Pancreas Islet Cell Transplant Program

Part 3: Facilities

This section must be completed when applying for a new program or reactivating an existing program.

1. Does this hospital presently have an OPTN approved pancreas transplant program?
   ___ Yes ___ No. If No, Part 7 of this application will need to be completed.

2. Year Islet Cell Transplant Program to Start (or started):_____

3. Provide the following required documents:

Check list	Required Supporting Documents
	Documentation that verifies that the program has adequate clinical and laboratory facilities for pancreatic islet transplantation as defined by the current regulations provided by the Food and Drug Administration (FDA)
	Copy of the transplant hospital's IND application form (2 pages) and a copy of the letter from the FDA that verifies receipt of the application
	Copy of written documentation provided by the FDA that confirms the active status of the IND (if received by transplant hospital at the time of OPTN application submission)
	Letter of agreement or contract with the transplant hospital's OPO that specifically indicates it will provide the pancreas for islet cell transplantation

4. Islet Isolation – Pancreatic islets must be isolated in a facility with an FDA Investigational New Drug (IND) application in effect, with documented collaboration between the program and such facility. Provide a description of how this criterion is being met.

PART 4: Personnel

PART 4A: Personnel – Transplant Program Director(s)

1. Identify the Surgical and/or Medical Director(s) of the islet cell transplant program (include C.V.). Briefly describe the leadership responsibilities for each.

Check list	Question Reference	Required Supporting Documents
	4A 1	Current C.V.

Name	Date of Appointment	Primary areas of responsibility

PART 4B, Section 1: Personnel – Surgical – Primary Surgeon

1. **Primary Islet Cell Transplant Surgeon.** Refer to the Bylaws for the necessary qualifications and more specific descriptions of the required supporting documents listed below.

Check list	Question Reference	Required Supporting Documents
	4B 1a	Current C.V.
	4B 1c	Letter from the Credentialing Committee of the applicant hospital stating that the surgeon meets all requirements to be in good standing. Please provide an explanation of any status other than active/full
	4B 1d,g,h	Letter from the Surgeon detailing his/her commitment to the program and describing their transplant experience/training.
	4B 1g	Formal Training: A letter from the training director verifying that the fellow has met the requirements
	4B 1g	Formal Training: A log (organized by date) of the transplant and procurement procedures.
	4B 1h	Transplant Experience: A letter from the program director verifying that the individual has met the requirements
	4B 1h	Transplant Experience: A log (organized by date) of the transplant and procurement procedures.
	4B	Other Letters of Recommendation (Reference)
	5a	Letter(s) of recommendation from person(s) named as primary surgeon and program director attesting to the individual's overall qualifications to act as primary surgeon and addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate.

a) Name: _____

b) Is this individual presently designated as the OPTN primary pancreas transplant surgeon for the pancreas transplant program? _____ Yes _____ No.
- If yes, supply the first 3 documents and the final document in the checklist above and answer question "i".
- If no, complete questions "c"-"k".

c)

Date of employment at this hospital (MM/DD/YY) _____
Date assumed role of primary surgeon (MM/DD/YY) _____

Does individual have FULL privileges at this hospital?
_____ Yes Provide copy of hospital credentialing letter.
_____ No If the individual does **not** have full privileges, explain why and provide the date the individual will be considered for full privileges. Include an explanation that describes the scope of privileges.

d) Percentage of professional time spent at this hospital : _____% = _____ hrs/week

e) List below the hospitals, health care facilities, and medical group practices and percentage of professional time spent on site at each:

Facility	Type	Location (City, State)	% Professional Time Spent on Site

f) Board certification type(s) or equivalent. If board certification is pending, indicate the date the exam has been scheduled. If individual has been recertified, **please use that date**.

Certification Type	Certificate Effective Date (MM/DD/YY)	Certificate Valid through Date (MM/DD/YY)	Certification Number

g) Transplant Training: List the name of the transplant hospital(s) at which pancreas, kidney/pancreas and/or islet cell transplant training (fellowship) was received. Include the program director(s) names, applicable dates, and the number of transplants and procurements performed. If the surgeon is qualifying as the primary surgeon through fellowship training also submit the supporting documents listed below. Refer to the Bylaws for the necessary qualifications and detailed descriptions of the required supporting documents.

- A letter from program director verifying that the fellow has met the requirements.
- Logs of the transplant and procurement procedures (Tables 4A and 4B). The logs should include a patient identifier/OPTN ID Number, transplant/procurement date and the surgeon's role in the procedure (i.e., primary or 1st assistant). These logs must be signed by the director of the training program.

Date From – To MM/DD/YY	**Transplant Hospital**	**Program Director**	**# Transplants as Primary Surgeon**			**# Transplants as 1st Assistant**			**# of Procurements as Primary or 1st Assistant**	
			PA	**KP**	**IS**	**PA**	**KP**	**IS**	**PA**	**KP**

h) Transplant Experience (Post fellowship):
List the name of the transplant hospital(s), program director(s) names, applicable dates, and number of pancreas, kidney/pancreas and/or islet cell transplants and procurements performed by the individual at each hospital. Refer to the Bylaws for the necessary qualifications and descriptions of the required supporting documents listed below.

