

Membership and Personnel Requirements for Intestine Transplant Programs

Sponsoring Committee:	Liver and Intestinal Organ Transplantation Committee
Policy/Bylaws Affected:	Bylaw Appendix F, Membership and Personnel Requirements for Liver Transplant Programs and Intestine Transplant Programs
Distributed for Public Comment:	January 27, 2015
Amended After Public Comment:	No
Effective Date:	Pending implementation and notice to members

Problem Statement

Previously there were no OPTN/UNOS requirements for qualifying intestinal programs, or their associated physicians, and surgeons. Due to this lack of requirements, any transplant program that was approved to perform liver transplants could also perform intestinal transplants.

Summary of Changes

This bylaw defines a designated intestine transplant program and establishes minimum qualifications for primary intestine transplant surgeons and physicians. The intent is to set minimum standards where none previously existed, without compromising quality or restricting new program formation. The bylaw includes a full approval pathway and a conditional approval pathway for intestine transplant programs.

What Members Need to Do

All transplant hospitals with intestine programs with a current status of “Active, Approval Not Required” will receive an OPTN intestine transplant program application. The application will include a submission deadline. If your transplant hospital receives this packet, you will be asked to complete all requisite information to apply for an intestine transplant program and submit the application within 120 days.

If you receive this application but do not intend to apply for an intestine transplant program, you need to document this in writing and submit that documentation to UNOS.

If your transplant hospital does not receive an application but you wish to apply for an intestine transplant program, you should contact the UNOS Membership Analyst for your region to get an application and the necessary instructions once the application period is announced.

The Bylaws will be slated for implementation following the 120-day application submission period. If UNOS receives your application during the submission period, we will act on it before the Bylaws are implemented. If we receive your application after the deadline, we will process it in the order it is received, but we cannot guarantee that we will be able to process it before the

implementation date. We will alert you of the status of your application before the implementation date.

Once the Bylaws are implemented, if your transplant hospital does not have an approved intestine transplant program, but you have intestine or liver-intestine candidates on your waiting list, you must follow the patient notice and transition plan requirements described in OPTN Bylaws Appendix K (Transplant Program Inactivity, Withdrawal, and Termination).

Affected Policy/Bylaw Language:

Appendix F: Membership and Personnel Requirements for Liver Transplant Programs and Intestine Transplant Programs

F.1 Membership and Personnel Requirements for Liver Transplant Programs

F.42 Liver Program Director, Primary Liver Transplant Surgeon and Primary Liver Transplant Physician

[Subsequent headings affected by the re-numbering of this policy will also be changed as necessary.]

F.7 Membership and Personnel Requirements for Intestine Transplant Programs

This appendix describes the information and documentation transplant hospitals must provide when:

- Submitting a completed membership application to apply for approval as a designated intestine transplant program.
- Completing a Personnel Change Application for a change in key personnel at a designated intestine transplant program.

All intestine transplant programs must also meet general membership requirements, which are described in Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs of these Bylaws.

For more information on the application and review process, see Appendix A: Membership Application and Review of these Bylaws.

F.8 Intestine Program Director, Primary Intestine Transplant Surgeon, and Primary Intestine Transplant Physician

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.

The program must also identify a qualified primary transplant surgeon and primary transplant physician, as described below. The primary surgeon and primary physician, along with the program director, must submit a detailed Program Coverage Plan to the OPTN Contractor. For detailed information about the Program Coverage Plan, see Appendix D, Section D.5.B: Surgeon and Physician Coverage of these Bylaws.

F.9 Primary Intestine Transplant Surgeon Requirements

A designated intestine transplant program must have a primary surgeon who meets all of the following requirements:

1. The surgeon must 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.
2. The surgeon must be accepted onto the hospital's medical staff, and be on site at this hospital.
3. The surgeon must have 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 on the hospital's medical staff.
4. The surgeon must have current certification by the American Board of Surgery, the American Board of Osteopathic Surgery, or the foreign equivalent.

In addition, the primary transplant surgeon must have completed at least *one* of the training or experience pathways listed below:

- The primary intestine transplant surgeon full approval pathway, as described in *Section F.9.A* below.
- The primary intestine transplant surgeon conditional pathway, as described in *Section F.9.B* below.

