Canadian Blood Services
Société canadienne du sang

Pancreas Data Working Group Report

November 04, 2016

For reprints, please contact:
Canadian Blood Services
1800 Alta Vista Drive
Ottawa ON K1G 4J5
Canada
613-739-2300
E-mail : info@blood.ca

Production of this report has been made possible through a financial contribution from Health Canada, and the Provinces and Territories (excluding Québec).

Letter of Introduction

One of the strategic objectives of Canadian Blood Services is to leverage the organization's services, tools, expertise and knowledge in, support of the national effort to improve patient outcomes. In alignment with this objective is the effort undertaken by the Organ Donation and Transplantation (ODT) Data Working Groups to build on a vision, defined by the Canadian Council for Donation and Transplantation (CCDT) in collaboration with the ODT community, for an integrated information system where, *"Every Canadian who needs a transplant has equitable and timely access to safe tissues and organs, and every Canadian who wishes to donate is optimally supported so donation is compassionate, safe and efficient."* (Information Management Blueprint, CCDT April 25, 2007).

Accurate, relevant and timely data is a critical enabler of a better information management system and Canadian Blood Services is proud to work with its national and provincial partners to continue evolving the CCDT vision, a vision that was further articulated at the June 2013 ODT Data, Analytics and Reporting System Workshop. Through the contributions made by the (ODT) Data Working Groups, we are steps closer to achieving the strategic imperative for improved, fair and transparent information management. The data identified will provide clarity for listing and allocation, organ-specific criteria which will in turn inform the evolving shared programs in the Canadian Transplant Registry (CTR).

On behalf of Canadian Blood Services, we would like to thank the Pancreas Data Working Group (PDWG) members for their participation. This effort represents an important step in building a national data system that will serve the needs of clinicians and researchers by facilitating clinical practice decision-making, developing standards, and informing outcomes reporting for pancreas and islet transplantation in Canada. It builds on work done previously by the CCDT, which included forums to consult with health professionals and other stakeholders on best practices in listing and allocation of organs.

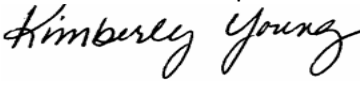
The report begins with a description of the objectives of the PDWG, including the scope, guiding principles, key considerations and the process followed by the group to arrive at a minimum data set. Chapter Seven of the report provides a summary of the recommendations and emerging issues that will be forwarded to the Pancreas Transplant Advisory Committee (PTAC). Subsequent chapters, still in development, will be released in the coming months and will outline how the data identified in the minimum data set will be collected, validated, measured, accessed, and audited.

Future work involves laying the fundamental building blocks of the new data system. Using this report, and the final reports of all ODT Data Working Groups, the following initiatives will be undertaken:

- communication of the report contents with ODT Operational groups and committees
- consolidation of the minimum data sets from all data working groups
- enhancement of the CTR to include the new data
- modification of existing data feeds, the development of new feeds or the implementation of CTR links with other data repositories
- implementation of data collection projects
- creation/revision of inter-provincial organ-sharing policies
- development of a process for accessing the CTR data system for research purposes
- implementation of standard data reviews
- establishment of regular performance and audit measures

Our work has just begun. We look forward to the opportunity to continue working together in key stakeholder groups to further advance this important initiative.

Kimberly Young, Director
Donation and Transplantation



Kathryn Tinckam, Medical Advisor
Transplantation

November 04, 2016

Table of Contents

1. Acronyms

CCDT	**Canadian Council for Donation and Transplantation**
CIHI	**Canadian Institute for Health Information**
CITR	**Collaborative Islet Transplant Registry**
CORR	**Canadian Organ Replacement Register**
CNTRP	**Canadian National Transplant Research Program**
CTR	**Canadian Transplant Registry**
DDDWG	**Deceased Donor Data Working Group**
ISAC	**Information Strategy Advisory Committee**
IPTR	**International Pancreas Transplant Registry**
PDWG	**Pancreas Data Working Group**
PTAC	**Pancreas Transplant Advisory Committee**
NHSBT	**National Health Services Blood and Transplant**
ODT	**Organ Donation Transplantation**
SRTR	**Scientific Registry of Transplant Recipients**

2. Background

The Pancreas Data Working Group (PDWG) was convened by Canadian Blood Services in October 2014 to develop pancreas and islet transplant data sets that will facilitate clinical practice decision-making, develop standards, and inform outcomes reporting for pancreas and islet transplantation in Canada. Canadian Blood Services is responding to the vision articulated in 2007 – and revisited at the June 2013 Organ Donation and Transplantation (ODT) Data, Analytics and Reporting System Workshop – to build a world-leading data system that provides timely access to high quality ODT information for patient care, system management, transplant measurement, outcome reporting, and accountability.

The provincial and territorial governments have funded Canadian Blood Services to continue to lead the development and operation of the Canadian Transplant Registry (CTR). The national registry system includes a data warehouse with business intelligence tools that provide accurate, timely, and comprehensive data to support research, measurement, and the modeling and analytical needs of the Canadian organ donation and transplantation community.

The PDWG had the following objectives:

1. Provide expert advice on data that will support inter-provincial and national operational and clinical policies, standards of practice, and evidence-based practice with respect to pancreas listing and allocation;
2. Develop pancreas and islet transplant data sets to facilitate clinical practice decision-making, develop practice standards, inform outcome reporting, and advance the science of pancreas and islet transplantation; and
3. Develop a framework for the creation and application of pancreas and islet transplant performance measures to track the quality and outcomes of care across the country.

The report recommends a national pancreas and islet data set to be incorporated in a Pan-Canadian organ donation and transplantation system, and advises on the development of data, analytics, and reporting for pancreas transplantation in Canada. In addition, it summarizes key considerations and activities of PDWG. The report will be presented and discussed at the Pancreas Transplant Advisory Committee (PTAC) and at the Information Strategy Advisory Committee (ISAC). This will be followed by further discussions with key stakeholder groups.

3. Scope of the Data Working Group

PDWG's scope encompasses matters related to inter-provincial pancreas and islet transplant practices, including listing and allocation practices and transplant outcomes in support of the CTR. To contribute to the data needs that will inform clinical decisions with respect to pancreas and islet transplantation and outcomes reporting, PDWG will:

1. Identify data points along the pancreas and islet donation, allocation, and transplantation critical path that are important to characterize and evaluate the journey of patients through the transplantation process;
2. Identify the availability and gaps in current data for living and deceased pancreas donors and recipients, and the comparability of data amongst transplant programs;
3. Develop a minimum data set for pancreas and islet transplantation with regards to wait-listing, events after wait-listing, the transplant procedure, and both short- and long-term outcomes; and
4. Advise on the scope of pancreas and islet data to improve health information management.

4. Principles

Building on the vision developed by CCDT in collaboration with the ODT community for better information management across Canada's OTDT System, Canadian Blood Services, in support of its role to lead the development and operation of the CTR and its shared programs, is committed to re-affirming the direction set for this vision, and to continuing to evolve a national information management network. This vision was further articulated at the June 2013 ODT Data, Analytics and Reporting System Workshop, at which a set of guiding principles for data was proposed that will promote accurate, timely and valid data that will move us closer to greater transparency in information management. The PDWG focused on these principles to guide it through the development of a national data set and assist it with the recommendations presented in this report. The principles are as follows:

1. Primarily, adopt the eight guiding principles for national organ transplant and donation data management as recommended by the participants of the June 2013 Data Analytics and Reporting System Workshop. The guiding principles focus on:
    a. Governance
    b. Data Scope
    c. Data Compliance
    d. Data Standardization
    e. Data Quality
    f. Data Stewardship
    g. Data Accessibility
    h. System Efficiency

In addition to the guiding principles listed above, the PDWG expanded its list of guiding principles to encompass elements specific to its scope of developing a national minimum data set for pancreas transplantation:

2. Data collection will be instrumental in advancing scientific, evidence-based healthcare.

3. Data chosen for the national data set is meaningful, comparable, measurable and unambiguous, making data collection easy for data collectors.

