OPTN Policy Notice
Changes to Islet Bylaws

Sponsoring Committee:	**Pancreas Transplantation Committee**
Policy/Bylaws Affected:	**OPTN Bylaws Appendices D.6 (Transplant Program Director), D.7 (Transplant Program Key Personnel), D.7.A (Primary Transplant Surgeon and Physician), D.8 (Changes in Key Transplant Program Personnel), D.11 (Review of Transplant Program Functional Inactivity), D.12 (Additional Transplant Program Requirements), G (Membership and Personnel Requirements for Pancreas and Pancreatic Islet Transplant Programs, G.4 (Requirements for Designated Pancreatic Islet Transplant Programs), G.5 (Primary Pancreatic Islet Transplant Surgeon Requirements), G.6 (Primary Pancreatic Islet Transplant Physician Requirements), K.1 (Transplant Program Inactivity)**
Public Comment:	**August 3 – October 3, 2018**
Effective Date:	**Pending Implementation and Notice to Members**

Problem Statement

Current islet Bylaw personnel requirements do not reflect the need for islet transplantation experience and expertise. This may prevent qualified candidates from leading programs and could prevent the field from growing. Inappropriate requirements may be harmful to patients if personnel who are inexperienced in islet transplantation oversee islet programs and islet patient care.

Summary of Changes

Require a single clinical leader of the islet program to replace the transplant surgeon and transplant physician roles. This person must have experience inclusive of pre-, peri-, and post-operative care, islet isolation, and a demonstrated background in transplantation medicine, immunosuppression management, beta cell biology, or endocrinology.

Require four different expert medical personnel roles with defined skill sets to provide key support in the delivery of islet transplant therapy: a pancreas, kidney, liver or intestines transplant surgeon, portal vein access specialist, immunosuppression management specialist, and endocrinologist. A single person can fill one or more of the aforementioned roles.

Allow islet programs to be affiliated with any designated abdominal transplant program (pancreas, kidney, liver, or intestines), not just a pancreas program.

What Members Need to Do

Because the changes to the Bylaws require different data submission from members, the Office of Management and Budget (OMB) will review and approve these changes prior to implementation. After UNOS staff update membership applications to reflect the changes to the requirements for islet

personnel, transplant hospital personnel will have to document that the new requirements are met in order to be eligible for those positions (specifically, the clinical leader and expert medical personnel positions). Islet programs will have separate membership applications from pancreas programs.

Any transplant hospital that intends to perform allogeneic islet transplants after implementation of these proposed Bylaws must complete and submit an islet transplant program application to the OPTN during the application submission period. Transplant hospitals that currently have an approved islet transplant program must submit one of the following to the OPTN during the application submission period:

- A completed islet transplant program application
- An opt out form indicating that the hospital will be voluntarily inactivating or withdrawing approval of its islet transplant program according to OPTN Bylaws Appendix L: Transplant Program Inactivity, Withdrawal, and Termination

Affected Bylaw Language

New language is underlined (example) and language that is deleted is struck through (~~example~~).

Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs

A transplant hospital member is any hospital that performs organ transplants and has current approval as a designated transplant program for at least one organ.

D.6 Transplant Program Director

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

The program director, along with ~~the primary surgeon and physician~~ program key personnel, has the responsibility to submit a detailed Program Coverage Plan (PCP) to the OPTN Contractor ~~that describes how continuous medical and surgical coverage is provided by transplant surgeons and physicians~~. See ~~*D.7.B*~~*D.8.A: Surgeon and Physician Coverage (Program Coverage Plan)* in this appendix and *Appendix K.1.A: Islet Transplant Program Clinical Leader Coverage (Program Coverage Plan)* for more information on the Program Coverage Plan.

D.7 Transplant Program Key Personnel

Designated transplant programs must have certain key personnel on site according to Table D-1 below.