A. Full Intestine Surgeon Approval Pathway

Surgeons can be fully approved as a primary intestine transplant surgeon by completing a formal 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 to include the isolated bowel and composite grafts, as primary surgeon or first assistant within the last 10 years. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair from the program where the experience or training was gained.
2. The surgeon performed 3 or more intestine procurements as primary surgeon or first assistant. These procurements must include selection and evaluation of the donor. These procurements must include 1 or more organ recovery that includes a liver. These procedures must be documented in a log that includes the date of procurement, location of the donor, and Donor ID. This log must be signed by the program director, division chief, or department chair from the program where the experience or training was gained.
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. This includes the management of patients with short bowel syndrome or intestinal failure, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, performing the transplant operation, immediate postoperative and continuing inpatient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of intestine allograft dysfunction, histologic interpretation of allograft biopsies, interpretation of ancillary tests for intestine dysfunction, and long term outpatient care.
4. The training was completed at a hospital with a transplant training program approved by the American Society of Transplant Surgeons (ASTS) or accepted by the OPTN Contractor as described in *Section F.12 Approved Intestine Transplant Surgeon Fellowship Training Programs* that follows. Foreign training programs must be accepted as equivalent by the Membership and Professional Standards Committee (MPSC).
5. The following letters are submitted to the OPTN Contractor:
 - a. 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.
 - b. 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 the surgeon's overall qualifications to act as a primary transplant surgeon, as well as the surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and 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.
- c. A letter from the surgeon that details the training and experience the surgeon gained in intestine transplantation.

B. 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, or its foreign equivalent. These transplants must be documented in a log that includes the date of transplant, the role of the surgeon in the procedure, and medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair from the program where the experience or training was gained. 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.
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, and selection and evaluation of the donor. This procedure must be documented in a log that includes the date of procurement, location of the donor, and Donor ID.
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. This includes the management of patients with short bowel syndrome or intestinal failure, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, performing the transplant operation, immediate postoperative and continuing inpatient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of intestine dysfunction in the allograft recipient, histologic interpretation of allograft biopsies, interpretation of ancillary tests for intestine dysfunction, and long term outpatient care.
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.
5. The following letters are sent to the OPTN Contractor:
 - a. 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.
 - b. A letter of recommendation from the primary surgeon and transplant program director at the transplant program last served by the surgeon, outlining the surgeon's overall qualifications to act as primary transplant surgeon, as well as the surgeon's personal integrity, honesty, familiarity with and experience in adhering to OPTN obligations, and 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.
 - c. 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.
 - d. A letter of commitment from the surgeon's mentor supporting the detailed plan developed by the surgeon to obtain full approval.

F.10 Primary Intestine Transplant Physician Requirements

A designated intestine transplant program must have a primary physician who meets all the following requirements:

1. The physician must have an M.D., D.O., or the equivalent degree from another country, with a current license to practice medicine in the hospital's state or jurisdiction.
2. The physician must be accepted onto the hospital's medical staff, and be on site at this hospital.
3. The physician must have 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 on the hospital's medical staff.
4. The physician must have current board certification in gastroenterology by the American Board of Internal Medicine, the American Board of Pediatrics, or the foreign equivalent.

In addition, the primary physician must have completed at least one of the training or experience pathways listed below:

- The primary intestine transplant physician full approval pathway, as described in Section F.10.A below.
- The primary intestine transplant physician conditional pathway, as described in Section F.10.B below.

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.

A. 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 a intestine transplant physician and in conjunction with an intestine transplant surgeon at a designated intestine transplant program. This care must be documented in a log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair from the program where the experience or training was gained.
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. This includes the management of patients with intestinal failure, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of intestine allograft dysfunction, histologic interpretation of allograft biopsies, interpretation of ancillary tests for intestine dysfunction, and long term outpatient care.
3. The physician must have observed at least 1 isolated intestine transplant and at least 1 combined liver-intestine or multi-visceral transplant.

4. The following letters are submitted to the OPTN Contractor:
 - a. A letter from the transplant program director documenting the physician's experience and training.
 - b. 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 the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and 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.
 - c. A letter from the physician that details the training and experience the physician gained in intestine transplantation.