4. The national data set will provide guidance on data definitions and interpretations where national data standardization is required. It will serve as a national minimal data platform, while provincial data sets can include additional data.

5. PDWG will ensure that the national data set lends itself to national and international benchmarking by pancreas transplant programs.

5. Key Considerations

During the development of the national minimum data set, PDWG made the following considerations:

1. The changes required as a result of the recommended national data set will impact pancreas transplant program data collection and reporting processes.

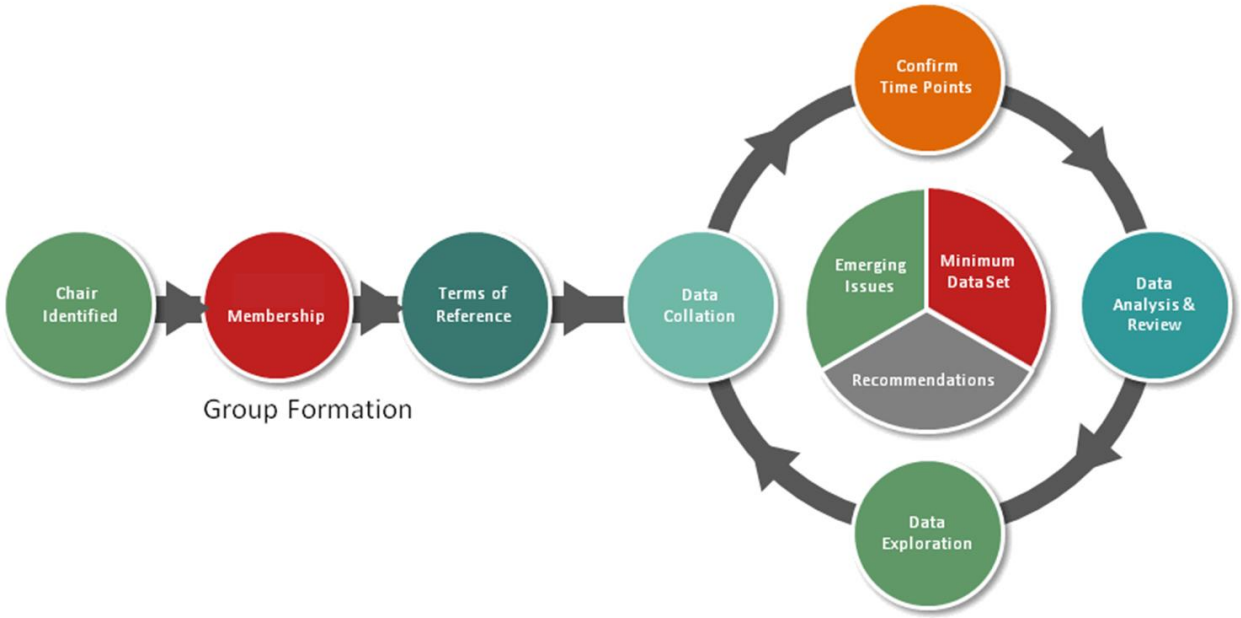
2. There is a definite financial impact to stakeholders due to the need for increased resources, infrastructure, and the development of the requirements necessary to support the recommended data collection and data linkages between systems.

3. The data set considers national practices and the data needs of all health care professionals involved on the patient critical pathway.

4. The transplant and donation community is working towards a national data, analytics, and reporting system that will benefit pancreas transplantation in Canada.

6. Process

The diagram below outlines the basic process methodolgy adopted by the group.



6.1 Group Formation

The Chair of the PDWG was appointed by Canadian Blood Services. Canadian Blood Services met with the Chair to discuss the objectives and scope of the PDWG. Once members of the PDWG were identified, an initial face-to-face meeting was convened to agree on terms of reference and the approach which PDWG would take to achieve its objectives. The PDWG informed Canadian Blood Services regarding the data sources they would analyze and review. Monthly teleconference meetings were set up in collaboration with Canadian Blood Services to discuss emerging issues, develop recommendations and gain expertise from other knowledge areas.

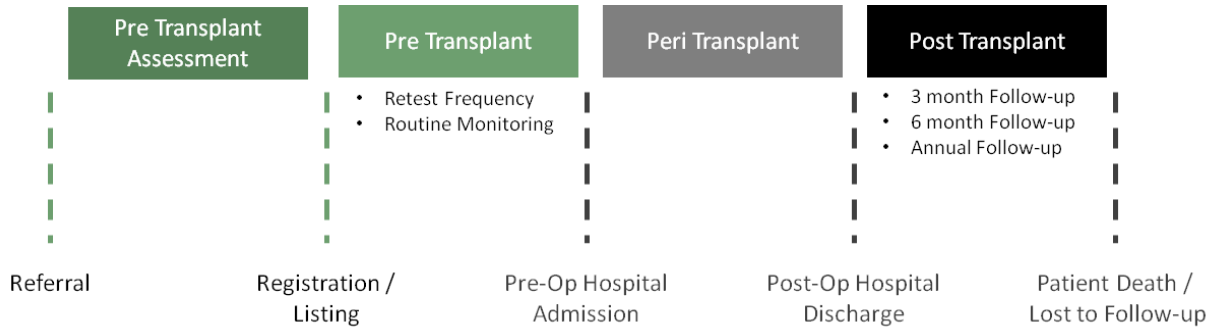
6.2 Data Collation

In order to best inform pancreas transplant reporting practices, an assessment of other transplant registries from the international community was produced by Canadian Blood Services. The outcome of this assessment was an environmental scan, containing data elements captured in CTR and other transplant registries. This would provide the group with perspective on what mature registries are collecting and would help inform what elements might be missing from the CTR. Secondly, there are some organ-specific organizations that perform detailed data collection that might be facilitated by the CTR in the future, and this review process presented an excellent opportunity to capture these data needs as well. The following sources were utilized as comparators by the PDWG:

1. Canadian Organ Replacement Register (CORR) – Canada
2. United Network of Organ Sharing (UNOS) – United States
3. National Health Services Blood and Transplant (NHSBT) Registry – Great Britain
4. International Pancreas Transplant Registry (IPTR)
5. Collaborative Islet Transplant Registry (CITR)

6.3 Time Point Definition

In the interest of consistency and thoroughness, a detailed timeline was necessary in order to ensure that all major events and data were captured at the appropriate point along the patient's critical pathway. The PDWG agreed on five specific reference points and four time periods in order to inform clinical practices and improve patient care through the transplant process. The major time points/periods are as follows:



Defining these different reference points is necessary in order to gain a clear understanding of the impact on both users and data systems.