D-1: Key Personnel Requirements for Designated Transplant Programs

Designated transplant program type:	**Required key personnel:**
Kidney, liver, heart, lung, pancreas, or vascularized composite allograft (VCA)	Primary surgeon and primary physician
Islet	Clinical leader

~~These key personnel include a qualified primary surgeon and primary physician that meet the requirements set forth in these Bylaws.~~ For the detailed primary surgeon, ~~and~~ primary physician, or clinical leader requirements for specific ~~organs~~ transplant programs, see the following appendices of these Bylaws:

- *Appendix E:Membership and Personnel Requirements for Kidney Transplant Programs*

- *Appendix F: Membership and Personnel Requirements for Liver Transplant Programs*
- *Appendix G: Membership and Personnel Requirements for Pancreas ~~and Pancreatic Islet~~ Transplant Programs*
- *Appendix H: Membership and Personnel Requirements for Heart Transplant Programs*
- *Appendix I: Membership and Personnel Requirements for Lung Transplant Programs*
- *Appendix J: Membership and Personnel Requirements for Vascularized Composite Allograft (VCA) Transplant Programs*
- *Appendix K: Membership and Personnel Requirements for Islet Transplant Programs*

~~A.~~D.8 Primary Transplant Surgeon and Physician

Section *D.8: Primary Transplant Surgeon and Physician* does not apply to islet transplant programs. See *Appendix K.1: Program Director and Clinical Leader*.

The primary surgeon and primary physician are responsible for ensuring the operation and compliance of the program according to the requirements set forth in these Bylaws. The transplant hospital must notify the OPTN Contractor immediately if at any time the program does not meet these requirements. The individuals reported to the OPTN Contractor as the program's primary surgeon and primary physician should be the same as those reported to the Center for Medicaid and Medicare Services (CMS).

A transplant hospital applying as a new member or for a key personnel change must include for the proposed primary surgeon or physician a report from the hospital credentialing committee that the committee has reviewed the individual's state licensing, board certification, and training and confirm that they are currently a member in good standing.

As part of the plan for continuing policy compliance that is required in the membership application, each primary surgeon or primary physician will submit an assessment of all physicians and surgeons in the program. This assessment must include any involvement in prior transgressions of OPTN obligations and plans to ensure compliance. This information is subject to medical peer review confidentiality requirements and must be submitted according to the guidelines provided in the application and to the satisfaction of the Membership and Professional Standards Committee (MPSC).

D.~~8~~9 Changes in Key Transplant Program Personnel

Designated transplant programs must have key personnel~~, specifically a primary surgeon and a primary physician,~~ who meet the required minimum levels of commitment to and knowledge of organ procurement and transplantation as specified in these Bylaws. All transplant programs should develop a succession plan that addresses changes in these key personnel.

When a designated transplant program is informed of a change in key personnel, it must notify the OPTN Contractor within seven business days in writing and follow the procedures that are described below. A change in key personnel can be *any* of the following:

- Departure of the primary surgeon, ~~or~~ primary physician, or clinical leader.
- Change in position from primary surgeon, ~~or~~ primary physician or clinical leader to an additional surgeon or physician.
- Temporary leave.
- Reinstatement of the previously designated primary surgeon, ~~or~~ physician, or clinical leader.

Transplant programs are also responsible for maintaining Program Coverage Plans ~~as described in~~ according to *Sections ~~D.7.~~ D.8.A* and *K.2.A* ***Error! Reference source not found.*** ~~above~~ during changes

in key personnel. The Program Coverage Plan must address instances when key personnel are unavailable to perform their transplant duties for short periods of time.

A. ~~Primary Surgeon or Primary Physician~~ Key Personnel Departure

When the transplant hospital is informed that either the primary surgeon, ~~or~~ primary physician, or clinical leader plans to leave the hospital or otherwise end their active participation in the transplant program, the transplant hospital must:

1. Notify the OPTN Contractor in writing within seven business days.
2. Submit a completed Personnel Change Application to the OPTN Contractor no less than 30 days before the end of the individual's active employment. The Personnel Change Application must document that the new primary surgeon, ~~or~~ primary physician, or clinical leader meets the requirements of these Bylaws.

   If the transplant hospital receives less than 60 days advance notice of the key personnel change, then the transplant hospital must submit a completed Personnel Change Application to the OPTN Contractor within 30 days from the date the OPTN Contractor was notified.

   If a program is unable to demonstrate through a completed Personnel Change Application that it has on site ~~both a transplant surgeon and a transplant physician~~ the required key personnel, ~~who meet the requirements for primary surgeon and primary physician,~~ the transplant hospital must *either*:

   - Inactivate the designated transplant program.
   - Withdraw its designated transplant program status ~~as described in~~ according to *Section ~~K.4~~L.4: Withdrawal or Termination of Designated Transplant Program Status* of these Bylaws.

