

OPTN Membership Application for Intestine Transplant Programs

CERTIFICATION

The undersigned, a duly authorized representative of the applicant, does hereby certify that the answers and attachments to this application are true, correct and complete, to the best of his or her knowledge after investigation. I understand that the intentional submission of false data to the OPTN may result in action by the Secretary of the Department of Health and Human Services, and/or civil or criminal penalties. By submitting this application to the OPTN, the applicant agrees: (i) to be bound by OPTN Obligations, 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.

If you have any questions, please call the UNOS Membership Team at 833-577-9469 or email MembershipRequests@unos.org.

OPTN Representative

Printed Name	Signature	Email Address
--------------	-----------	---------------

Program Director

Printed Name	Signature	Email Address
--------------	-----------	---------------

Program Director (if applicable)

Printed Name	Signature	Email Address
--------------	-----------	---------------

Program Director (if applicable)

Printed Name	Signature	Email Address
--------------	-----------	---------------

Program Director (if applicable)

Printed Name	Signature	Email Address
--------------	-----------	---------------

Proposed Primary Surgeon

Printed Name	Signature	Email Address
--------------	-----------	---------------

Proposed Primary Physician

Printed Name	Signature	Email Address
--------------	-----------	---------------

Part 1: General Information

Name of Transplant Hospital: _____

OPTN Member Code (4 Letters): _____

Transplant Program Office Address

Street: _____ Ste: _____ Phone #: _____

City: _____ ST: _____ Zip: _____ Fax #: _____

Name of Person Completing Form: _____ Title: _____

Email Address of Person Completing Form: _____

Date Form is submitted to OPTN Contractor: _____

Part 2: Program Director(s)

An intestine transplant program must identify at least one designated staff member to act as the transplant program director. The director must be a surgeon or physician who is a member of the transplant hospital staff.

Name of Program Director(s) (list all):	New	Existing
_____	<input type="checkbox"/>	<input type="checkbox"/>
_____	<input type="checkbox"/>	<input type="checkbox"/>
_____	<input type="checkbox"/>	<input type="checkbox"/>
_____	<input type="checkbox"/>	<input type="checkbox"/>

Include the resume/CV of each individual listed.

Part 3: Primary Program Administrator

A primary program administrator is the identified administrative lead for the transplant program.

Name of Primary Program Administrator:

Credentials:

Title at Hospital:

Phone Number:

Email:

Part 4: Primary Data Coordinator

A primary data coordinator is the identified data lead for the transplant program.

Name of Primary Data Coordinator:

Credentials:

Title at Hospital:

Phone Number:

Email:

Part 5: Primary Intestine Transplant Surgeon Requirements

1. Name of Proposed Primary Intestine Transplant Surgeon (as indicated in Certificate of Assessment):

Name	NPI #
------	-------

2. Check yes or no for each of the following. Provide documentation where applicable:

Yes No

- 2a. Does the surgeon have an M.D., D.O., or equivalent degree from another country, with a current license to practice medicine in the hospital's state or jurisdiction?

Provide a copy of the surgeon's resume/CV.

- 2b. Has the surgeon been accepted onto the hospital's medical staff, and is practicing on site at this hospital?

Provide documentation from the hospital credentialing committee that it has verified the surgeon's state license, board certification, training, and transplant continuing medical education, and that the surgeon is currently a member in good standing of the hospital's medical staff.

3. Certification. Check one and provide corresponding documentation:

- 3a. The surgeon is currently certified by the American Board of Surgery, the American Board of Osteopathic Surgery, or the Royal College of Physicians and Surgeons of Canada.

Provide a copy of the surgeon's current board certification.

- 3b. The surgeon has just completed training and is pending certification by the American Board of Surgery, the American Board of Osteopathic Surgery, or the Royal College of Physicians and Surgeons of Canada. Therefore, the surgeon is requesting conditional approval for 24 months to allow time to complete board certification, with the possibility of renewal for one additional 24-month period.