Time Point	Definition	Rationale for Collection
Referral	Time when patient is first referred to pancreas transplant program	Monitors initial time point when patient becomes known to the transplant centre.
Registration / Listing	Time when patient is activated on the pancreas transplant waiting list or activated for living donor transplant	Provides a snapshot of patient information at the time of wait-listing for deceased donor pancreas, or at time of suitability for living donor transplant.
Pre-Transplant	From the time of registration/listing up to pre-op hospital admission	This time range results from routine monitoring and testing that may occur while the patient is waiting for a transplant.
Peri- Transplant	From pre-op admission date to post-op hospital discharge, including the transplant surgery	This time range includes all surgical detail and complications as well as early graft function and treatment details up to the time of discharge from hospital after the pancreas transplant procedure.
Post-Transplant	From hospital discharge to graft failure, death, or lost to follow-up	This time range includes regular follow-up/updates at three months, six months, twelve months and annually thereafter as long as the allograft is functioning.

6.4 Data Analysis and Review

The PDWG was responsible for highlighting potential data gaps and determining what elements are required to reconcile these disparities. To accommodate the identification of data gaps, the environmental scan was organized along two axes: data category and time point (chronology). This set up provided the PDWG with a detailed understanding of what elements are currently collected in the CTR for different data categories (see Appendix B for details) at each major time point from referral through to follow-up. This framework, coupled with indicators of what other major international registries and pertinent pancreas community organizations are collecting, provided the PDWG with the means to perform a detailed scan of the various data areas and bolster the data element list where needed.

The identification of data gaps, while not formally documented, is indicated in the environmental scan, where new data fields were added, modified, or expanded.

The PDWG employed an iterative review approach in order to refine the data set and ensure that all aspects of the recipient's critical path were captured with the appropriate level of detail.

As part of the analysis process, specific sub-areas of interest were assigned to individual members for further independent exploration. The results of these analyses were presented to the larger group for discussion, modification, approval, and inclusion into the final data set.

7. Recommendations

7.1 Minimum Data Set

The national pancreas and islet data sets are detailed in Appendix B and C respectively. Both appendices contain a detailed description of the data set. They present the data element and description grouped by the defined time points.

7.2 Deceased Donor Data

The PDWG made a recommendation on deceased donor data that should be mandatory from the perspective of the pancreas community. This recommendation will be taken to the Deceased Donor Data Working Group (DDDWG) and will be considered as part of the development of the deceased donor minimum data set. The recommended data is presented in Appendix D – Deceased Donor Data for Pancreas Community.

7.3 Time Points

The PDWG identified several key time points along a patient's critical path, and recommended that certain elements be collected at predetermined points along this timeline (See Appendix B). It is the recommendation of the PDWG that these time points and related data gathering practices be adopted nationally for pancreas transplant patient data.

7.4 Quality Control Strategy

Part of the PDWG's scope was to develop a data control strategy by which the quality, completeness, and accuracy of data submissions would be assessed and measured. To help inform the group's strategy recommendations, the PDWG reviewed the outcomes of the Data, Analytics and Reporting Systems Workshop, at which the ISAC outlined a national guiding principle for data quality:

> *High data quality (accurate, reliable, complete, and timely) is paramount to achieving a trusted system from informed decision making. Data should be validated at multiple levels to*

ensure quality (e.g., audits, cross-validation through existing data-sets, checks when entering data, essential data quality recognized at data entry).

Furthermore, the PDWG was presented with the Data Quality Framework, as developed by the CORR:

Canadian Institute for Health Information's (CIHI) Data Quality Framework (2009) sets out an approach to systematically assess, document and improve data quality for all of our data holdings. This framework is based on the five dimensions of quality and helps us identify both strengths and limitations in our data. After the assessment, we identify how to improve the data, and we provide documentation to help users determine whether the data meets their needs and, if so, how to use it appropriately.

CIHI uses five dimensions to define data and information quality:

i. *Accuracy—How well information from a data holding reflects the reality it was designed to measure*
ii. *Timeliness—How current the data is at the time of release*
iii. *Comparability—The extent to which a data holding is consistent over time and collects data in a way similar to other data holdings*
iv. *Usability—The ease with which data can be accessed and understood*
v. *Relevance—The degree to which a data holding meets users' current and potential future needs*[1]

[1]**Source:** CIHI.ca [online], Health Care Data Quality and Information Quality, available at: http://www.cihi.ca/CIHI-ext-portal/internet/en/tabbedcontent/standards+and+data+submission/data+quality/cihi021513#_Data_Quality_Framework [Accessed 20 Aug 2013]

7.5 Emerging Issues

The PDWG identified a few issues that they felt were important and should be brought to the attention of the ISAC as items with relevance across all organ groups which will require further discussion and development within the CTR. These emerging issues are as follows:

Emerging Issues	Comment	Recommendation
Comorbidities - Adult	Best approach and time points to capture comorbid disease burden of transplant candidates/recipients	Take to ISAC
Serology	Need a national strategy for a serology data set for all organs	Take to ISAC
Data Linkages	Creation of data-linkages with international existing databases.	Take to ISAC

Appendix A – Pancreas Data Working Group Membership

Jeffery Schiff (Chair)	Medical Director, Kidney-Pancreas Transplant Program Toronto General Hospital Toronto, Ontario
Patricia Campbell, MD	Director, Histocompatibility Laboratory Department of Pathology & Laboratory Medicine University of Alberta Edmonton, Alberta
Marcelo Cantarovich, MD	Medical Director, Kidney and Pancreas Transplant Program MUHC – Royal Victoria Hospital Montreal, Quebec
Tammy Keough-Ryan, MD	Staff Nephrologist, Division of Nephrology Capital District Health Authority Halifax, Nova Scotia
Steven Paraskevas, MD	Director, Pancreas and Islet Transplant Program McGill University Health Centre Royal Victoria Hospital Montreal, Quebec
Markus Selzner, MD	Director, Abdominal Organ Transplant Fellowship Associate Professor of Surgery, University of Toronto Toronto General Hospital Toronto, Ontario
Alp Sener, MD	Multi-Organ Transplant Program Western University London Health Sciences Centre – University Hospital London, Ontario
James Shapiro, MD	Medical Director, Clinical Islet Transplant Program University of Alberta Edmonton, Alberta
Kathryn Tinckam, MD	Medical Advisor, Transplantation Canadian Blood Services

Sean Delaney	Associate Director, Listing, Allocation and Transplantation Canadian Blood Services
Machi Danha	Program Manager, Listing and Allocation Canadian Blood Services
Kyle Maru	Data Analyst, Information Management Canadian Blood Services

Appendix B –Pancreas and Islet National Data Set

The PDWG is recommending a national data set of 212 mandatory fields (119 new), 51 optional fields (28 new), 7 fields that are mandatory at the post-transplant point and optional at earlier (6 new) and 51 calculated fields (3 new) for a total of 321 distinct data elements.

Pancreas Data Working Group Data Set Recommendation Summary

	Total	● New Fields	● Modified	● No Change
All Fields	**321**	**156**	**38**	**127**
Mandatory	**219***†	125†	26*	68
Calculated	**51**	3	5	43
Optional	**58***†	34†	8*	16

*Includes 1 item that is optional at pre-transplant and peri-transplant, and mandatory at post-transplant.
†Includes 6 items that are optional prior to transplant and mandatory after transplant

Appendix B lists the recommended data elements being proposed by the PDWG, grouped for the critical path time points outlined in the Process section of this document:

1. Referral (R)
2. Registration / Listing (L)
3. Pre-Transplant (PR)
4. Peri-transplant (PE)
5. Post-transplant (PO)

Beside each element is a letter (M, O or C). These letters indicate whether PDWG is proposing the element as Mandatory (M), Optional (O) or Calculated (C). Each element is listed with a colour indicator. These indicators help demonstrate potential resource impact, both from system design and maintenance perspective as well as a data collection requirement.

