Department of Health and Human Services
Health Resources and Services Administration

OMB No. PENDING
Expiration Date: PENDING

APPLICATION FOR APPROVAL OF

LIVING DONOR KIDNEY TRANSPLANTATION

IN AN EXISTING MEMBER TRANSPLANT CENTER THAT IS APPROVED FOR KIDNEY TRANSPLANTATION.

ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK (OPTN)

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 center, 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: ______________________________

Print Name: ______________________________

Center Code: ________

Print Title: ______________________________

Version date pending

Application Instructions

1. A duly authorized representative of the transplant center must review the answers and attachments to the change forms, perform sufficient investigation to determine accuracy and completeness, and sign and date the Certification on the cover page of the form. Failure to furnish accurate and complete information in connection with the form and subsequent site visits and requests for supplemental information, constitutes grounds for denial or suspension of OPTN membership. (Authorized representatives include hospital CEO/President, OPTN Representative, and Program Directors. **Individuals whose credentials are being submitted should not sign the application)**

2. Application responses must be typed and complete. Do not omit pages that were not used. Electronic versions (WORD) of this application are available upon request.

3. Do not submit two-sided pages.

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. "See C.V." and "see logs" are not acceptable answers.

6. CV's should be included for all primary and new personnel listed. Abbreviated CV's that do not include publications and presentations are preferred.

7. Each set (original and copy) should be loose bound with tabs. Originals and copy should be organized in the following sequence:
   a) Application form (including signed certification page) and staffing survey (Parts 1-5).
   b) Documentation of Medicare/Medicaid certification of this program (as applicable).
   c) Letters from Hospital Credentialing Committee.
   d) Letters of Commitment.
   e) Letters of Reference.
   f) Nephrectomy – Experience and Training (Table 1 within document).
   g) Nephrectomy log for the donor surgeon (Table 2 within document).
      Title each log with surgeons name, date range, and hospital where the experience occurred.
      Please use a separate log for each institution.
   h) CV's (individual CV's must be stapled together in the original and hardcopy).

8. Supporting documentation such as letters of support, letters of commitment, and logs must be included as requested to document compliance with OPTN requirements. Documentation may be blinded in such a way as to protect patient confidentiality. Check lists are provided throughout the application to help applicants compile the documentation that is required. Each item in the checklist is cross referenced to the application questions.

9. 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.

10. The Criteria for Institutional Membership are found in the Bylaws which can be accessed on the OPTN website at www.optn.org.

11. Return the original and one (1) complete paper copy of all application materials. Also provide a copy of the application that has been scanned to a CD in PDF format. Label the CD with the Hospital name, contact name, date, and include an electronic table of contents.

12. Completed packets should be shipped as listed below:

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

Kidney Transplant Program that Performs Living Donor Transplants

Part 1 - General

Application for __ Open ___Laparoscopic (Check all that apply)

1. Answer the questions below that describe this program/proposed program.

a) Year Program to Start(ed):		
	Yes	**No**
b) Does/will this program perform living donor kidney transplants in patients under age 18?		
c) Is this center a stand-alone pediatric hospital? (If yes, answer #2 below)		
d) If no, is there a stand-alone pediatric facility affiliated with this hospital? If yes, specify facility:		
e) Is this program certified by Medicare? If yes, provide the CMS provider number:________ Certification date:_________ Attach evidence of Medicare certification.		

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

Hospital Name	Location

Part 2A - Personnel - Director(s)

1. Identify the Transplant Program Surgical and/or Medical Director(s) role in living donor kidney transplantation (include C.V.). Briefly describe the leadership responsibilities for each individual.

Check list	Required Supporting Documents
	Current C.V.

Name	Date of Appointment as Director	Primary Areas of Responsibility

Part 2B - Personnel –Existing Kidney Transplant Program

1. Identify the Primary Surgeon and Primary Physician for the kidney transplant program:

Role	Name
Primary Kidney Transplant Surgeon:	
Primary Kidney Transplant Physician:	

Part 2C 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
	2,C,1	Current C.V.
	2,C,1,d	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.
	2,C,1, c; e; f;& h	Letter from the Surgeon detailing his/her commitment to the program and describing their previous experience/training.
	2,C,1 e& i	ASTS Certificate in Kidney (as applicable)
	2,C,1,f	Experience/Training Log (Table 1)
	2,C,1,g	Log of nephrectomies (Table 2)

1. Name: ____

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

b) Date of Appointment (MM/DD/YY): Facility: _____ To this position: ______

c) Percentage of professional time spent at this facility: _______% = _____ 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. Also 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.		
Institution:		
Fellowship Program Director:		
Date of training: mm/dd/yy format): Start ________ End: ___________		

ii) Qualifying by Experience/Training:

	Yes	**No**
Has this individual performed 10 or more open nephrectomies (to include living donor nephrectomy, deceased donor nephrectomy, removal of polycystic or diseased kidneys) as the primary surgeon or first assistant, within the prior 5-year period?		

f) Complete **TABLE 1** (at the end of this document) summarizing this individuals training and experience. Include the number of open nephrectomy (and laparoscopic if applicable) cases in which the individual participated as the primary surgeon or first assistant.

g) Nephrectomy Log: Provide documentation that demonstrates that this individual has experience as the primary surgeon or first assistant in at least 10 open nephrectomies (to include living donor nephrectomy, deceased donor nephrectomy, and removal of polycystic or diseased kidneys) within the prior 5-year period. A blank log for documenting open and laparoscopic living donor nephrectomies has been provided as **TABLE 2** 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 optional but recommended.