- Letter(s) of reference from the program director(s) listed below.
- Logs of the transplant and procurement procedures (Tables 4A and 4B). The logs should include a patient identifier/OPTN ID Number, transplant/procurement date and the surgeon's role in the procedure (i.e., primary or 1st assistant).
  Each transplant log(s) should be signed by the program director, division chief, or department chair from the program where the experience was gained.

Date From – To MM/DD/YY	**Transplant Hospital**	**Program Director**	**# Transplants as Primary Surgeon**			**# Transplants as 1st Assistant**			**# of Procurements as Primary or 1st Assistant**	
			PA	**KP**	**IS**	**PA**	**KP**	**IS**	**PA**	**KP**

i) Summarize how the surgeon's experience fulfills the membership criteria.
(Check all that apply)

Membership Criteria	Yes
1. On site	
2. Certified by the American Board of Surgery, Urology, Osteopathic Surgery, or the foreign equivalent	
3. Two Year Transplant Fellowship	
a. Primary surgeon or 1st assistant on at least 15 pancreas transplants	
b. Primary surgeon or 1st assistant on at least 10 pancreas procurements	
c. Involved in all levels of pre-, peri-, and post-operative patient care within the last 2 years	
d. Training program approved by the Education Committee of the American Society of Transplant Surgeons or UNOS	
4. Experience (Post Fellowship)	
a. Primary surgeon or 1st assistant on 20 or more pancreas transplants over a minimum of 2 years and a maximum of 5 years	
b. Primary surgeon or 1st assistant on 10 or more pancreas procurements	
c. Involved in all levels of pre-, peri-, and post-operative patient care within the last 2 years	
5. Pediatric Pathway	
a. Program serves predominantly pediatric patients	
b. Individual has maintained current working knowledge in all aspects of pancreas transplantation and patient care within the last 2 years	
c. Transplant hospital has petitioned the Membership and Professional Standards Committee for approval under this pathway	
d. A preliminary interview before the Membership and Professional Standards Committee shall be required	

j) Describe in detail the proposed primary surgeon's level of involvement in this transplant program, and if applicable, describe the surgeon's plan for coverage of transplant programs located in multiple transplant hospitals . (Expand rows below as necessary and use complete sentences (i.e. narrative descriptions) for each).

	Describe Involvement
Management of Patients with Diabetes Mellitus	
Recipient Selection	
Donor Selection	
Histocompatibility and Tissue Typing	
Transplant Surgery	
Immediate Post-Operative and Continuing Inpatient Care	
Post-Operative	

	Describe Involvement
Immunosuppressive Therapy	
Differential Diagnosis of Pancreatic Dysfunction in the Allograft Recipient	
Histologic Interpretation of Allograft Biopsies	
Interpretation of Ancillary Tests for Pancreatic Dysfunction	
Long-Term Outpatient Follow-up	
Coverage of Multiple Transplant Hospitals (if applicable)	
Additional Information:	

k) Describe the proposed primary surgeon's transplant training and experience in the areas listed below. (Expand rows below as necessary and use complete sentences (i.e. narrative descriptions) for each).

	Describe Training/Experience
Management of Patients with Diabetes Mellitus	
Recipient Selection	
Donor Selection	
Histocompatibility and Tissue Typing	
Transplant Surgery	
Immediate Post-Operative and Continuing Inpatient Care	
Post-Operative Immunosuppressive	

Therapy	
Differential Diagnosis of Pancreatic Dysfunction in the Allograft Recipient	
Histologic Interpretation of Allograft Biopsies	
Interpretation of Ancillary Tests for Pancreatic Dysfunction	
Long-Term Outpatient Follow-up	
Additional Information:	

PART 4B, Section 2: Personnel – Additional/OtherSurgeons

Complete this section of the application to describe the involvement, training, and experience of any other surgeons participating in the program. **Surgeons must be designated as Additional or Other as described below**. All surgeons must be listed in Table 1 (Certificate of Investigation) in this application.

The Bylaws provide the following definition of Additional Transplant Surgeon:

> *Additional Transplant Surgeons must be credentialed by the institution to provide transplant services and be able to independently manage the care of transplant patients including performing the transplant operation and procurement procedures.*

Surgeons that also support this program but who do not meet the definition of "primary" or additional," should complete this section as well. The type should be indicated as "other."

Duplicate pages as needed.