B. ~~Primary Surgeon or Primary Physician~~Key Personnel Change in Role

When the transplant hospital plans to propose a new primary surgeon, ~~or~~ primary physician, or clinical leader and the currently designated primary surgeon, ~~or~~ physician or clinical leader will remain on staff as an additional surgeon or physician, the transplant hospital must:

1. Notify the OPTN Contractor in writing within seven business days.
2. Submit a completed Personnel Change Application to the OPTN Contractor no less than 30 days before the change will take effect. The Personnel Change Application must document that the new primary surgeon, ~~or~~ physician or clinical leader meets the requirements of these Bylaws.

The transition to the new primary surgeon, ~~or~~ primary physician, or clinical leader is effective after the application has been reviewed and approved by the MPSC or an Ad hoc Subcommittee of the MPSC, ~~as described in~~ according to *Appendix A: Membership Application and Review* of these Bylaws.

C. ~~Primary Surgeon or Primary Physician~~ Key Personnel Temporary Leave

If the primary surgeon, ~~or~~ physician, or clinical leader must take a temporary leave of absence or otherwise temporarily cease their active participation with the transplant program, the transplant hospital must:

1. Notify the OPTN Contractor in writing within seven business days.

2. Submit a completed Personnel Change Application to the OPTN Contractor no less than 30 days before the individual's leave begins. The Personnel Change Application must document that the replacement primary surgeon, ~~or~~ physician, or clinical leader meets the requirements of these Bylaws.

Temporary leave is defined in these Bylaws as greater than 30 days but less than one year.

If the transplant hospital receives less than 60 days advance notice of the leave, then the transplant hospital must submit a complete Personnel Change Application to the OPTN Contractor within 30 days from the date the OPTN Contractor was notified.

If a program is unable to demonstrate through a completed Personnel Change Application that it has on site ~~both a transplant surgeon and a transplant physician~~ the required key personnel ~~who meet the requirements for primary surgeon and physician~~, the transplant hospital must *either*:

- Inactivate the designated transplant program.
- Withdraw its designated transplant program status ~~as described in~~ according to *Appendix ~~K~~L:* of these Bylaws.

D. Reinstatement of Previously Designated ~~Primary Surgeon or Primary Physician~~ Key Personnel

If the previously designated primary surgeon, ~~or~~ primary physician, or clinical leader returns to the same transplant program within one year of departure the individual can be considered for reinstatement ~~as the primary surgeon or primary physician~~. The transplant hospital must submit a written reinstatement request to the OPTN Contractor.

The written reinstatement request must include *all* of the following:

1. A letter from the Transplant program director, department chair, or chief of the division, verifying the individual's current working knowledge and experience.
2. A letter from the individual confirming the individual's on-site availability and commitment to the program.
3. A current letter from the hospital credentialing committee verifying that the individual meets the requirements and is qualified and able to resume as primary surgeon, ~~or~~ primary physician, or clinical leader.

The MPSC or an Ad hoc Subcommittee of the MPSC will review requests for reinstatement, as described below. In cases where reinstatement of a surgeon, ~~or~~ physician, or clinical leader affects the transplant program's current status, the MPSC will recommend the appropriate new program status, along with any resulting special conditions.

E. Failure to Notify the OPTN Contractor of Key Personnel Changes

A member's failure to notify the OPTN of a primary surgeon, ~~or~~ physician, or clinical leader change or to submit the required Personnel Change Application within the periods specified will be considered a noncompliance with OPTN Obligations that may result in an OPTN action according to *Appendix ~~L~~M: Reviews and Actions*.

D.~~11~~12 Review of Transplant Program Functional Activity

A. Functional Inactivity

Each transplant program must remain functionally active by performing a minimum number of transplants. For purposes of these Bylaws, functional inactivity is defined as the failure to perform

a transplant during the periods defined according to Table D-~~1~~ 2 below.

Table D-~~1~~2: Functional Inactivity Periods

Program Type	Inactive Period
Kidney, Liver or Heart	*3 consecutive months*
Pancreas or Lung	*6 consecutive months*
Stand-alone pediatric transplant programs	*12 consecutive months*

Functional inactivity thresholds have not been established for ~~pancreatic~~ islet, intestinal, and VCA transplant programs.

D.~~12~~13 Additional Transplant Program Requirements

A. Transplant Program Performance

~~*Appendix D.12.A* does not apply to VCA transplants.~~

The MPSC will conduct reviews of transplant program performance to identify underperforming transplant programs and require the implementation of quality assessment and performance improvement measures. One measure of transplant program performance is triggered through a review of the one-year graft and patient survival rates. The MPSC utilizes performance metrics produced by the Scientific Registry of Transplant Recipients (SRTR) as the principal tool to identify transplant programs that have lower than expected outcomes.