● indicates existing mandatory, optional or calculated data elements that will require no change to system function or data collection requirements.

● indicates existing mandatory, optional or calculated data elements that will require some change to system function or data collection requirements. Typically, these indicate fields that have shifted from optional collection to mandatory collection. Though they will have minor impact on system design, the majority of the impact will be on the data collection resources required to collect this data.

● indicates new mandatory, optional or calculated elements that will have both system design impact as well as data collection implications.

Name	Description	Values	Data Rules	R	L	PR	PE	PO
Registration								
Transplant Referral Information								
Year of Diabetes Diagnosis		Year	≤ current year	M	M			
Age of Diabetes Onset		Numeric	Calculated based on date of diagnosis. Age in years.	M	M			
Diabetes Type	aka Cause of Diabetes	Retransplant/Graft Failure Diabetes Mellitus – Type I Diabetes Mellitus – Type II Diabetes Secondary to Chronic Pancreatitis without pancreatectomy Diabetes Secondary to Cystic Fibrosis without pancreatectomy Pancreatic Cancer Bile duct Cancer Other cancers Pancreatectomy prior to Pancreas Transplant Other	Single selection list	M	M			
Date of Transplant Referral		Date	≤ current date	M				
Transplant Consultation Information								
Was patient seen by a physician at the transplant centre?		Yes No	If yes, then date of first visit with physician at the transplant centre	M				
Date of first visit with physician at the transplant centre		Date	≤ current date	M				
Patient died before wait-listing or final disposition		Yes No	n/a	M				
Date of final disposition regarding wait list activation		Date	≤ current date	M				

Name	Description	Values	Data Rules	R	L	PR	PE	PO
Decision regarding final disposition		Activate to deceased donor waiting list Do not activate to deceased donor waiting list	Single selection list. If activate is selected, then specify type (s) of deceased donor waiting lists and specify main reason (s).	M				
Main reason for non-activation to deceased donor waiting list		High-risk cardiovascular disease Recent/metastatic malignancy Active/untreated infection Unstable/untreated psychiatric illness Current drug abuse Poor life expectancy History of poor medical adherence Patient left for another program Patient left country Patient declined Excessive surgical risk Does not meet indications for transplant Other specify	Multiple selection list	M				
Identifying Information								
Date of Birth	Date of birth of patient.	Date	≤ current date	M	M	M	M	M
First Name	First name of patient.	Name	≤ 50 characters		M	M	M	M
Middle Name	Middle name of patient.	Name	≤ 50 characters		O	O		
Last Name	Last name of patient.	Name	≤ 50 characters		M	M	M	M
Former Last Name	Former last name of patient.	Name	≤ 50 characters		O	O		
Local Recipient ID	Unique local identifier provided by local Transplant Program.	Identifier	≤ 50 characters		O	O	O	O
National Recipient ID	Unique national identifier created by the Canadian Transplant Registry.	Identifier	n/a		C	C	C	C

	Name	Description	Values	Data Rules	R	L	PR	PE	PO
	PHN	Provincial health number of patient.	Identifier	≤ 50 characters If patient has a PHN then PHN and PHN Province are required.		M	M	M	M
	PHN/Home/Listing Province	Province associated to PHN or Home or Listing province of patient.	Alberta British Columbia Manitoba New Brunswick, Newfoundland & Labrador Northwest Territories Nova Scotia Nunavut Ontario Prince Edward Island Quebec, Saskatchewan Yukon	If patient has a PHN then PHN and PHN province are required. If patient does not have a PHN then another government health identifier and Home province are required. If patient's home is out of country, then Listing province is required.		M	M	M	M
Contact Information									
	Address	Address where patient can be contacted by Transplant Program This could be a temporary address.	Address line 1 and 2	≤ 70 characters		O			
	City	City associated to patient's address where they can be contacted.	City	≤ 70 characters	M	M			
	Email	Email address used to contact patient.	Text	≤ 50 characters		O			
	Postal Code	Postal code associated to patient's address where they can be contacted.	Postal code	Format must be X9X 9X9	M	M			
	Province	Province associated to patient's address where they can be contacted.	Alberta British Columbia Manitoba New Brunswick, Newfoundland & Labrador Northwest Territories	Single selection list	M	M			

Name	Description	Values	Data Rules	R	L	PR	PE	PO
		Nova Scotia Nunavut Ontario Prince Edward Island Quebec, Saskatchewan Yukon Not Applicable						
Telephone-Home	Telephone-Home used to contact patient.	Phone number	Format must be masked			O		
Telephone-Mobile	Telephone-Mobile used to contact patient.	Phone number	Format must be masked			O		
Telephone-Work	Telephone-Work used to contact patient.	Phone number	Format must be masked			O		
Demographics								
Body Metrics								
Age	Age of patient.	Age in years, months, weeks	Calculated by the system based on Date of Birth.	C	C	C	C	C
Sex	Biological sex of patient.	Male Female Other	Single selection list	M	M			
Height	Height of patient.	cm	If in-utero=no, then this field must be 0.0 to 300.0. Else if in-utero=yes then this field is not required to be entered (it may be null).		M	M	M	M
Weight	Weight of patient.	kg	If in-utero=no, then this field must be 0.0 to 700.0. Else if in-utero=yes then this field is not required to be entered (it may be null).		M	M	M	M
BMI	Body mass index of patient.	Numeric	BMI = weight(kg)/ (height(m) * height(m))		C	C	C	C
Waist Circumference	Wait circumference of patient.	cm	0.0 to 150.0		O	O	O	O

	Name	Description	Values	Data Rules	R	L	PR	PE	PO
●	ABO	Blood group of patient.	A B AB O unknown	Initially ABO may be unknown.		M	M		
●	Confirm ABO	Confirm blood group of patient.	Free text entry	≤ 4 characters		M	M		
●	RH	RH of patient.	+ -	Single selection list		M	M		
●	Confirm RH	Confirm RH of patient.	Free text entry	≤ 4 characters		O	O		
Social Details									
●	Citizenship	Citizenship of patient.	List of countries	Multiple selection list		M		M	
●	Immigration Status	Immigration status of patient.	Citizen Permanent Resident Study Visa Work Visa Visitor Visa	Single selection list		M		M	
●	Country of Residence	Country of Residence of patient.	List of countries	Single selection list		M			
●	Ethnicity	Ethnicity of patient.	Aboriginal Black Caucasian Indian subcontinent Latin American Middle Eastern/Arabian Pacific Islander Other/Multicultural Unknown	Single selection list	M	M			

	Name	Description	Values	Data Rules	R	L	PR	PE	PO
●	Highest Educational Level	Highest educational level of primary care giver and patient.	None Grade 1-6 Grade 7-12 High School Diploma University Undergraduate Degree University Graduate Degree Community College or Vocational Program	Single selection list		O			
●	Academic Activity Level	Pediatric patient's academic activity level.	Full Academic Load Reduced Academic Load Unable to Participate in Academic due to Disease or Condition Not Applicable < 5 Years Old / High School Graduate or GED Status Unknown	Single selection list. Pediatric patients only.		O			
●	Academic Progress	Pediatric patient's academic progress.	Within One Grade Level of Peers Delayed Grade Level Special Education Not Applicable < 5 Years Old / High School Graduate / GED Status Unknown	Single selection list. Pediatric patient only.		O			
●	Working for Income	Working for income of primary care giver and patient.	<20,000/year 20-50,000/year 50-100,000/year >100,000/year Not working Unknown	Single selection list		M		M	M
●	Reason Not Working for Income	Reason not working for income for patient.	Disability Inability to Find Work Patient Choice Unknown	Required if patient is not working for income.		O		O	O
Treating Facilities									
●	Transplant Centre	Centre responsible for providing transplant surgery.	List of Transplant Centres	Single selection list	M	M		M	