PART 4B, Section 2: Personnel – Additional/Other Surgeons

2. **Additional/Other Surgeons** (duplicate this section as needed). Provide the attachments listed below:

Check list	Question Reference	Required Supporting Documents
	4B 2a	Current C.V.
	4B 2b	A letter from the Credentialing Committee of the applicant hospital stating that the surgeon meets all requirements to be in good standing. Please provide an explanation of any status other than active/full.
	4B 2c,e,f	A letter from the Surgeon detailing his/her commitment to the program and level of involvement in substantive patient care.

a) Name: _____

For Pancreas Islet Cell transplantation this individual is classified as (Check only one)
___ Additional Surgeon
___ Other Surgeon

b)

Date of employment at this hospital (MM/DD/YY): _____

Does individual have FULL privileges at this hospital?
_____ Yes Provide copy of hospital credentialing letter.
_____ No If the individual does **not** have full privileges, explain why and provide the date the individual will be considered for full privileges. Include an explanation that describes the scope of privileges.

c) Percentage of professional time spent on site: _____% = _____ hrs/week

d) Board certification type(s) or equivalent. If board certification is pending, indicate the date the exam has been scheduled. If individual has been recertified, **please use that date.**

Certification Type	Certificate Effective Date (MM/DD/YY)	Certificate Valid through Date (MM/DD/YY)	Certification Number

e) Transplant Training (Fellowship): List the name of the transplant hospital(s) at which pancreas, kidney/pancreas and/or islet cell transplant training (fellowship) was received. Iinclude the program director(s) names, applicable dates, and the number of transplants and procurements the individual performed.

Date From – To MM/DD/YY	**Transplant Hospital**	**Program Director**	**# Transplants as Primary Surgeon**			**# Transplants as 1st Assistant**			**# of Procurements as Primary or 1st Assistant**	
			PA	**KP**	**IS**	**PA**	**KP**	**IS**	**PA**	**KP**

f) Transplant Experience (Post fellowship): List the name of the transplant hospital(s), program director(s), applicable dates, and number of pancreas, kidney/pancreas and/or islet cell transplants and procurements performed by the individual at each hospital .

Date From – To MM/DD/YY	**Transplant Hospital**	**Program Director**	**# Transplants as Primary Surgeon**			**# Transplants as !st Assistant**			**# of Procurements as Primary or 1st Assistant**	
			PA	**KP**	**IS**	**PA**	**KP**	**IS**	**PA**	**KP**

g) Describe the surgeon's level of involvement in this pancreas islet transplant program in the areas listed below. (Expand rows as necessary and use complete sentences (i.e. narrative descriptions) for each).

	Describe Involvement
Management of Patients with Diabetes Mellitus	
Recipient Selection	
Donor Selection	
Histocompatibility and Tissue Typing	
Transplant Surgery	
Immediate Post-Operative and Continuing Inpatient Care	
Post-Operative Immunosuppressive Therapy	
Differential Diagnosis of Pancreatic Dysfunction in the Allograft Recipient	
Histologic Interpretation of Allograft Biopsies	
Interpretation of Ancillary Tests for Pancreatic Dysfunction	
Long-Term Outpatient Follow-up	
Coverage of Multiple Transplant Hospitals (if applicable)	
Additional Information:	

h) Describe the surgeon's pancreas and pancreas islet transplant training and experience in the areas listed below. (Expand rows as necessary and use complete sentences (i.e. narrative descriptions) for each).

	Describe Training/Experience
Management of Patients with Diabetes Mellitus	
Recipient Selection	
Donor Selection	
Histocompatibility and Tissue Typing	
Transplant Surgery	
Immediate Post-Operative and Continuing Inpatient Care	
Post-Operative Immunosuppressive Therapy	
Differential Diagnosis of Pancreatic Dysfunction in the Allograft Recipient	
Histologic Interpretation of Allograft Biopsies	
Interpretation of Ancillary Tests for Pancreatic Dysfunction	
Long-Term Outpatient Follow-up	
Additional Information:	

PART 4C, Section 1: Personnel – Medical – Primary Physician

1. **Primary Islet Cell Transplant Physician.** Refer to the Bylaws for necessary qualifications. Provide the attachments listed below.

Check list	Question Reference	Required Supporting Documents
	4C 1a	Current C.V.
	4C 1c	Letter from the Credentialing Committee of the applicant hospital stating that the physician meets all requirements to be in good standing. Please provide an explanation of any status other than active/full.
	4C 1d,g,h	Letter from the Physician detailing his/her commitment to the program; level of involvement with substantive patient care; and summarizing their previous transplant experience.
	4C 1g	Formal Training: A letter from training director verifying that the fellow has met the requirements
	4C 1g	Formal Training: A letter from supervising qualified pancreas transplant physician verifying that the fellow has met the requirements
	4C 1g	Formal Training: Log(s) (organized by date of transplant) of the transplant recipients followed.
	4C 1h	Transplant Experience: A letter from qualified transplant physician and/or pancreas transplant surgeon directly involved with the individual verifying that the individual has met the requirements
	4C 1h	Transplant Experience: Logs (organized by date of transplant) of the transplant recipients followed.
	4C	Other Letters of Recommendation (Reference)
	5a	Letter(s) of recommendation from person(s) named as primary physician and program director attesting to the individual's overall qualifications to act as primary physician and addressing the individual's personal integrity, honesty, familiarity with and experience in adhering to OPTN requirements and compliance protocols, and other matters as deemed appropriate

a) Name:_____

b) Is this individual presently designated as the OPTN primary pancreas transplant physician for the pancreas transplant program? _____ Yes _____ No.
- If Yes, supply the first 3 documents and the final document requested above and answer question "j".
- If no, complete questions "c" – "l".