B. 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 current board certification in gastroenterology by the American Board of Internal Medicine, the American Board of Pediatrics, or the foreign equivalent.
2. 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 care must be documented in a recipient log that includes the date of transplant and the medical record number or other unique identifier that can be verified by the OPTN Contractor. This log must be signed by the program director, division chief, or department chair from the program where the experience or training was gained.
3. 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. This includes the management of patients with intestine failure, the selection of appropriate recipients for transplantation, donor selection, histocompatibility and tissue typing, immediate post-operative patient care, the use of immunosuppressive therapy including side effects of the drugs and complications of immunosuppression, differential diagnosis of intestine allograft dysfunction, histologic interpretation of allograft biopsies, interpretation of ancillary tests for intestine dysfunction, and long term outpatient care.
4. 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, or the foreign equivalent. These 12 months of experience must be acquired within a 2-year period.
5. The physician develops 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.
6. The following letters are submitted to the OPTN Contractor:
 - a. 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.
 - b. A letter of recommendation from the primary physician and transplant program director at the transplant program last served by the physician outlining the physician's overall qualifications to act as a primary transplant physician, as well as the physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations, and 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.
- c. 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.
 - d. A letter of commitment from the physician's mentor supporting the detailed plan developed by the physician to obtain full approval.

F.11 Conditional Intestine Program Approval

Either the primary surgeon or primary physician must qualify through one of the full approval pathways described above in sections F.9.A or F.10.A for the program to be eligible for conditional approval status. If either the primary surgeon or primary physician qualify through one of the conditional pathways described above in sections F.9.B or F.10.B, the program must meet the requirements as described below to obtain full approval:

- The transplant program is granted 36 months to fully comply with all membership requirements. This option is available to new programs as well as previously approved programs that experience a change in key personnel.
- The program must comply with all policies and procedures as required by the MPSC. This includes submitting reports describing the surgeon or physician's progress towards meeting the requirements, and any other conditions as requested by the MPSC to demonstrate ongoing quality and efficient patient care.
- During this 36-month period of conditional approval, the surgeon must be present at all intestine transplant surgeries.
- During this 36-month period, the physician must be directly involved in the primary care of all intestine patients, including new recipients.

Prior to the end of each year of conditional approval, the program must provide an annual report documenting at least one of the following:

- The designated surgeon has met or is making sufficient progress toward performing 3 or more intestine transplants
- The designated physician has met or is making sufficient progress toward the direct involvement in the primary care of 3 or more intestine transplant patients
- The program is making sufficient progress in employing a transplant surgeon or physician who meets this, as well as all other criteria, for a primary intestinal transplant surgeon or physician

Should the surgeon or physician meet the requirements before the conditional approval period ends, the program may submit a progress report and request a review by the MPSC.

A. Full Approval Following Conditional Approval

The conditional approval period begins on the first approval date granted to the application, whether it is interim approval granted by the MPSC subcommittee, the MPSC or approval granted by the full Board of Directors. The conditional approval period ends 36 months after the first approval date of the application.

The MPSC may consider on a case-by-case basis granting a 12-month extension to a transplant program that provides substantial evidence of progress toward fulfilling the requirements, but is unable to complete the requirements within the 36-month approval period.

Once the program has met the full approval requirements for both primary surgeon and primary physician, the program may petition the OPTN Contactor in writing for full approval.

B. Rejection of Conditional Approval

If the program is unable to demonstrate that it has a designated surgeon and physician on site who can fully meet the primary surgeon and primary physician requirements as described above at the end of the 36-month conditional approval period, it must stop performing intestine transplants and either:

- Inactivate the intestine transplant program for a period up to 12 months
- Withdraw the intestine transplant program until it can meet the requirements for full approval

The requirements for program inactivation and withdrawal are described in *Appendix K: Transplant Program Inactivity, Withdrawal, and Termination* of these Bylaws.

F.12 Approved Intestine Surgeon Transplant Fellowship Programs

Surgeons qualifying as primary transplant surgeon through a formal transplant fellowship must complete their training at a fellowship program approved by the MPSC. Any program approved by the Fellowship Training Committee of the American Society of Transplant Surgeons is automatically accepted by the MPSC, as well as any program that meets *all* of the following criteria:

1. The program is at a hospital that transplants one or more organs, including intestines.
2. The program is at an institution that has a proven commitment to graduate medical education.
3. The program director is a board-certified surgeon who meets the OPTN Contractor requirements for primary intestine transplant surgeon.
4. The program is at a hospital that is affiliated with a histocompatibility laboratory that meets the OPTN Contractor requirements for histocompatibility laboratories.
5. The program is at a hospital that is affiliated with an organ procurement organization (OPO) that meets the OPTN Contractor requirements for OPOs.
6. The program performs at least 10 intestine transplants each year.
7. The program has the resources, including adequate clinical facilities, laboratory research facilities, and appropriately trained faculty and staff, to provide research experience.