For programs performing 10 or more transplants in a 2.5 year period, the MPSC will review a transplant program if it has a higher hazard ratio of mortality or graft failure than would be expected for that transplant program. The criteria used to identify programs with a hazard ratio that is higher than expected will include *either* of the following:

1. The probability is greater than 75% that the hazard ratio is greater than 1.2.
2. The probability is greater than 10% that the hazard ratio is greater than 2.5.

For programs performing 9 or fewer transplants in a 2.5 year period, the MPSC will review a transplant program if the program has one or more events in a 2.5 year cohort.

The MPSC review will be to determine if the higher hazard ratio or events can be explained by patient mix or some other unique clinical aspect of the transplant program. If a program's performance cannot be explained by patient mix or some other unique clinical aspect of the transplant program, the program, in cooperation with the MPSC, will adopt and promptly implement a plan for quality improvement. The member's failure to adopt and promptly implement a plan for quality improvement will be considered a noncompliance with OPTN Obligations and may result in an OPTN action according to *Appendix ~~L~~M: Reviews and Actions*.

As part of this process, the MPSC may conduct a peer visit to the program at the member's expense. The MPSC may also require, at its discretion, that the member participate in an informal discussion. The informal discussion will be conducted according to *Appendix ~~L~~M: Reviews and Actions*.

The MPSC may recommend that a member inactivate a program, or a component of a program, or withdraw its designated transplant program status based on patient safety concerns arising from review of the program's graft and patient survival. The MPSC must offer the member an informal discussion before recommending that the program inactivate or withdraw its designated transplant program status. A program's failure to inactivate or withdraw its designated transplant program status when the MPSC recommends it do so will be considered a noncompliance with OPTN Obligations and may result in an OPTN action according to *Appendix ~~L~~M: Reviews and Actions*.

Appendix G:
Membership and Personnel Requirements for Pancreas ~~and Pancreatic Islet~~ Transplant Programs

This appendix describes the information and documentation transplant hospitals are required to provide when:

- Submitting a completed membership application for approval as a designated pancreas ~~or pancreatic islet~~ transplant program.
- Completing a Personnel Change Application for a change in key personnel at a designated pancreas ~~or pancreatic islet~~ transplant program.

It does not include the general membership requirements that all transplant programs must meet, 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.

~~G.4 Requirements for Designated Pancreatic Islet Transplant Programs~~

~~All pancreatic islet transplant programs must meet the following criteria:~~

1. ~~All of the requirements of a designated pancreas transplant program as defined in the sections above *or* meet the criteria for an exception as detailed in *Section G.4.D: Programs Not Located at an Approved Pancreas Transplant Program* below.~~
2. ~~Demonstrate that the required resources and facilities are available as described in the sections that follow.~~

~~A. Transplant Facilities~~

~~The program must document adequate clinical and laboratory facilities for pancreatic islet transplantation as defined by current Food and Drug Administration (FDA) regulations. The program must also document that the required Investigational New Drug (IND) application is in effect as required by the FDA.~~

~~B. Expert Medical Personnel~~

~~The program must have a collaborative relationship with a physician qualified to perform portal vein cannulation under direction of the transplant surgeon. It is further recommended that the program have on site or adequate access to:~~

1. ~~A board-certified endocrinologist~~
2. ~~A physician, administrator, or technician with experience in compliance with FDA regulations~~
3. ~~A laboratory-based researcher with experience in pancreatic islet isolation and transplantation~~

~~Adequate access is defined as having an agreement with another institution for access to employees with the expertise described above.~~

~~C. Islet Isolation~~

~~Pancreatic islets must be isolated in a facility with an FDA IND application in effect, with documented collaboration between the program and the facility.~~

~~D. Programs Not Located at an Approved Pancreas Transplant Program~~

~~A program that meets all requirements for a designated pancreatic islet transplant program but is not located at a hospital approved as a designated pancreas transplant program may qualify as a pancreatic islet transplant program if the following additional criteria are met:~~