Name	Description	Values	Data Rules	R	L	PR	PE	PO
Referral Centre	Centre that assesses/monitors patients before transplant, but does not perform the transplant for the specific organ request (e.g. St John's, Regina). A Transplant Centre may be a Referral Centre for patients of organs for which it does not perform transplants.	List of Transplant Centres and Referral Centres	Single selection list	M	M			
Follow Up Centre	Centre where primary post -transplant follow up takes place. These are centres responsible for pre-transplant and post-transplant care but the actual transplant is carried out by a Transplant Centre.	List of Transplant and Referral Centres	Single selection list		M			
Follow-Up Care Provided By	Physician or health care team providing regular outpatient pancreas transplant care to the patient.	Transplant Centre Non Transplant Centre Specialty Physician Primary Care Physician Other Specify	If other selected, then specify.		M			
HLA Lab	HLA Lab responsible for providing HLA Typing and Antibody Screening results on patient.	List of HLA Labs	Derived by system based on associated Transplant Centre.		M			
ODO	Organ Donation Organization associated to patient's Transplant Centre.	List of ODOs	Derived by system based on associated Transplant Centre.		M			

Name	Description	Values	Data Rules	R	L	PR	PE	PO
Physician								
Referral Physician Type		Nephrologist Endocrinologist Family Doctor General Internist Other		M				
Referral Physician City	City or town where referral physician practices	Text		M				
Consent								
Consent to be in Registry	Date consent to be in CBS registry obtained. If this date is not entered, then identifiable patient information must not be shared.	Date	≤ current date Entered by Canadian Blood Services Customer Solutions only. Conditional mandatory – patients can be listed before written consent received by Canadian Blood Services.		O			
Consent Received by CBS	Consent Form has been received by CBS.	Yes No	Entered by Canadian Blood Services Customer Solutions only. Conditional mandatory – patients can be listed before written consent received by Canadian Blood Services.		O			
Consent for Research	Date consent for research obtained.	Date	≤ current date		O			
Registry Entry Date/Time	Date and time patient record created in registry.	Date and time	n/a		C			
Withdrew Consent	Date and time patient has withdrawn consent to be in the registry.	Date and time			O			

Name	Description	Values	Data Rules	R	L	PR	PE	PO
Organ Request								
Organ Requested	Organ requested for transplant (single or multiple) at time of registration. A patient can have multiple organ requests over time, i.e., one in 1970 and another in 1990.	Heart Lung Liver Pancreas Kidney Small Bowel Stomach	Multiple selection list		M			
Organ Type Requested		Whole Pancreas Islets Right lung Left lung Single lung Single or bilateral lung Bilateral lung Right or Bilateral Lung Left or Bilateral Lung Right Left	Single selection list		M			
Organ Request State	State of patient's readiness to accept an offer of an organ.	New File Active On Hold Off List	For each organ requested one state is required.		M			

	Name	Description	Values	Data Rules	R	L	PR	PE	PO
●	Organ Request State Reason	Reason for recipient organ request being changed to a specific state.	<u>On Hold Reasons:</u> Medically Unsuitable – Temporary Psychological Issue (s) – Temporary Not Available (Away) Pending Investigation or Tests Other <u>Off List Reasons:</u> Unsuitable for Transplant – Psychological Unsuitable for Transplant – Non Compliance Medically Unsuitable – Permanent Medically improved no longer eligible Decision Not to Proceed at this time – Patient Choice Transplanted – Out of Country Transplanted – Local – Donor not in CTR Deceased Consent Withdrawn Entered in Error Other	For each organ requested, one reason is required if state = On Hold or Off List.		O			
●	Organ Request State Change Date/Time	Date and Time Organ Request State is updated in registry.	Date and time	Single selection list		C			
●	List Date/Time	Date and time patient is listed.	Date and time	≤ current date/time. ≥ (date of birth - 1 year).		M			
●	Transplant Type	The type of transplant requested i.e. Kidney, combined Kidney-Other.	Single Multiple Same Donor Multiple	Single selection list		M			
	Medical History								
	Past Medical History								
●	Type of Insulin Delivery		Intermittent Continuous (pump)			M	M		
●	Mean Daily Insulin Requirement		Units per day			M			
●	History of Diabetic Retinopathy		Yes No			M			

	Name	Description	Values	Data Rules	R	L	PR	PE	PO
	Previous Cardiac Surgery	Flag indicating if patient has previous cardiac surgery	Yes No	If yes, then specify type of previous cardiac surgery.		M			
	Amputation Status	Patient's amputation status pre-transplant	Yes No	If yes, then specify date of amputation (optional).		M			
	Previous Transplant								
	Date of previous transplant		Date	≤ current date. Previous transplant can be manually entered into CTR or when transplant recorded in registry then this is derived by registry. Multiple dates can be provided for each patient. For combined transplants a date of previous transplant will be derived for each organ transplanted.		M			
	Organ Previously Transplanted		Heart Lung Liver Pancreas Kidney Small Bowel Stomach	Single selection list		M			
	Organ Type of Previous Transplant		Right Lung Left Lung Double Lung Whole Liver Left Lobe Liver Right Lobe Liver Whole Pancreas Islets Head Tail Right Kidney Left Kidney	Single selection list		M			

Name	Description	Values	Data Rules	R	L	PR	PE	PO
		Dual Kidney						
Transplant Centre of Previous Transplant		List of transplant centres	Single selection list		O			
Number of Previous Transplants		Numeric	Calculation of previous transplants by system. Transplants that took place before CTR can be added and included in the calculation.		C			
Previous Graft Failure Date		Date	≤ current date		O			
Diagnoses								
Organ Primary Diagnosis	The diagnoses that is responsible for cause of organ failure.	Retransplant/Graft Failure Diabetes Mellitus – Type I Diabetes Mellitus – Type II Diabetes Secondary to Chronic Pancreatitis without pancreatectomy Diabetes Secondary to Cystic Fibrosis without pancreatectomy Pancreatic Cancer Bile duct Cancer Other cancers Pancreatectomy prior to Pancreas Transplant Other	Single selection list. If other specify selected, then diagnosis required.		M			
Organ Secondary Diagnosis	A secondary diagnosis that may have contributed to the organ failure but was not the primary cause of organ failure (e.g., membranous nephropathy as primary and diabetes as secondary).	Retransplant/Graft Failure Diabetes Mellitus – Type I Diabetes Mellitus – Type II Diabetes Secondary to Chronic Pancreatitis without pancreatectomy Diabetes Secondary to Cystic Fibrosis without pancreatectomy Pancreatic Cancer Bile duct Cancer Other cancers Pancreatectomy prior to Pancreas Transplant Other	Single selection list. If other specify selected, then diagnosis required.		O			