c)
Date of employment at this hospital (MM/DD/YY):' _____
Date assumed role as primary physician (MM/DD/YY): _____

Does individual have FULL privileges at this hospital?
_____ Yes Provide copy of hospital credentialing letter.
_____ No If the individual does **not** have full privileges, explain why and provide the date the individual will be considered for full privileges. Include an explanation that describes the scope of privileges.

d) Percentage of professional time on site: _____% = _____ hrs/week

e) List below other hospitals, health care facilities, and medical group practices and percentage of professional time spent on site at each facility:

Facility	Type	Location (City, State)	% Professional Time Spent on Site

f) Board certification type (s) or equivalent. If board certification is pending, indicate the date the exam has been scheduled. If individual has been recertified, **please use that date.**

Certification Type	Certificate Effective Date (MM/DD/YY)	Certificate Valid through Date (MM/DD/YY)	Certification Number

g) Training (Fellowship): List the program(s) at which pancreas, kidney/pancreas, and/or islet cell transplant training was received. Include the name of the transplant hospital(s), program director(s) names, applicable dates, and the number of transplant patients for whom the physician provided substantive patient care (pre-, peri- and post-operatively from the time of transplant). If the physician is qualifying as the primary physician through fellowship training, also submit the supporting documents listed below.

Refer to the Bylaws for the necessary qualifications and descriptions of the required supporting documents .

- Letters from the Director of fellowship training program and the supervising qualified pancreas transplant physician verifying that the fellow has met the requirements.
- Recipient log (organized by date of transplant) that includes the date of transplant and the patient's medical record and/or OPTN ID number (Table 4C). Each log must be signed by the director of the training program and/or primary transplant physician at that transplant program.

Date From To mm/dd/yy	Transplant Hospital	Program Director	# Pancreas Patients Followed			# Kidney/Pancreas Patients Followed			# Islet Patients Followed		
			Pre	Peri	Post	Pre	Peri	Post	Pre	Peri	Post

h) Transplant Experience (Post fellowship only): List the name of the transplant hospital(s), program director(s) names, applicable dates, and number of pancreas, kidney/pancreas, and/or islet cell transplant patientsfor whom the Transplant Physician accepted primary responsibility for substantive patient care (pre-, peri-, and post-operatively from the time of transplant). Refer to the Bylaws for the necessary qualifications and descriptions of the required supporting documents listed below.

- Supporting letter(s) from the qualified transplant physician and/or the pancreas transplant surgeon who has been directly involved with the individual
- Recipient log that includes the date of transplant and the patient's medical record and/or OPTN ID number (Table 4C). Each log should be signed by the program director, division chief, or department chair from the program where the experience was gained.

Date From To mm/dd/yy	Transplant Hospital	Program Director	# Pancreas Patients Followed			# Kidney/Pancreas Patients Followed			# Islet Patients Followed		
			Pre	Peri	Post	Pre	Peri	Post	Pre	Peri	Post

i) Training/Experience. Describe how the physician fulfills the criteria for participating as an observer in 3 organ procurements and 3 pancreas transplants, as well as observing the evaluation of the donor and donor process, and management of at least 3 multiple organ donors that include the pancreas.

- Provide a log (Table 4D) of these cases that includes the date of procurement/transplant, medical record ID number and/or OPTN ID number, and the location of the donor.
- If these criteria have not been met, submit a plan explaining how the individual will fulfill them.

Date From To mm/dd/yy	Transplant Hospital	# of PA Procurements Observed	# of PA Transplants Observed	# of PA Donors/ Donor Process	# of Multi-Organ Donors Observed Mgmt.

j) Summarize how the Transplant Physician's experience fulfills the membership criteria. (Check all that apply)

Membership Criteria	Yes
1. On site	
2. M.D., D.O. or equivalent degree	
3. Certified by the American Board of Internal Medicine, Pediatrics or the foreign equivalent in:	
a. Nephrology	
b. Endocrinology	
c. Diabetology	
4. Achieved eligibility in:	
a. Nephrology	
b. Endocrinology	
c. Diabetology	
5. Direct involvement in pancreas transplant patient care within the last 2 years	
6. 12-month Transplant Medicine Fellowship	
a. Involved in primary care of 8 or more pancreas transplant recipients for a minimum of 3 months from the time of their transplant	
b. Observed 3 procurements and 3 pancreas transplants	
c. Observed the evaluation of the donor and donor process, and management of at least 3 multiple organ donors which include the pancreas	
d. Didactic curriculum approved by the RRC-IM	
7. Experience in pancreas transplantation	
a. 2-5 years experience on an active pancreas transplant service	
b. Involved in primary care of 15 or more pancreas transplant recipients for a minimum of 3 months from the time of their transplant	
c. Observed 3 procurements and 3 pancreas transplants	
d. Observed the evaluation of the donor and donor process, and management of at least 3 multiple organ donors which include the pancreas	
8. Pediatric Pathway	