Provide documentation supporting that training has been completed and certification is pending, which must include the anticipated date of board certification and where the surgeon is in the process to be certified.

- 3c. The surgeon is without certification from American Board of Surgery, the American Board of Osteopathic Surgery, or the Royal College of Physicians and Surgeons of Canada.

If this option is selected:

- **The surgeon must be ineligible for American board certification. Provide an explanation why the individual is ineligible:**

- **Provide a plan for continuing education that is comparable to American board maintenance of certification; and**

- **Provide at least 2 two letters of recommendation from directors of designated transplant programs not employed by the applying hospital that address**
 - o *why an exception is reasonable,*
 - o *the individual's overall qualifications to act as a primary intestine transplant surgeon,*
 - o *the individual's personal integrity and honesty,*
 - o *the individual's familiarity with and experience in adhering to OPTN obligations and compliance protocols, and*
 - o *any other matters judged appropriate.*

4. Summarize the surgeon's training and experience in transplant:

Date (MM/DD/YY)		Approved Fellowship Program?		Transplant Hospital	Program Director	# Intestine Transplants as Primary	# Intestine Transplants as 1 st Assistant	# of Intestine Procurements as Primary or 1 st Assistant
Start	End	Yes	No					

5. Which of the following pathways is the proposed primary surgeon applying (check one, and complete the corresponding pathway section below):

- The **full approval pathway**, as described in *Section 5* Error: Reference source not found below.
- The **conditional pathway**, as described in *Section 5B: Conditional Intestine Surgeon Approval Pathway* below.

5A: Full Intestine Surgeon Approval Pathway

Surgeons can be fully approved as a primary intestine transplant surgeon by completing a formal surgical transplant fellowship or by completing clinical experience at an intestine transplant program if *all* of the following conditions are met:

1. *The surgeon performed 7 or more intestine transplants at a designated intestine transplant program, to include the isolated bowel and composite grafts, as primary surgeon or first assistant within the last 10 years.*
This experience must be documented on the log provided.
2. *The surgeon performed 3 or more intestine procurements as primary surgeon or first assistant. These procurements must include 1 or more organ recovery that includes a liver.*

This experience must be documented on the log provided.

3. *The surgeon must maintain a current working knowledge of intestine transplantation, defined as direct involvement in intestine transplant patient care within the last 5 years.*

Check all that apply

- The surgeon has experience managing patients with short bowel syndrome or intestinal failure.*
- The surgeon has experience with recipient selection.*
- The surgeon has experience with donor selection.*
- The surgeon has experience with histocompatibility and tissue typing.*
- The surgeon has experience with performing the transplant operation.*
- The surgeon has experience with immediate postoperative and continuing inpatient care.*
- The surgeon has experience with the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression.*
- The surgeon has experience with differential diagnosis of intestine allograft dysfunction.*
- The surgeon has experience with histologic interpretation of allograft biopsies.*
- The surgeon has experience with interpretation of ancillary tests for intestine dysfunction.*
- The surgeon has experience with long term outpatient care.*

If a box is not checked, please provide an explanation:

4. ***Provide the following letters with the application:***

- *A letter from the qualified intestine transplant physician and surgeon who have been directly involved with the surgeon documenting the surgeon's experience and competence.*
- *A letter of recommendation from the primary surgeon and transplant program director at the fellowship training program or transplant program last served by the surgeon outlining
 - o *the individual's overall qualifications to act as a primary transplant surgeon,*
 - o *the individual's personal integrity and honesty,*
 - o *The individual's familiarity with and experience in adhering to OPTN obligations, and*
 - o *any other matters judged appropriate.*The MPSC may request additional recommendation letters from the primary surgeon, primary physician surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.*
- *A letter from the surgeon that details the training and experience the surgeon gained in intestine transplantation.*

5B: Conditional Intestine Surgeon Approval Pathway

Surgeons can meet the requirements for conditional approval as primary intestine transplant surgeon through experience gained during or post-fellowship, if *all* of the following conditions are met:

1. *The surgeon has performed **at least 4** intestine transplants that include the isolated bowel and composite grafts and must perform **3 or more** intestine transplants over the next 3 consecutive years as primary surgeon or first assistant at a designated intestine transplant program. Each*

year of the surgeon's experience must be substantive and relevant and include pre-operative assessment of intestine transplant candidates, transplants performed as primary surgeon or first assistant and post-operative management of intestine recipients.