Name	Description	Values	Data Rules	R	L	PR	PE	PO
Pancreatic Diagnoses								
Prior Use of Oral Hypoglycemic		Yes No Unknown	Single selection list		M	M		
Diabetic Complications: Diabetic Neuropathy	Flag indicating if patient has diabetic neuropathy (based on patient symptoms)	Yes No Unknown	Single selection list		M	M		
Diabetic Complications: Diabetic Retinopathy	Flag indicating if patient has diabetic retinopathy, and if so, whether intervention was applied	Yes: Intervention Yes: No intervention Yes: Intervention unknown No Unknown	Single selection list		M	M		
Diabetic Complications: Diabetic Nephropathy	Flag indicating if patient has diabetic nephropathy, defined as microalbuminuria or any more significant renal dysfunction	Yes No Unknown	Single selection list		M	M		
Diabetic Complications: Diabetic Gastro paresis	Flag indicating if patient has diabetic gastro paresis (based on patient symptoms)	Yes No Unknown	Single selection list		M	M		
Hypoglycemia	Flag indicating if patient has episodes of hypoglycemia	Yes No Unknown	Single selection list		M	M		
Comorbidities – For each comorbidity - multiple time points can be captured - required at time of listing, transplant and 1-year post transplant - initial result must be carried forward								
Cardiovascular Disease	Flag indicating if patient has cardiovascular disease	Yes No	Data element to be confirmed during pancreas data set consolidation with heart, lung and liver data sets.		M		M	M

Name	Description	Values	Data Rules	R	L	PR	PE	PO
Cerebral Vascular Disease	Flag indicating if patient has cerebral vascular disease (e.g. any evidence of stroke or TIA)	Yes No	Data element to be confirmed during pancreas data set consolidation with heart, lung and liver data sets.		M		M	M
Peripheral Vascular Disease	Flag indicating if patient has peripheral vascular disease	Yes No	Data element to be confirmed during pancreas data set consolidation with heart, lung and liver data sets.		M		M	M
Congestive Heart Failure	Flag indicating if patient has congestive heart failure.	Yes No	Data element to be confirmed during pancreas data set consolidation with heart, lung and liver data sets.		M		M	M
COPD	Flag indicating if patient has COPD	Yes No	Data element to be confirmed during pancreas data set consolidation with heart, lung and liver data sets.		M		M	M
Hyperlipidemia	Flag indicating if patient has Hyperlipidemia	Yes No	Data element to be confirmed during pancreas data set consolidation with heart, lung and liver data sets.		M		M	M
Hypertension	Flag indicating if patient has Hypertension	Yes No	Data element to be confirmed during pancreas data set consolidation with heart, lung and liver data sets.		M		M	M
Thrombophilia	Flag indicating if patient has Thrombophilia	Yes No	Data element to be confirmed during pancreas data set consolidation with heart, lung and liver data sets.		M		M	M

Name	Description	Values	Data Rules	R	L	PR	PE	PO
Myocardial Infarction	Flag indicating if patient has myocardial infarction	Yes No	Data element to be confirmed during pancreas data set consolidation with heart, lung and liver data sets.		M		M	M
Percutaneous coronary intervention	Flag indicating if patient has percutaneous coronary intervention	Yes No	Data element to be confirmed during pancreas data set consolidation with heart, lung and liver data sets.		M		M	M
Peptic Ulcer Disease		Yes No			M			
Connective Tissue Disease		Yes No			M			
Previous Blood Transfusions		Yes No			M			M
Psychosocial History								
Smoking History	Flag indicating if patient is a current or previous smoker	Yes No Unknown	Single selection list. If yes, then specify whether the patient is current or past smoker.		M			
Current or Past Smoker	Patient smoking in past 6 months is a current smoker	Current Past	Single selection list. If current, then specify pack year history of smoking. If past then specify pack year history of smoking and year quit smoking.		M			
Pack Year History of Smoking		Number	If current or past smoker, then specify pack year history of smoking.		M			
Year Quit Smoking	The last time patient quit smoking	Year	< current year. If past smoker, then specify year quit smoking.		M			

	Name	Description	Values	Data Rules	R	L	PR	PE	PO
●	Family history of diabetes		Type I Type II Both None Unknown	Single selection list		M			
●	Number of pregnancies		Number	< 20		M			M
●	Followed by Psychologist/Psychiatrist		Yes No Unknown	n/a		M			
Malignancies									
●	Malignancy Diagnosis Date	Date of each malignancy diagnosis	Date	≤ current date. For each malignancy that is specified a date is required.		M			M
●	Malignancy	Flag indicating if patient has malignancy and type of malignancy.	Yes No Unknown	Single selection list. If yes, then specify all that apply and the diagnosis date for each: Skin Melanoma Skin Non-Melanoma CNS Tumour Genitourinary Breast Thyroid Tongue/Throat/Larynx Lung Leukemia/Lymphoma Liver Hepatocellular Carcinoma – Liver only Other specify		M			M

	Name	Description	Values	Data Rules	R	L	PR	PE	PO
●	Malignancy De Novo Tumour	Flag indicating patient has Malignancy De Novo Tumour	Yes No Unknown	Single selection list. If yes then specify all that apply: Skin Melanoma, Skin Non-Melanoma, CNS Tumour, Genitourinary, Breast, Thyroid, Tongue, Throat, Larynx, Lung, Leukemia/Lymphoma, Liver, Hepatocellular Carcinoma, Other-please specify		M			M
●	Malignancy De Novo Lymphoproliferative Disease and Lymphoma	Flag indicating Malignancy De Novo Lymphoprofilerative Disease and Lymphoma.	Yes No Unknown	n/a					M
●	Cancer Free Date		Date	≤ current date		M			M
	Laboratory / Diagnostics								
	Serology – For each serology - multiple time points can be captured - a test type must be recorded for each serology result - sample drawn date/time recorded for each result								
●	CMV	CMV result based on IgG test.	Positive Negative Indeterminate Not Tested	Single selection list		M			
●	EBV	EBV result based on the following tests: IgG (VCA) or IgG (EBNA), NAT.	Positive Negative Indeterminate Not Tested	Single selection list Antibody testing used pre-transplant. NAT testing used post-transplant for surveillance.		M			
●	Varicella	Varicella test result based on IgG test	Positive Negative Indeterminate Not Tested	Single selection list.		M			

Name	Description	Values	Data Rules	R	L	PR	PE	PO
Hepatitis B Core Antibody	HBV result based on Anti-HBc (HBcAb) test.	Positive Negative Indeterminate Not Tested	Single selection list		M			
Hepatitis B Surface Antibody	HBV result based on Anti-HBs (HBsAb) test.	Positive Negative Indeterminate Not Tested	Single selection list		M			
Hepatitis B Surface Antigen	HBV result based on the following test: HBsAG test, NAT.	Positive Negative Indeterminate Not Tested	Single selection list		M			
Hepatitis B e Antibody	Hepatitis B e Antibody test result	Positive Negative Indeterminate Not Tested	Single selection list.		O			
Hepatitis B e Antigen	Hepatitis B e Antigen test result	Positive Negative Indeterminate Not Tested	Single selection list		O			
Hepatitis B DNA	Hepatitis B DNA test result	Positive Negative Indeterminate Not Tested	Single selection list		O			
Hepatitis C Antibody	HCV result based on IgG test.	Positive Negative Indeterminate Not Tested	Single selection list		M			
Hepatitis C Genotype	Hepatitis C Genotype test result.	1a 1b 2 3 4 5 6 unknown	Multiple selection list		O			

