

OPTN Membership Application for Islet 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 |
| | Position _____ | |
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Part 1: General Information

Name of Transplant Hospital: _____

OPTN Member Code (4 Letters): _____

Transplant Hospital Address (where transplants occur)

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 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.

| 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 new individual listed.

Part 3: Primary Program Administrator

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

Complete this section only if you are updating the Primary Program Administrator position for the 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.

Complete this section only if you are updating the Primary Data Coordinator position for the program.

Name of Primary Data Coordinator:

Credentials:

Title at Hospital:

Phone Number:

Email:

Part 5: Islet Transplant Program Clinical Leader Requirements

1. Name of Proposed Islet Program Clinical Leader (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 clinical leader 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 clinical leader's resume/CV.

- 2b. Has the clinical leader 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 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.

3. The clinical leader has been directly involved in the management and care of **at least 6** islet transplant patients, with the management and care of **at least one** islet transplant patients having occurred in the last two years. Of the 6 islet transplant patients, **at least one** must be an **allogeneic** islet transplant patient. **This experience must be documented on a log.**

4. The clinical leader has maintained a current working knowledge of all aspects of islet transplantation, defined as direct involvement in islet transplant patient care

Check all that apply

- The clinical leader has been directly involved with selecting donors.
 The clinical leader has been directly involved with evaluating islets.
 The clinical leader has been directly involved with accessing the portal vein for islet transplant procedures.
 The clinical leader has been directly involved with overseeing the islet infusion.
 The clinical leader has been directly involved with managing immunosuppression.

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

-
5. The clinical leader observed or performed **at least three** islet isolations, of which **at least one** must be an allogeneic islet isolation.

This experience must be documented on a log.

6. The clinical leader has a background in transplantation medicine, immunosuppression management, beta cell biology, or endocrinology.

This experience should be reflected in the clinical leader's resume/CV, included with the application.

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

- 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
 - o the proposed clinical leader’s overall qualifications to act as islet transplant program clinical leader,
 - 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 similar letters of recommendation from others affiliated with any islet transplant program previously served by the individual, at its discretion.

- A letter from the proposed clinical leader that details the training and experience the individual has gained in islet transplantation.

8. **The clinical leader is a (check one):**

- Surgeon (if checked, see 9. And do not complete 10.)**
- Physician (if checked, see 10. And do not complete 9.)**

9. **If the clinical leader is a surgeon, check one and provide corresponding documentation:**

- 9a. *The clinical leader is currently certified by the American Board of Urology, the American Board of Osteopathic Surgery, or the Royal College of Physicians and Surgeons of Canada.*
Provide a copy of the clinical leader’s current board certification.
- 9b. *The clinical leader has just completed training and is pending certification by the American Board of Urology, the American Board of Osteopathic Surgery, or the Royal College of Physicians and Surgeons of Canada. Therefore, the clinical leader 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 clinical leader is in the process to be certified.
- 9c. *The clinical leader is without certification from American Board of Urology, the American Board of Osteopathic Surgery, or the Royal College of Physicians and Surgeons of Canada.*
If this option is selected:
 - **The clinical leader 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 clinical leader in islet transplantation,**

- 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.*

10. If the clinical leader is a physician, check one and provide corresponding documentation:

- 10a. The clinical leader is currently certified nephrology, endocrinology, immunology, or diabetology by the American Board of Internal Medicine, the American Board of Pediatrics, of the Royal College of Physicians and Surgeons of Canada.

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

- 10b. The clinical leader is without certification in nephrology, endocrinology, immunology, or diabetology by the American Board of Internal Medicine, the American Board of Pediatrics, of the Royal College of Physicians and Surgeons of Canada.

- The clinical leader 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 clinical leader in islet transplantation,*
 - 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.*

Part 6: Islet Transplant Program Additional Requirements

Yes No

Is the islet transplant program at a hospital that has approval of a designated pancreas, kidney, liver, or intestine transplant program?

If the answer is no, the program must meet the criteria for an exception:

What designated pancreas, kidney, liver or intestine transplant program, is the islet affiliated (including on-site admitting privileges for the pancreas, kidney, liver or intestine transplant program's primary transplant surgeon and physician)?

Name of affiliated program: _____

The islet transplant program provides protocols documenting its commitment and ability to counsel patients about all their options for the medical treatment of diabetes.

Provide this documentation.

The program demonstrates availability of qualified personnel to address pre-, peri-, and post-operative care issues regardless of the treatment option ultimately selected.

Provide this documentation.

Yes No

Are islet cells isolated and processed at a location other than the transplant facility?

If the answer is yes, provide the name(s) of the processor(s) and any available arrangement documentation.

The program must demonstrate that the required resources and facilities are available:

The program has adequate clinical and laboratory facilities for islet transplantation as defined by current Food and Drug Administration (FDA) regulations. **Provide documentation that supports this claim.**

The required Investigational New Drug (IND) application or approved Biologics License Application (BLA) is in effect as required by the FDA. **Provide documentation that supports this claim.**

The program has a letter of agreement or contract with the transplant hospital's OPO that specifically indicates it will provide the pancreas for islet cell transplantation. **Provide the letter of agreement or contract with the OPO.**

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

The program has a pancreas, kidney, liver, or intestine transplant surgeon on site.

Name of transplant surgeon who will be involved in islet program:

The program has a surgeon or interventional radiologist who has performed **at least three** portal vein access procedures on site.

Name of surgeon or interventional radiologist who meets this criteria and will be involved in islet program:

*The program has a collaborative relationship with a physician qualified to perform portal vein cannulation under direction of the transplant surgeon. **Name of physician who meets this criteria and will be involved in islet program:***

*The program has a physician to handle immunosuppression who has managed **at least six** immunosuppression management cases on site.
Name of physician who meets this criteria and will be involved in islet program:*

*The program has on site, or adequate access to a board-certified endocrinologist.
Name of endocrinologist who meets this criteria and will be involved in islet program:*

*The program has an endocrinologist or physician who is experienced in metabolic studies on site.
Name of endocrinologist or physician who meets this criteria and will be involved in islet program:*

*The program has on site, or adequate access, to a person with experience in compliance with FDA regulations.
Name of individual who meets this criteria and will be involved in islet program:*

*The program has on site, or adequate access, to a diabetes educator.
Name of individual who meets this criteria and will be involved in islet program:*

*The program has on site, or adequate access, to a laboratory-based researcher with experience in pancreatic islet isolation and transplantation.
Name of individual who meets this criteria and will be involved in islet program:*

*The program has on site, or adequate access, to a scientist with experience in islet quality assessment.
Name of individual who meets this criteria and will be involved in islet program:*

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

Part 7: Programs Not Located at an Approved Pancreas Transplant Hospital

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. **Name of affiliated transplant hospital:** _____

Provide hospital credentialing letters for the primary pancreas transplant surgeon and physician from the affiliated hospital.

2. The program is committed to and has the ability to counsel patients about all their options for the medical treatment of diabetes. **Provide documented protocols that support this claim.**
3. The program demonstrates availability of qualified personnel to address pre-, peri-, and post-operative care issues regardless of the treatment option ultimately selected. **Provide documentation that support this claim.**

An informal discussion with the MPSC is also required.

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 07/31/2023. 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 2 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.