This experience must be documented on the log provided.

2. *The surgeon has performed **at least 3** intestine procurements as primary surgeon or first assistant. These procurements must include **at least 1** procurement of a graft that includes a liver.*

This experience must be documented on the log provided.

3. *The surgeon has maintained a current working knowledge of intestine transplantation, defined as direct involvement in intestine transplant patient care within the last 5 years.*

Check all that apply

- The surgeon has experience with managing patients with short bowel syndrome or intestinal failure.*
- The surgeon has experience with the selection of appropriate recipients for transplantation.*
- The surgeon has experience with donor selection.*
- The surgeon has experience with histocompatibility and tissue typing.*
- The surgeon has experience with performing the transplant operation.*
- The surgeon has experience with immediate postoperative and continuing inpatient care.*
- The surgeon has experience with the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression.*
- The surgeon has experience with differential diagnosis of intestine dysfunction in the allograft recipient.*
- The surgeon has experience with histologic interpretation of allograft biopsies.*
- The surgeon has experience with interpretation of ancillary tests for intestine dysfunction.*
- The surgeon has experience with long term outpatient care.*

If a box is not checked, please provide an explanation:

4. *The surgeon develops a formal mentor relationship with a primary intestine transplant surgeon at another approved intestine transplant program. The mentor will discuss program requirements, patient and donor selection, recipient management, and be available for consultation as required until full approval conditions are all met.*

Provide a letter from the transplant surgeon's mentor discussing this relationship.

5. ***Provide the following letters with the application:***

- *A letter from the director of the transplant program and chair of the department or hospital credentialing committee verifying that the surgeon has met the above requirements and is qualified to direct an intestine transplant program.*
- *A letter of recommendation from the primary surgeon and transplant program director at the transplant program last served by the surgeon, outlining
 - *the individual's overall qualifications to act as primary transplant surgeon,*
 - *the individual's personal integrity and honesty,*
 - *The individual's familiarity with and experience in adhering to OPTN obligations, and**

o other matters judged appropriate.

The MPSC may request additional recommendation letters from the primary surgeon, primary physician, director, or others affiliated with any transplant program previously served by the surgeon, at its discretion.

- A letter from the surgeon that details the training and experience the surgeon gained in intestine transplantation as well as detailing the plan for obtaining full approval within the 3-year conditional approval period.
- A letter of commitment from the surgeon's mentor supporting the detailed plan developed by the surgeon to obtain full approval.

Part 6: Primary Intestine Transplant Physician Requirements

1. **Name of Proposed Primary Intestine Transplant Physician (as indicated in Certificate of Assessment):**

Name	NPI #
------	-------

2. **Check yes or no for each of the following. Provide documentation where applicable:**

Yes No

- 2a. Does the physician have an M.D., D.O., or equivalent degree from another country, with a current license to practice medicine in the hospital's state or jurisdiction?

Provide a copy of the physician's resume/CV.

- 2b. Has the physician been accepted onto the hospital's medical staff, and is practicing on site at this hospital?

Provide documentation from the hospital credentialing committee that it has verified the physician's state license, board certification, training, and transplant continuing medical education, and that the physician is currently a member in good standing of the hospital's medical staff.

3. **Certification. Check one and provide corresponding documentation:**

- 3a. The physician is currently certified in gastroenterology by the American Board of Internal Medicine, the American Board of Pediatrics, or the Royal College of Physicians and Surgeons of Canada.

Provide a copy of the physician's current board certification.