1. ~~The program demonstrates a documented affiliation with a designated pancreas transplant program, including on-site admitting privileges for the primary pancreas transplant surgeon and physician.~~
2. ~~The program provides protocols documenting its commitment and ability to counsel patients about all their options for the medical treatment of diabetes.~~
3. ~~The program demonstrates availability of qualified personnel to address pre-, peri-, and post-operative care issues regardless of the treatment option ultimately selected. An informal discussion with the MPSC is also required.~~

~~G.5 Primary Pancreatic Islet Transplant Surgeon Requirements~~

~~The program must have on site a qualified surgeon who is designated as the primary pancreatic islet transplant surgeon and meets the requirements for pancreas transplant surgeon defined in these Bylaws.~~

~~G.6 Primary Pancreatic Islet Transplant Physician Requirements~~

~~The program must have on site a qualified physician who is designated as the primary pancreatic islet transplant physician and meets the requirements for pancreas transplant physician defined in these Bylaws.~~

Appendix K: Membership and Personnel Requirements for Islet Transplant Programs

This appendix describes the information and documentation transplant hospitals are required to provide when:

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

Transplant programs must also meet certain 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 D: Membership Requirements for Transplant Hospitals and Transplant Programs* of these Bylaws.

K.1 Program Director and Clinical Leader

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

The program must also identify a qualified clinical leader as described below. The clinical leader is responsible for ensuring the operation and compliance of the program according to the requirements set forth in these Bylaws. The transplant hospital must notify the OPTN Contractor immediately if at any time the program does not meet these requirements.

As part of the plan for continuing policy compliance that is required in the membership application, each clinical leader will submit an assessment of all physicians and surgeons in the program. This assessment must include any involvement in prior transgressions of OPTN obligations and plans to ensure compliance. This information is subject to medical peer review confidentiality requirements and must be submitted according to the guidelines provided in the application and to the satisfaction of the Membership and Professional Standards Committee (MPSC).

A. Islet Transplant Program Clinical Leader Coverage (Program Coverage Plan)

The program director, in conjunction with the clinical leader, must submit a detailed Program Coverage Plan to the OPTN Contractor. The Program Coverage Plan must describe how continuous medical and surgical coverage is provided by the clinical leader, expert medical personnel and additional clinicians who have been credentialed by the transplant hospital to provide transplant services to the program.

An islet transplant program must inform its patients if the level of program staffing may create instances where potential unavailability of certain staff could affect patient care, including the ability to accept organ offers, procurement, and transplantation.

The Program Coverage Plan must address *all* the following requirements:

1. Islet transplant programs must have personnel available 365 days a year, 24 hours a day, 7 days a week to provide program coverage, unless a written explanation is provided that justifies the current level of coverage to the satisfaction of the MPSC.
2. Islet transplant programs must provide patients with a written summary of the Program Coverage Plan when placed on the waiting list and when there are any substantial changes in the program or its personnel.
3. An islet clinical leader or additional clinician must be readily available in a timely manner to facilitate organ acceptance, procurement, and transplantation.
4. Unless the MPSC provides an exemption for specific reasons, the clinical leader cannot be designated as the clinical leader at more than one islet transplant hospital unless there are additional clinicians at each of those facilities.
5. Additional clinicians must be credentialed by the transplant hospital to provide islet transplant services and be able to independently manage the care of islet transplant patients.

K.2 Islet Transplant Program Clinical Leader Requirements

The program must identify a surgeon or physician who serves as the clinical leader of the islet transplant program. The clinical leader of the program, 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 *Section K.1.A: Islet Transplant Program Clinical Leader Coverage (Program Coverage Plan)* of these Bylaws.

The islet transplant program clinical leader must meet *all* the following requirements:

1. 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. Be accepted onto the hospital's medical staff, and be on site at this hospital.