Membership Criteria	Yes
a. Program serves predominantly pediatric patients	
b. Individual has maintained current working knowledge in all aspects of pancreas transplantation and patient care within the last 2 years.	
c. Transplant hospital has petitioned the Membership and Professional Standards Committee for approval under this pathway	
d. A preliminary interview before the Membership and Professional Standards Committee shall be required	
9. Conditional Pathway – ***Only available to Existing Programs***	
a. Board certified in nephrology, endocrinology, or diabetology	
b. Qualifying by virtue of training	
i. Involved in the primary care of 4or more pancreas transplant recipients for a minimum of 3 months from the time of their transplant	
c. Qualifying by virtue of acquired clinical experience	
i. Involved in the primary care of 8 or more pancreas transplant recipients for a minimum of 3 months from the time of their transplant	
ii. Has acquired experience equal to 12 months on an active pancreas transplant service over a maximum of 2 years	
d. Consulting relationship established with counterparts at another member transplant hospital approved for pancreas transplantation (include letter of support)	

k) Describe in detail the proposed primary transplant physician's involvement in the management of patients in this program and, if applicable, their plan for coverage of multiple transplant hospitals . (Expand rows as necessary and use complete sentences (i.e. narrative descriptions) for each).

	Describe Involvement
Management of Patients with End Stage Pancreas Disease	
Candidate Evaluation Process	
Donor Selection	
Recipient Selection	
Histocompatibility and Tissue Typing	
Immediate Post-Operative Patient Care	
Post-Operative Immunosuppressive Therapy	
Differential Diagnosis of Pancreas Dysfunction in the Allograft Recipient	
Histologic Interpretation of Allograft Biopsies	
Interpretation of Ancillary Tests for Pancreas	

Dysfunction	
Long-term Outpatient Follow-up	
Coverage of Multiple Transplant Hospitals	
Additional Information	

l) Describe the proposed primary physician's transplant training and experience in the areas listed below. (Expand rows as necessary)

	Training/Experience
Management of Patients with End Stage Pancreas Disease	
Candidate Evaluation Process	
Donor Selection	
Recipient Selection	
Histocompatibility and Tissue Typing	
Immediate Post-Operative Patient Care	
Post-Operative Immunosuppressive Therapy	
Differential Diagnosis of Pancreas Dysfunction in the Allograft Recipient	
Histologic Interpretation of Allograft Biopsies	
Interpretation of Ancillary Tests for Pancreas Dysfunction	
Long-term Outpatient Follow-up	
Additional Information	

PART 4C, Section 2: Personnel – Additional/Other Physicians

Complete this section of the application to describe the involvement, training, and experience of other physicians associated with the program. **Physicians must be designated as Additional or Other as described below**.

All physicians must be listed in Table 1 (Certificate of Investigation) in this application.

The Bylaws provide the following definition of Additional Transplant Physician:

> *Additional Transplant Physicians must be credentialed by the institution to provide transplant services and be able to independently manage the care of transplant patients.*

Physicians that also support this program but who do not meet the definition of "primary" or "additional," should complete this section of the application. The type should be indicated as "other."

Duplicate pages as needed.

PART 4C, Section 2: Personnel – Additional/Other Physicians

2. **Additional/Other Physicians** (Duplicate this section as needed). Refer to the Bylaws for the necessary qualifications and descriptions of the required supporting documents listed below.

Check list	Question Reference	Required Supporting Documents
	4C 2a	Current C.V.
	4C 2b	A letter from the Credentialing Committee of the applicant hospital stating that the physician meets all requirements to be in good standing. Please provide an explanation of any status other than active/full.
	4C 2c,e,f	A letter from the Physician detailing his/her commitment to the program and level of involvement in substantive patient care.

a) Name: _____

For Pancreas Islet Cell transplantation this individual is classified as (Check only one)
___ Additional Physician
___ Other Physician

b)
Date of employment at this hospital (MM/DD/YY): _____

Does individual have FULL privileges at this hospital?
_____ Yes Provide copy of hospital credentialing letter.
_____ No If the individual does **not** have full privileges, explain why and provide the date the individual will be considered for full privileges. Include an explanation that describes the scope of privileges.

c) Percentage of professional time spent on site: _____% = _____ hrs/week

d) Board certification type(s) or equivalent. If board certification is pending, indicate the date the exam has been scheduled. If individual has been recertified, **please use that date.**

Certification Type	Certificate Effective Date (MM/DD/YY)	Certificate Valid through Date (MM/DD/YY)	Certification Number

e) Transplant Training (Fellowship): List the program(s) at which pancreas, kidney/pancreas, and/or islet cell transplant training was received. Iinclude the name of the transplant hospital(s), program director(s) names, applicable dates, and the number of transplant patients for whom the physician provided substantive patient care (pre-, peri- and post-operatively from the time of transplant).