Name	Description	Values	Data Rules	R	L	PR	PE	PO
Hepatitis D Ab	IgG test	Positive Negative Indeterminate Not Tested	Single selection list		O			
HIV I and II Antibody	HIV I and II result based on any of the following tests: IgG, Antibody/p24antigen.	Positive Negative Indeterminate Not Tested	Single selection list		M			
HIV I and II NAT	HIV I and II result based on any of the following tests: HIV NAT (HIV DNA, HIV Single NAT), Double NAT (HIV, HCV), and Triple NAT (HIV, HCV, and HBV).	Positive Negative Not Tested	Single selection list. Double NAT and Triple NAT cannot be Indeterminate. If HIV NAT positive, then provide viral load.		O		O	
HSV	HSV test result based on IgG.	Positive Negative Indeterminate Not Tested	Single selection list		O			
HTLV I and II	HTLV I and II result based on IgG test.	Positive Negative Indeterminate Not Tested	Single selection list		M			
Syphilis	Syphilis result based on the following tests: EIA, RPR, VDRL, FTA-ABS.	Positive Negative Indeterminate Not Tested	Single selection list		M			
West Nile	West Nile result based on IgG, IgM, NAT.	Positive Negative Indeterminate Not Tested	Single selection list		O			

Name	Description	Values	Data Rules	R	L	PR	PE	PO
Haemotology – For each haemotology - multiple time points can be captured - collection date/time recorded for each result								
Haemoglobin	Hgb	g/L	≥ 0.0 and ≤ 500.0		O			
Haemoglobin A1C	HbA1c	%	≥ 0.0 and ≤ 100.0	O	O			
White Blood Cell Count	WBC	4.0 – 10.0 X 10 9 L	≥ 0.0 and ≤ 99.9		O			
Lymphocyte Count		1.5 - 4.0 X 10 9 L	≥ 0.0 and ≤ 99.9		O			
Platelet Count		130-400 X 10 9 L	≥ 0.0 and ≤ 999.9		O			
INR		ratio	≥ 0.0 and ≤ 999.9		O			
Prothrombin Time	PTT	seconds	≥ 0.0 and ≤ 999.9		O			
Chemistry – For each chemistry - multiple time points can be captured - collection date/time recorded for each result								
Serum Albumin		g/L	≥ 0 and ≤ 99. Required at time of discharge.		M	M		M
Serum Amylase		U/L	≥ 0 and ≤ 9999		M	M		M
Serum Lipase		U/L	≥ 0 and ≤ 9999		M	M		M
C-Reactive Protein (CRP)		U/L	≥ 0 and ≤ 99999		O	O		O

Name	Description	Values	Data Rules	R	L	PR	PE	PO
Electrolytes – For each electrolyte - multiple time points can be captured - collection date/time recorded for each result								
Serum Creatinine		µmol/L	≥ 0 and ≤ 9999		M	M		M
C-peptide		nmol/L	≥ 0 and ≤ 20.		M	M		M
Urine Sample								
Proteinuria		Grams per day	≥ 0 and ≤ 99.		M			M
Cardiothoracic Profile								
Exercise Stress Test		Positive for ischemia Negative for ischemia	Single selection list			O		O
Nuclear Stress Test		Positive for ischemia Negative for ischemia	Single selection list			O		O
Renal Profile								
CrCl Cockroft Gault	Estimated Glomerular Filtration Rate based on Creatinine Clearance.	ml/min/1.73m2	Creatinine Clearance = ((140- Recipient Age at Collection Date) * Weight * constant)/serum creatinine Constant is 1.23 for men and 1.04 for women. Required at time of discharge and post-transplant.				C	C
eGFR-MDRD	Estimated Glomerular Filtration Rate based on MDRD methodology.	ml/min/1.73m2	MDRD = 32788 * Serum Creatinine$^{-1.154}$ * Age at Collection Date$^{-0.203}$ * (1.212 if Black) * (0.741 if female). Note: Creatinine levels in µmol/L can be converted to mg/dL by dividing them by 88.4. The 32788 number above is				C	C

Name	Description	Values	Data Rules	R	L	PR	PE	PO
			equal to 186 * 88.4-$^{1.154}$ Required at time of discharge and post-transplant.					
eGFR-Schwartz	Estimated Glomerular Filtration Rate based on Schwartz methodology.	ml/min/1.73m2	Pediatric patients only Schwartz = (constant * height)/ serum creatinine Constant is 36.5 = (0.413 * 88.4) Required at time of discharge and post-transplant.				C	C
eGFR-CKD/EPI (ml/min/1.73m^2)	Estimated Glomerular Filtration Rate based on CKD-EPI methodology.	ml/min/1.73m2	GFR = 141 * min(Scr/κ,1)$^{\alpha}$ * max (Scr/κ, 1)$^{-1.209}$ * 0.993^{Age} * 1.018 [if female] * 1.159 [if black] Scr is serum creatinine (mg/dL), κ is 0.7 for females and 0.9 for males, α is -0.329 for females and -0.411 for males, min indicates the minimum of Scr/κ or 1, and max indicates the maximum of Scr/κ or 1. Note: Creatinine levels in µmol/L can be converted to mg/dL by dividing them by 88.4.				C	C
HLA Typing – Conditional mandatory rules - Required for virtual cross match								
A_1	HLA typing of patient.	Molecular allele	≤ 20 characters		M			
A_2	HLA typing of patient.	Molecular allele	≤ 20 characters		M			

Name	Description	Values	Data Rules	R	L	PR	PE	PO
B_1	HLA typing of patient.	Molecular allele	≤ 20 characters		M			
B_2	HLA typing of patient.	Molecular allele	≤ 20 characters		M			
C_1	HLA typing of patient.	Molecular allele	≤ 20 characters		M			
C_2	HLA typing of patient.	Molecular allele	≤ 20 characters		M			
DRB1_1	HLA typing of patient.	Molecular allele	≤ 20 characters		M			
DRB1_2	HLA typing of patient.	Molecular allele	≤ 20 characters		M			
DRB3_1	HLA typing of patient.	Molecular allele	≤ 20 characters Of the six text-entry fields which are available for the locus DRB3, DRB4, and DRB5, a maximum of two values may be entered, and a minimum of one value must be entered.		M			
DRB3_2	HLA typing of patient.	Molecular allele	≤ 20 characters		M			
DRB4_1	HLA typing of patient.	Molecular allele	≤ 20 characters		M			
DRB4_2	HLA typing of patient.	Molecular allele	≤ 20 characters		M			
DRB5_1	HLA typing of patient.	Molecular allele	≤ 20 characters		M			
DRB5_2	HLA typing of patient.	Molecular allele	≤ 20 characters		M			
DRB 3/4/5 Tested, but not present	Flag indicating if DRB3, DRB4 and DRB5 tested but not present.	Yes No	When no values are entered for DRB3, DRB4, and DRB5, and the HLA typing is to be considered		M			

Name	Description	Values	Data Rules	R	L	PR	PE	PO
			complete, then indicate that DRB3, DRB4, and DRB5 were “Tested, but not present”.					
DPA1_1	HLA typing of patient.	Molecular allele	≤ 20 characters		M			
DPA1_2	HLA typing of patient.	Molecular allele	≤ 20 characters		M			
DPB1_1	HLA typing of patient.	Molecular allele	≤ 20 characters		M			
DPB1_2	HLA typing of patient.	Molecular allele	≤ 20 characters		M			
DQA1_1	HLA typing of patient.	Molecular allele	≤ 20 characters		M			
DQA1_2	HLA typing of patient.	Molecular allele	≤ 20 characters		M			
DQB1_1	HLA typing of patient.	Molecular allele	≤ 20 characters		M			
DQB1_2	HLA typing of patient.	Molecular allele	≤ 20 characters		M			
HLA Typing Confirmed	User confirms HLA Typing.	Yes No	Default = blank		M			
HLA Typing Confirmed By	User who confirmed HLA Typing along with date/time of confirmation.	Date/Time of Confirmation and User Name	n/a		C			
HLA Typing Complete	System verifies HLA Typing complete based on organ specific rules.	Yes No	n/a		C			
HLA Typing Last Updated By	User who last updated HLA Typing along with date/time of update.	Date/Time of Update and User Name	n/a		C			
HLA Comments	General HLA comments.	Free text comments	≤ 1024 characters		O			