- 3b. The physician is without certification in gastroenterology by the American Board of Internal Medicine, the American Board of Pediatrics, or the Royal College of Physicians and Surgeons of Canada.

If this option is selected:

- **The physician must be ineligible for American board certification. Provide an explanation why the individual is ineligible:**

- **Provide a plan for continuing education that is comparable to American board maintenance of certification**
- **Provide at least 2 two letters of recommendation from directors of designated transplant programs not employed by the applying hospital that address**
 - o **why an exception is reasonable,**
 - o **the individual's overall qualifications to act as a primary intestine transplant physician,**
 - o **the individual's personal integrity and honesty,**

- o the individual's familiarity with and experience in adhering to OPTN obligations and compliance protocols, and*
- o any other matters judged appropriate.*

4. Summarize the physician's training and experience in transplant:

Date (MM/DD/YY)		Transplant Hospital	# of Isolated Intestine Transplants Observed	# of Combined Liver-Intestine Transplants Observed	# of Multi-Visceral Transplants Observed
Start	End				

5. Pediatric-specific physician requirement for a program the serves predominantly pediatric patients:

Any physician who meets the criteria as a primary intestine transplant physician can function as the primary intestine transplant physician for a program that serves predominantly pediatric patients, if a pediatric gastroenterologist is also involved in the care of the transplant recipients.

Name of Pediatric Gastroenterologist:

6. Which of the following pathways is the proposed primary physician applying (check one, and complete the corresponding pathway section below):

- The primary intestine transplant physician **full approval** pathway, as described in *Section 6A: Full Intestine Physician Approval Pathway* below.
- The primary intestine transplant physician **conditional** pathway, as described in *Section 6B: Conditional Intestine Physician Approval Pathway* below.

6A. Full Intestine Physician Approval Pathway

Physicians can meet the requirements for a primary intestine transplant physician during the physician's adult gastroenterology fellowship, pediatric gastroenterology fellowship, or through acquired clinical experience (including accumulated training during any fellowships) if all of the following conditions are met:

1. *The physician has been directly involved within the last 10 years in the primary care of **7 or more** newly transplanted intestine recipients and continued to follow these recipients for a minimum of 3 months from the time of transplant. This clinical experience must be gained as the primary intestine transplant physician or under the direct supervision of an intestine transplant physician and in conjunction with an intestine transplant surgeon at a designated intestine transplant program.*

This experience must be documented on the log provided.

2. *The physician has maintained a current working knowledge of intestine transplantation, defined as direct involvement in intestine transplant patient care within the last 5 years.*

Check all that apply

- The physician has experience with managing patients with short bowel syndrome or intestinal failure.*
- The physician has experience with the selection of appropriate recipients for transplantation.*
- The physician has experience with donor selection.*
- The physician has experience with histocompatibility and tissue typing.*
- The physician has experience with performing the transplant operation.*
- The physician has experience with immediate postoperative and continuing inpatient care.*
- The physician has experience with the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression.*
- The physician has experience with differential diagnosis of intestine dysfunction in the allograft recipient.*
- The physician has experience with histologic interpretation of allograft biopsies.*
- The physician has experience with interpretation of ancillary tests for intestine dysfunction.*
- The physician has experience with long term outpatient care.*

If a box is not checked, please provide an explanation:

3. *The physician has observed **at least 1** isolated intestine transplant and **at least 1** combined liver-intestine or multi-visceral transplant.*

This experience must be documented on the log provided.

4. ***Provide the following letters with the application:***

- A letter from the transplant program director documenting the physician's experience and training.

- A letter of recommendation from the primary physician and transplant program director at the fellowship training program or transplant program last served by the physician outlining
 - o the individual's overall qualifications to act as a primary transplant physician,
 - o the individual's personal integrity and honesty,
 - o The individual's familiarity with and experience in adhering to OPTN obligations, and
 - o any other matters judged appropriate.The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
- A letter from the physician that details the training and experience the physician gained in intestine transplantation.