Date From To mm/dd/yy	Transplant Hospital	Program Director	# Pancreas Patients Followed			# Kidney/Pancreas Patients Followed			# Islet Patients Followed		
			Pre	Peri	Post	Pre	Peri	Post	Pre	Peri	Post

f) Transplant Experience (Post fellowship only): List the name of the transplant hospital(s), program director(s), applicable dates, and number of pancreas, kidney/pancreas, and/or islet cell patients for whom the transplant physician accepted primary responsibility for substantive patient care (pre-, peri-, and post-operatively from the time of transplant).

Date From To mm/dd/yy	Transplant Hospital	Program Director	# Pancreas Patients Followed			# Kidney/Pancreas Patients Followed			# Islet Patients Followed		
			Pre	Peri	Post	Pre	Peri	Post	Pre	Peri	Post

g) Describe in detail the transplant physician's involvement in this islet cell transplant program. (Expand rows as necessary and use complete sentences (i.e. narrative descriptions) for each).

	Describe Involvement
Management of Patients with End Stage Pancreas Disease	
Candidate Evaluation Process	
Donor Selection	
Recipient Selection	
Histocompatibility and Tissue Typing	
Immediate Post-Operative Patient Care	
Post-Operative Immunosuppressive Therapy	
Differential Diagnosis of Pancreas Dysfunction in the Allograft Recipient	
Histologic Interpretation of Allograft Biopsies	
Interpretation of Ancillary Tests for Pancreas Dysfunction	
Long-term Outpatient Follow-up	
Additional Information	

h) Describe the physician's transplant training and experience in the role of transplant patient management in the areas listed below. (Expand rows as necessary and use complete sentences (i.e. narrative descriptions) for each).

	Training/Experience
Management of Patients with End Stage Pancreas Disease	
Candidate Evaluation Process	
Donor Selection	
Recipient Selection	
Histocompatibility and Tissue Typing	
Immediate Post-Operative Patient Care	
Post-Operative Immunosuppressive Therapy	
Differential Diagnosis of Pancreas Dysfunction in the Allograft Recipient	
Histologic Interpretation of Allograft Biopsies	
Interpretation of Ancillary Tests for Pancreas Dysfunction	
Long-term Outpatient Follow-up	
Additional Information	

Part5: Supporting Personnel

1. Provide documentation that verifies that the program has a collaborative relationship with a physician qualified to cannulate the portal system under direction of the transplant surgeon.

   Name of designated physician: _____

   Provide the following supporting documentation:

Check list	Required Supporting Documents
	Current C.V.
	A letter from the Credentialing Committee of the applicant hospital that states that the physician is qualified to perform this procedure and has privileges to practice in this hospital. Please provide an explanation of any status other than active/full.
	A letter from the physician detailing his/her level of commitment to the program.

2. Describe the program's access to the personnel listed below. Include the individual's name, and if they are on site or not. (Adequate access is defined by an agreement of affiliation with counterparts at another transplant hospital who employ individuals with the expertise described below). Provide a letter of commitment/support from each individual listed.

   a) Board-certified endocrinologist

      Name: _____

      Percentage of time on site: _____

      Provide the following supporting documentation:

Check list	Required Supporting Documents
	Current C.V.
	A letter from the Credentialing Committee of the applicant hospital that indicates if the physician has privileges to practice in this hospital. Please provide an explanation of any status other than active/full.
	A letter from the physician detailing his/her level of commitment to the program and involvement with substantive patient care.

   b) A physician, administrator, or technician with experience in compliance with FDA regulations.

      Name: _____

      Percentage of time on site: _____

      Provide the following supporting documentation:

Check list	Required Supporting Documents
	Current C.V.
	A letter from the physician detailing his/her level of commitment and experience.

c) A laboratory-based researcher with experience in pancreatic islet isolation and transplantation.

Name: _____

Percentage of time on site: _____

Provide the following supporting documentation:

Check list	Required Supporting Documents
	Current C.V.
	A letter from the physician detailing his/her level of commitment and experience.

Part 6: Programs not Located at an Approved Pancreas Transplant Hospital

A program that meets all requirements for a pancreatic islet transplant program set forth in the Bylaws, including, without limitation, requirements applicable generally for membership and without regard to organ specificity, with the sole exception that the program is not located at a transplant hospital approved under the Bylaws to perform whole pancreas transplantation, may nevertheless qualify as a pancreatic islet transplant program.

A preliminary interview with the Membership and Professional Standards Committee is required for programs seeking approval under this pathway.

Please provide the following additional documentation to demonstrate that this program can qualify for approval under this pathway.

1. Provide documentation of an affiliation relationship with an OPTN approved pancreas transplant program, including on site admitting privileges at this applicant hospital for the primary whole pancreas transplant surgeon and physician.

   a) Name of Affiliated transplant hospital: _____

   b) Name of designated surgeon: _____

   Percentage of time on site: _____

   Provide the following supporting documentation for this surgeon:

Check list	Required Supporting Documents
	Current C.V.
	A letter from the Credentialing Committee of the applicant hospital that states that the surgeon has on site admitting privileges. Please provide an explanation of any status other than active/full.
	A letter from the surgeon detailing his/her level of commitment to the program and involvement with substantive patient care.

   c) Name of designated physician: _____

   Percentage of time on site: _____

   Provide the following supporting documentation:

Check list	Required Supporting Documents
	Current C.V.
	A letter from the Credentialing Committee of the applicant hospital that states that the physician has on site admitting privileges. Please provide an explanation of any status other than active/full.
	A letter from the physician detailing his/her level of commitment to the program and involvement with substantive patient care.

