by		
the MPSC. Is this program requesting an exemption?		
If yes, provide explanation:		
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:		
Additional information:		