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.

i) Are there other individuals in the program who routinely perform open donor nephrectomies for the living donor program? ___ Yes __ No. If yes, complete **Part 2E** of this application.

Part 2D 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
	2,D,1	Current C.V.
	2,D,1,d	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.
	2,D,1, c; e; f; & h	Letter from the Surgeon detailing his/her commitment to the program and describing their previous experience/training.
	2,D,1,g	Log of nephrectomies

1. Name: ____

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

   b) Date of Appointment (MM/DD/YY): Facility: __________ To this position: ___________

   c) Percentage of professional time spent at this facility: _______% = _____ 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. Also include an explanation that describes the scope of privileges.

   e) Experience/Training:

	Yes	No
Does this individual have experience as the primary surgeon or first assistant in 15 laparoscopic nephrectomies (including deceased donor nephrectomy, removal of polycystic or diseased kidneys, etc.), within the prior 5-year period.		

   f) Complete **TABLE 1** (within this document) summarizing this individuals training and experience. Include the number of laparoscopic nephrectomies (and open nephrectomy if applicable) cases in which the individual participated as the primary surgeon or first assistant.

g) Nephrectomy 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 prior 5-year period. A blank log for documenting open and laparoscopic living donor nephrectomies has been provided as **TABLE 2** 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. 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.

j) Are there other individuals in the program who also perform laparoscopic nephrectomies for the living donor program? ___ Yes __ No. If yes, complete **Part 2E** of this application:

Part 2E 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 live donor nephrectomies at this center. Provide the following documents:

Check list	Question Reference	Required Supporting Documents
	2,E,1	Current C.V.
	2,E,1,d	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.
	2,E,1,c;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 Appointment (MM/DD/YY): Facility: _____ To this position: ______

   c) Percentage of professional time spent at this facility: _______% = _____ 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. Also, include an explanation that describes the scope of privileges.

   e) Complete **TABLE 1** (at the end of this document) summarizing this individuals training and experience. Include the number of open nephrectomy and laparoscopic cases 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 2F- Other Staff and Resources

1. How does the center assess that the short and long term risks for the potential live donor are acceptable to the medical staff at the transplant center and the donor? 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 is independent of the decision to transplant the potential recipient.

Part 3 - Protocols:

1. Kidney transplant programs that perform living donor kidney transplants must demonstrate that they have the following 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; and • 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; and		
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; and		

Written protocols must address at a minimum the areas listed below:	**Included in Protocol?**	
	Yes	No
• 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.		

2. How will the center assess its compliance with each protocol listed above?

PART 4: Certification of Investigation

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) What steps will be/were 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.

Part 5 - OPTN Staffing Report **KIDNEY TRANSPLANT PROGRAM – LIVING DONOR STAFF**

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 #:	

Identify the **Medical and/or Surgical Director(s)** of this transplant program:

Name	**Address**	**Phone**	**Fax**	**Email**

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

Name	**Address**	**Phone**	**Fax**	**Email**

Identify the **Hospital Administrative Director/Manager** who will provide oversight to this transplant program. Use an * to indicate which individual will serve as the primary Transplant Administrator if more than one.

Name	Address	Phone	Fax	Email

List the **clinical transplant coordinators** who participate in the care of the living donor:

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

List the **Independent Donor Advocate(s) (IDA)** who participate in the care of the living donor:

Name	Address	Phone	Fax	Email

Identify the **Social Worker(s)** and other **Mental Health Professionals** who will be prominently involved in the care of the living donor:

Name	Address	Phone	Fax	Email

TABLE 1 – Open and Laparoscopic Nephrectomies
SUMMARY OF EXPERIENCE AND TRAINING FOR DR. ______________________________
List each institution on a separate row.
This summary must document (at a minimum) that the individual:

1) performed no fewer than 10 open nephrectomies (to include living donor nephrectomy, deceased donor nephrectomy, and removal of polycystic or diseased kidneys) as primary surgeon or first assistant within the prior 5-year period; and/or
2) acted as primary surgeon or first assistant in performing no fewer than 15 laparoscopic nephrectomies within the prior 5-year period.

Periods of training and post-fellowship experience must be listed on separate rows.

Date From To mm/dd/yy	Institution	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 2
Nephrectomy Log (Sample)

(Header should include the following information. Cases should be listed by type, then date order)

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

Name of Proposed Primary Donor Surgeon:	
Name of transplant center where he/she was working when the nephrectomies were performed:	

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

1) performed at least 10 open nephrectomies (to include living donor nephrectomy, deceased donor nephrectomy, and removal of polycystic or diseased kidneys) as primary surgeon or first assistant within the prior 5-year period; and/or
2) acted as primary surgeon or first assistant in performing at least 15 laparoscopic nephrectomies within the prior 5-year period.

Applicable CPT codes are listed on the next page.

#	Date of Nephrectomy	Donor ID Number	Nephrectomy site (hospital)	Procedure (Check Type)		CPT Code (Optional)
				Open	Laparoscopic	
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:

Code	Description
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:

Code	Description
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