6B. Conditional Intestine Physician Approval Pathway

Physicians can meet the requirements for approval as primary intestine transplant physician through a conditional approval pathway if *all* of the following conditions are met:

1. *The physician has been involved in the primary care of **at least 4** newly transplanted intestine recipients, and has followed these patients for at least 3 months from the time of their transplant. Additionally, the physician must become involved in the care of **3 or more** intestine recipients over the next 3 consecutive years. This clinical experience must be gained as the primary intestine transplant physician or under the direct supervision of an intestine transplant physician and in conjunction with an intestine transplant surgeon at a designated intestine transplant program.*

This experience must be documented on the log provided.

2. *The physician has maintained a current working knowledge of intestine transplantation, defined as direct involvement in intestine transplant patient care within the last 5 years.*

Check all that apply

- The physician has experience with managing patients with short bowel syndrome or intestinal failure.*
- The physician has experience with the selection of appropriate recipients for transplantation.*
- The physician has experience with donor selection.*
- The physician has experience with histocompatibility and tissue typing.*
- The physician has experience with performing the transplant operation.*
- The physician has experience with immediate postoperative and continuing inpatient care.*
- The physician has experience with the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression?*
- The physician has experience with differential diagnosis of intestine dysfunction in the allograft recipient.*
- The physician has experience with histologic interpretation of allograft biopsies.*
- The physician has experience with interpretation of ancillary tests for intestine dysfunction.*
- The physician has experience with long term outpatient care.*

If a box is not checked, please provide an explanation:

-
3. *The physician has **12 months experience** as the primary intestine transplant physician or under the direct supervision of a qualified intestine transplant physician along with an intestine transplant surgeon at a designated intestine transplant program. These 12 months of experience must be acquired within a 2-year period.*

 4. *The physician developed a formal mentor relationship with a primary intestine transplant physician at another approved designated intestine transplant program. The mentor will discuss program requirements, patient and donor selection, recipient management, and be available for consultation as required.*
Provide a letter from the transplant physician's mentor discussing this relationship.

 5. ***Provide the following letters along with your application:***
 - A letter from the qualified intestine transplant physician and surgeon who were directly involved with the physician verifying that the physician has satisfactorily met the above requirements to become the primary transplant physician of an intestine transplant program.
 - A letter of recommendation from the primary physician and transplant program director at the transplant program last served by the physician outlining
 - o the physician's overall qualifications to act as a primary transplant physician,
 - o the physician's personal integrity and honesty,
 - o familiarity with and experience in adhering to OPTN obligations, and
 - o any other matters judged appropriate.The MPSC may request additional recommendation letters from the primary physician, primary surgeon, director, or others affiliated with any transplant program previously served by the physician, at its discretion.
 - A letter from the physician that details the training and experience the physician gained in intestine transplantation as well as a detailed plan for obtaining full approval.
 - A letter of commitment from the physician's mentor supporting the detailed plan developed by the physician to obtain full approval.

PUBLIC BURDEN STATEMENT

The private, non-profit Organ Procurement and Transplantation Network (OPTN) collects this information in order to perform the following OPTN functions: to assess whether applicants meet OPTN Bylaw requirements for membership in the OPTN; and to monitor compliance of member organizations with OPTN Obligations. 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 information collection is 0915-0184 and it is valid until XX/XX/2023. This information collection is required to obtain or retain a benefit per 42 CFR §121.11(b)(2). All data collected will be subject to Privacy Act protection (Privacy Act System of Records #09-15-0055). Data collected by the private non-profit OPTN also are well protected by a number of the Contractor's security features. The Contractor's security system meets or exceeds the requirements as prescribed by OMB Circular A-130, Appendix III, Security of Federal Automated Information Systems, and the Departments Automated

Information Systems Security Program Handbook. The public reporting burden for this collection of information is estimated to average 3 hours per response, including the time for reviewing instructions, searching existing data sources, 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 14N136B, Rockville, Maryland, 20857 or paperwork@hrsa.gov.