3. Have documentation from the hospital credentialing committee that it has verified the clinical leader's state license, board certification, training, and transplant continuing medical education, and that the clinical leader is currently a member in good standing of the hospital's medical staff.
4. Have demonstrated direct involvement in the management and care of at least 6 islet transplant patients, which cumulatively includes selecting donors, evaluating islets, accessing the portal vein for islet transplant procedures, overseeing the islet infusion and managing immunosuppression. Of the 6 islet transplant patients, at least one must be an allogeneic islet transplant patient. The management and care of at least one islet transplant patient must have occurred in the last two years. The management and care of these islet transplant patients must be documented in a log that includes the date of the care provided, the category of care provided as described above, whether the patient was an autologous or allogeneic islet transplant patient, and the patient's medical record number or other unique identifier. This log should be signed by the program director, division chief, or department chair from the program where the experience was gained.
5. Observe or perform at least three islet isolations, of which at least one must be an allogeneic islet isolation. These islet isolations must be documented in a log that includes the date of the isolation procedure, whether the isolation was observed or performed, whether the isolation was for an autologous or an allogeneic islet transplant and the patient's medical record number or other unique identifier for autologous transplant use or donor ID for allogenic transplant use. This log should be signed by the program director, division chief, or department chair from the program where the isolations were observed or performed.
6. Have a background in transplantation medicine, immunosuppression management, beta cell biology, or endocrinology. This background must be demonstrated in documentation submitted to the OPTN contractor of a clinical fellowship lasting at least 6 months in transplantation medicine, transplantation surgery, immunosuppression management, beta cell biology, or endocrinology.
7. The following letters must be submitted directly to the OPTN Contractor:
    a. A letter from the director or Chair of the islet program or the director or Chair of another islet transplant program where the physician or surgeon has served outlining the proposed clinical leader's overall qualifications to act as islet transplant program clinical leader as well as the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN obligations, and any other matters judged appropriate. The MPSC may request similar letters of recommendation from others affiliated with any islet transplant program previously served by the individual, at its discretion.
    b. A letter from the proposed clinical leader that details the training and experience the individual has gained in islet transplantation.

A. Board Certification Requirements for a Surgeon Serving as the Clinical Leader

If the clinical leader is a surgeon, the surgeon must have current certification by the American Board of Surgery, the American Board of Urology, the American Board of Osteopathic Surgery, or the Royal College of Physicians and Surgeons of Canada. In the case of a surgeon who has just completed training and whose American Board of Urology certification is pending, the Membership and Professional Standards Committee (MPSC) may grant conditional approval for 16 months to allow time for the surgeon to complete board certification, with the possibility of one additional 16-month extension.

In place of current certification by the American Board of Surgery, the American Board of Urology, the
American Board of Osteopathic Surgery, the Royal College of Physicians and Surgeons of Canada,
or pending certification by the American Board of Urology, the surgeon must:

a. Be ineligible for American board certification.
b. Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that the surgeon obtains 60 hours of Category I continuing medical education (CME) credits with self-assessment that are relevant to the individual's practice every three years. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program. A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve an acceptable self-assessment score are allowed. The transplant hospital must document completion of this continuing education.
c. Provide to the OPTN Contractor two letters of recommendation from directors of designated transplant programs not employed by the applying hospital. These letters must address:

i. Why an exception is reasonable.
ii. The surgeon's overall qualifications to act as clinical leader of the islet transplant program.
iii. The surgeon's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.
iv. Any other matters judged appropriate.

If the surgeon has not adhered to the plan for maintaining continuing education or has not obtained the necessary CME credits with self-assessment, the transplant program will have a six month grace period to address these deficiencies. If the surgeon has not fulfilled the requirements after the six month grace period, and a key personnel change application has not been submitted, then the transplant program will be referred to the MPSC for appropriate action according to *Appendix M* of these Bylaws. If the OPTN Contractor becomes aware that a clinical leader has not been compliant for 12 months or more and deficiencies still exist, then the transplant program will not be given any grace period and will be referred to the MPSC for appropriate action according to *Appendix M* of these Bylaws.

B. Board Certification Requirements for a Physician serving as the Clinical Leader

If the clinical leader is a physician with a background in transplantation medicine, immunosuppression management, beta cell biology, or endocrinology, the physician must have current board certification in nephrology, endocrinology, immunology, or diabetology by the American Board of Internal Medicine, the American Board of Pediatrics, or the Royal College of Physicians and Surgeons of Canada.

In place of current certification in nephrology, endocrinology, immunology, or diabetology by the American Board of Internal Medicine, the American Board of Pediatrics, or the Royal College of Physicians and Surgeons of Canada, the physician must:

a. Be ineligible for American board certification.
b. Provide a plan for continuing education that is comparable to American board maintenance of certification. This plan must at least require that the physician obtains 60 hours of Category I continuing medical education (CME) credits with self-assessment that are relevant to the individual's practice every three years. Self-assessment is defined as a written or electronic question-and-answer exercise that assesses understanding of the material in the CME program. A score of 75% or higher must be obtained on self-assessments. Repeated attempts to achieve an acceptable self-assessment score are allowed. The transplant hospital must document completion of this continuing education.
c. Provide to the OPTN Contractor two letters of recommendation from directors of designated transplant programs not employed by the applying hospital. These letters must address:

i. Why an exception is reasonable.
ii. The physician's overall qualifications to act as a clinical leader of an islet transplant program.
iii. The physician's personal integrity, honesty, and familiarity with and experience in adhering to OPTN obligations and compliance protocols.

iv. iv. Any other matters judged appropriate.