2. Provide documentation that demonstrates the availability of qualified personnel to address pre-, peri-, and post-operative care issues regardless of the treatment option ultimately selected.

3. Provide a copy of the written protocols that demonstrate the program's commitment and ability to counsel patients regarding all their options for appropriate medical treatment for diabetes.

Table 1: Certificate of Investigation

List all transplant surgeons and physicians currently involved in the program,

The Bylaws state that "***Each primary surgeon or primary physician*** *listed on the application as a part of the plan for* ***who shares coverage responsibility*** *shall submit an assessment, subject to medical peer review confidentiality requirements and which follows guidelines provided in the application and is satisfactory to the MPSC, of* ***all physicians and surgeons*** *participating in the program regarding their involvement in prior transgressions of UNOS requirements and plans* ***to ensure that the improper conduct is not continued."*** *(Emphasis added)*

a) This hospital has conducted its own peer review of all surgeons and physicians listed below to ensure compliance with applicable OPTN/UNOS Bylaws.

Names of Surgeons*

Names of Physicians*

b) If prior transgressions were identified, has the hospital developed a plan to ensure that the improper conduct is not continued? ____ Yes ___ No ___ Not Applicable

c) If yes, what steps are being taken to correct the prior improper conduct or to ensure the improper conduct is not repeated in this program? Provide a copy of the plan.

I certify that this review was performed for each named surgeon and physician according to the hospital's peer review procedures.

Signature of Primary Surgeon: Date:

Print name:

Signature of Primary Physician: Date:

Print name:

* Expand rows as needed.

Table 2 - Program Coverage Plan

Please answer the questions below and provide a written copy of the current Program Coverage Plan. The plan must be signed by either:

a. the OPTN/UNOS Representative;
b. the Program Director(s); or
c. the Primary Surgeon and Primary Physician.

In accordance with the Bylaws, the program director, in conjunction with the primary transplant surgeon and transplant physician, must submit to UNOS a written Program Coverage Plan, which documents how 100% medical and surgical coverage is provided by individuals credentialed by the transplant hospital to provide transplant service for the program. A transplant program served by a single surgeon or physician shall inform its patients of this fact and potential unavailability of one or both of these individuals, as applicable, during the year. The Program Coverage Plan must address the following requirements:

	Yes	**No**
Is this a single surgeon program?		
Is this a single physician program?		
If the answer to either one of the above questions is "Yes," explain the protocol for notifying patients.		
Does this transplant program have transplant surgeon(s) and physician(s) available 365 days a year, 24 hours a day, 7 days a week to provide program coverage?		
If the answer to the above question is "No", an explanation must be provided that justifies why the current level of coverage should be acceptable to the MPSC.		
Transplant programs shall provide patients with a written summary of the Program Coverage Plan at the time of listing and when there are any substantial changes in program or personnel. Has this program developed a plan for notification?		
Is a surgeon/physician available and able to be on the hospital premises within one-hour ground transportation time to address urgent patient issues?		
Is a transplant surgeon readily available in a timely manner to facilitate organ acceptance, procurement, and implantation?		
Unless exempted by the MPSC for specific causal reasons, the primary transplant surgeon/primary transplant physician cannot be designated as the primary surgeon/primary transplant physician at more than one transplant hospital unless there are additional transplant surgeons/transplant physicians at each of those facilities. Is this program requesting an exemption? If yes, provide explanation below.		
Additional information:		

Table 3: OPTN Staffing Report

PANCREAS ISLET TRANSPLANT PROGRAM

Member Code:	Name of Transplant Hospital:	
Main Program Phone Number	Main Program Fax Number:	Hospital URL: http://www
Toll Free Phone numbers for Patients: Hospital #: Program #:		

Answer the questions below for this transplant program. Since this information will be used to update UNet[sm] and the Membership Directory, make sure to include the best (most accurate) telephone number and address for each person. Use additional pages as necessary. The surgeons and physicians named below should match those listed on the Certificate of Investigation.

Identify the **Transplant Program Medical and/or Surgical Director(s)**:

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

The **surgeons** who perform transplants are:

Name	**Additional**	**Other**	**Address**	**Phone**	**Fax**	**Email**

The **physicians** (internists) who participate in this transplant program are:

Name	Additional	Other	Address	Phone	Fax	Email

Identify the **Hospital Administrative Director/Manager** who will be involved with this program: **Use an * to indicate** which individual will serve as the primary Transplant Administrator if more than one is listed.

Name	Address	Phone	Fax	Email

Identify the **Financial Counselor(s)** who will be involved with this program:

Name	Address	Phone	Fax	Email

The **clinical transplant coordinators** who participate in this transplant program are:

Name	Address	Phone	Fax	Email

List the **data coordinators** for this transplant program below. **Use an * to indicate** which individual will serve as the primary data coordinator.