If the physician has not adhered to the plan for maintaining continuing education or has not obtained the necessary CME credits with self-assessment, the transplant program will have a six month grace period to address these deficiencies. If the physician has not fulfilled the requirements after the six month grace period, and a key personnel change application has not been submitted, then the transplant program will be referred to the MPSC for appropriate action according to *Appendix M* of these Bylaws. If the OPTN Contractor becomes aware that a physician clinical leader has not been compliant for 12 months or more and deficiencies still exist, then the transplant program will not be given any grace period and will be referred to the MPSC for appropriate action according to *Appendix M* of these Bylaws.

K.3 Additional Requirements for Designated Islet Transplant Programs

All islet transplant programs must:

1. Be at a hospital that has approval of a designated pancreas, kidney, liver or intestine transplant program *or* meet the criteria for an exception as detailed in *Section K.4.D: Programs Located at a Hospital that does not have an Approved Pancreas, Kidney, Liver or Intestine Transplant Program* below.
2. Demonstrate that the required resources and facilities are available as described in the sections that follow.

A. Transplant Facilities

The program must document adequate clinical and laboratory facilities for islet transplantation as defined by current Food and Drug Administration (FDA) regulations. The program must also document that the required Investigational New Drug (IND) application or approved Biologics License Application (BLA) is in effect as required by the FDA.

B. Expert Medical Personnel

The program must have on site:

1. A pancreas, kidney, liver, or intestine transplant surgeon
2. A surgeon or interventional radiologist who has performed at least three portal vein access procedures
3. A physician to handle immunosuppression who has managed at least six immunosuppression management cases
4. An endocrinologist or physician who is experienced in metabolic studies

Any individual, including the clinical leader, may fill one or more of the expert medical personnel positions.

C. Additional Medical Personnel

The program must have on site, or adequate access, to:

1. A person with experience in compliance with FDA regulations
2. A diabetes educator
3. A scientist with experience in islet quality assessment

Adequate access is defined as having an agreement with another institution for access to employees with the expertise described above.

D. Programs Located at a Hospital that does not have an Approved Pancreas, Kidney, Liver, or Intestine Transplant Program

A program that meets all requirements for a designated islet transplant program but is not located at a hospital that has approval of a designated pancreas, kidney, liver, or intestine transplant program may qualify as an islet transplant program if the following additional criteria are met:

1. The program demonstrates a documented affiliation with a designated pancreas, kidney, liver or intestine transplant program, including on-site admitting privileges for the pancreas, kidney, liver or intestine transplant program's primary transplant surgeon and physician.
2. The program provides protocols documenting its commitment and ability to counsel patients about all their options for the medical treatment of diabetes.
3. The program demonstrates availability of qualified personnel to address pre-, peri-, and post-operative care issues regardless of the treatment option ultimately selected.

E. Islet Isolation

Islets must be isolated in a facility with an FDA IND or approved BLA application in effect, with documented collaboration between the program and the facility.

Appendix ~~K~~L:
Transplant Program Inactivity, Withdrawal, and Termination

This appendix defines transplant program inactivity, withdrawal, and termination, and outlines what members must do to be in compliance with OPTN obligations during these periods.

~~K~~L.1 Transplant Program Inactivity

Transplant programs must remain active in transplantation to maintain membership in the OPTN. There are two types of member inactivity:

1. Short-term Inactivity
2. Long-term Inactivity

A member may voluntarily inactivate a transplant program, on a short-term or long-term basis, for reasons including but not limited to:

- The inability to meet functional activity requirements.
- The inability to serve potential candidates, candidates, recipients, potential living donors, or living donors for a period of 15 or more consecutive days.
- Temporarily lacking required ~~physician or surgeon~~ key personnel coverage.
- A substantial change in operations that requires an interruption in transplantation.

For more information about the functional activity requirements for transplant programs, see *Section D.~~11~~12: Review of Transplant Program Functional Activity* of these Bylaws.

[Subsequent heading numbers, and any table captions and cross-references, affected by the re-numbering of these bylaws will also be changed as necessary.]

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