Name	Address	Phone	Fax	Email

Identify the **Social Worker(s)** who will be involved with this program:

Name	Address	Phone	Fax	Email

Identify the **Pharmacist (s)** who will be involved with this program:

Name	Address	Phone	Fax	Email

Identify the **Director of Anesthesiology** who will be involved with this program:

Name	Address	Phone	Fax	Email

Identify the **Designated FDA Regulations Expert(s)** who will be involved with this program

Name	Address	Phone	Fax	Email

Identify the **Designated Laboratory-based Researcher** who will be involved with this program:

Name	Address	Phone	Fax	Email

Table 4A – Primary Surgeon - Transplant Log (Sample)
Complete a separate form for each transplant hospital

Organ:	
Name of Proposed Primary Surgeon:	
Name of transplant hospital where transplants were performed:	
Date range of surgeon's appointment/training: MM/DD/YY to MM/DD/YY	

List cases in date order

#	Date of Transplant	Medical Record/ OPTN ID #	Primary Surgeon	1st Assistant
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				
21				
22				
23				
24				
25				
26				
27				
28				
29				
30				

Extend lines on log as needed
Patient ID should <u>not</u> be name or Social Security Number.

Director's Signature: _____ Date: _____

Table 4B - Primary Surgeon - Procurement Log (Sample)
Complete separate form for each transplant hospital

Organ:	
Name of Proposed Primary Surgeon:	
Name of transplant hospital where surgeon was employed when procurements were performed:	
Date range of surgeon's appointment/training: MM/DD/YY to MM/DD/YY	

List cases in date order

#	Date of Procurement	Medical Record/ OPTN ID # of Donor	Location of Donor (hospital)	Comments (LRD/CAD/Multi-organ)
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
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28				
29				
30				
31				
32				
33				
34				
35				

Extend lines on log as needed

Director's Signature: _____ Date: _____

Table 4C - Primary Physician – Recipient Log (Sample)

Complete separate form for each transplant hospital

Organ:	
Name of Proposed Primary Physician:	
Name of transplant hospital where transplants were performed:	
Date range of physician's appointment/training: MM/DD/YY to MM/DD/YY	

List cases in date order.

List only those patients followed for 3 months from the time of transplant (including pre-, peri-, and post-operative management)

#	Date of Transplant	Medical Record/ OPTN ID #	Pre-Operative	Peri-Operative	Post-Operative (90-days follow-up care)	Comments
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						
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22						
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30						
31						
32						
33						
34						
35						

Extend lines on log as needed

Director's Signature: _____ **Date:** _____

Table 4D - Primary Physician – Observation Log (Sample)

Organ:	
Name of Proposed Primary Physician	
Name of hospital where physician was employed when observations were performed	
Date range of physician's appointment/training MM/DD/YY to MM/DD/YY	

In the tables below, document how the physician fulfills the requirements for participation as an observer in organ procurements and transplants, as well as observing the selection and management of at least 3 multiple organ donors that include the organ for which application is being submitted. *List cases in date order*.

Procurements Observed

#	Date of Procurement	Medical Record/ OPTN ID #	Location of Donor (Hospital)
1			
2			
3			
4			
5			

Transplants Observed

#	Date of Transplant	Medical Record/ OPTN ID #	Location (Transplant Hospital)
1			
2			
3			
4			
5			

Donor Selection and Management

#	Date of Procurement	Medical Record/ OPTN ID #	Location of Donor (Hospital)	Specify Organ specific or Multi-organ?
1				
2				
3				
4				
5				

Table 4E - Reporting: Islet Cell Transplants Performed by Transplant Hospital Center Code _____

Once approved the program must submit data to UNOS through use of standardized forms. Data requirements include submission of information on all deceased and living donors, potential transplant recipients, and actual transplant recipients. Pending development of standardized data forms for pancreatic islet transplantation, the program must provide patient logs to UNOS every six months and on an annual basis, reporting transplants performed, by patient name, social security number, date of birth, and donor identification number, as well as whether patient is alive or dead, and whether the pancreas was allocated for islet or whole organ transplantation. The logs shall be cumulative.

Islet Cell Transplants Performed by Transplant Hospital (to date) – sort by Patient ID, then by transplant date.

#	Date of Transplant	Pt. Name	SSN	Date of Birth	Donor ID Number(s)	Pt. Status Alive/deceased	Pancreas allocated for Islet or whole organ
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							
13							
14							
15							
16							
17							
18							
19							
20							

Table 4F - Report – Pancreas Allocation

Center Code: _____

For each donor pancreas allocated to the program for islet transplantation, the program must report to UNOS whether the islets were used for clinical islet transplantation and, if not, why and their ultimate disposition, together with such other information as requested on the Pancreatic Islet Donor Form.

(*List in date order)*

#	Date Pancreas allocated	Islets used for clinical Islet TX	If no, Explain	Disposition
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				