Name	Description	Values	Data Rules	R	L	PR	PE	PO
A_1	HLA typing of patient.	Serological equivalent	Calculated serological equivalent derived from National Canadian HLA Dictionary.		C			
A_2	HLA typing of patient.	Serological equivalent	See rules in A_1 serological equivalent.		C			
B_1	HLA typing of patient.	Serological equivalent	See rules in A_1 serological equivalent.		C			
B_2	HLA typing of patient.	Serological equivalent	See rules in A_1 serological equivalent.		C			
Bw4	HLA typing of patient.	Serological equivalent	Defaulted to a derived value from National Canadian HLA Dictionary User can modify the suggested value.		M			
Bw6	HLA typing of patient.	Serological equivalent	Defaulted to a derived value from National Canadian HLA Dictionary User can modify the suggested value.		M			
Cw_1	HLA typing of patient.	Serological equivalent	See rules in A_1 serological equivalent.		C			
Cw_2	HLA typing of patient.	Serological equivalent	See rules in A_1 serological equivalent.		C			
DR_1	HLA typing of patient.	Serological equivalent	See rules in A_1 serological equivalent.		C			
DR_2	HLA typing of patient.	Serological equivalent	See rules in A_1 serological equivalent.		C			
DR52	HLA typing of patient.	Serological equivalent	See rules in A_1 serological equivalent.		C			
DR53	HLA typing of patient.	Serological equivalent	See rules in A_1 serological equivalent.		C			
DR51	HLA typing of patient.	Serological equivalent	See rules in A_1 serological equivalent.		C			

	Name	Description	Values	Data Rules	R	L	PR	PE	PO
	DPA_1	HLA typing of patient.	Serological equivalent	See rules in A_1 serological equivalent.		C			
	DPA_2	HLA typing of patient.	Serological equivalent	See rules in A_1 serological equivalent.		C			
	DPB_1	HLA typing of patient.	Serological equivalent	See rules in A_1 serological equivalent.		C			
	DPB_2	HLA typing of patient.	Serological equivalent	See rules in A_1 serological equivalent.		C			
	DQA_1	HLA typing of patient.	Serological equivalent	See rules in A_1 serological equivalent.		C			
	DQA_2	HLA typing of patient.	Serological equivalent	See rules in A_1 serological equivalent.		C			
	DQB_1	HLA typing of patient.	Serological equivalent	See rules in A_1 serological equivalent.		C			
	DQB_2	HLA typing of patient.	Serological equivalent	See rules in A_1 serological equivalent.		C			
	Antibody Testing – Conditional mandatory rules - Required for calculated PRA and virtual cross matching								
	Serum Collection Date	Date serum collected for antibody screening.	Date	≤ current date. Required for every antibody screening result provided At least one set of results is required for VXM.	M	M	M		M
	Antibody Testing Method		CDC ELISA Flow Luminex Other	Single selection list	M	M	M		M
	Acceptable Antibody Results	HLA serum results of patient.	Acceptable antigens	Cumulative and current are captured.	M	M	M		M
	Unacceptable Antibody Results	HLA serum results of patient.	Unacceptable antigens	Cumulative and current are captured. Need ability to define unacceptable DQA and DQB combinations.	M	M	M		M

Name	Description	Values	Data Rules	R	L	PR	PE	PO
Indeterminate Antibody Results	HLA serum results of patient.	Indeterminate antigens	Cumulative and current are captured.	M	M	M		M
Not Tested Antibody Results	HLA serum results of patient.	Not tested antigens	Cumulative and current are captured.	M	M	M		M
Allele-Specific Antibody Results	HLA serum results of patient.	Allele specific antigens	Cumulative and current are captured. For every antigen selected as allele specific then the unacceptable molecular allele (s) can be defined.	M	M	M		M
Antibodies Confirmed	User confirms antibody test results.	Yes No	Default = blank	M	M	M		M
Antibodies Confirmed By	User who confirmed HLA Typing along with date/time of confirmation.	Date and time of Confirmation and User Name	n/a	C	C	C		C
PRA Results Calculation Date	Date of calculation by CTR and there could be many things to trigger an update.	Date	n/a	C	C	C		C
Cumulative PRA	Cumulative Class I and II calculated PRA.	%	n/a	C	C	C		C
Cumulative PRA Class I	Cumulative Class I calculated PRA.	%	n/a	C	C	C		C
Cumulative PRA Class II	Cumulative Class II calculated PRA.	%	n/a	C	C	C		C
Current PRA	Current Class I and II calculated PRA.	%	n/a	C	C	C		C
Current PRA Class I	Current Class I calculated PRA.	%	n/a	C	C	C		C
Current PRA Class II	Current Class II calculated PRA.	%	n/a	C	C	C		C

Name	Description	Values	Data Rules	R	L	PR	PE	PO
Medications								
Oral Diabetes Medication		Yes No Unknown	Single selection list		M	M	M	M
Daily units of insulin		Unit			O	O	M	M
Oral Anticoagulants		Yes No Unknown	Single selection list		M	M	M	M
Aspirin		Yes No Unknown	Single selection list		M	M	M	M
Other Antiplatelet Therapy Drug		Yes No Unknown	Single selection list		M	M	M	M
Plasmapheresis		Yes No Unknown	Single selection list				M	M
Ace Inhibitors/ARB		Yes No Unknown	Single selection list				O	O
Intravenous Heparin		Yes No Unknown	Single selection list				M	
Matching								
Donor Acceptance Criteria								
Accept Incompatible ABO	Flag indicating willing to accept incompatible ABO	Yes No	Default = No.		M	M		
Virtual Cross Match								
ABO Match Result	Blood group compatibility test between a donor and list of recipients.	Yes No	If virtual cross match run and patient's blood group exists, then ABO match result provided based on the following rules: - O donor can match to an O, A, B, or AB			C		

Name	Description	Values	Data Rules	R	L	PR	PE	PO
			recipient - A donor can match to an A or AB recipient - B donor can match to a B or AB recipient - AB donor can match to an AB recipient					
VXM Result	HLA compatibility test between a donor and list of recipients.	Positive Negative	If virtual cross match run and patient's antibody results exist, then VXM result provided based on the following rules: Donor-recipient matches are positive when the donor has HLA antigens that have been listed in the recipient's record as being unacceptable.			C		
Actual Cross Match								
HLA Lab who performed actual xm		List of HLA Labs	n/a				C	C
Organ associated to actual xm		Heart Lung Liver Pancreas Kidney Small Bowel Stomach	≤ 100 characters				C	C
Recipient ID associated to actual xm		Identifier	System derived when offer recorded.				C	C
Donor ID associated to actual xm		Identifier	System derived when offer recorded.				C	C
XM Date		Date	≤ current date				M	M

Name	Description	Values	Data Rules	R	L	PR	PE	PO
XM Method		Flow Luminex Unknown	Single selection list.				M	M
XM Result		Negative Positive	Single selection list. Required if XM data entered.				M	M
XM Result Reason		Due to HLA antibody Due to Non-HLA antibody Auto Antibody Allo Antibody Indeterminate Unknown	Single selection list. Required if XM result = positive				O	O
Epitope Analysis		Positive Negative	Single selection list				O	O
Auto XM Serum Date		Date	≤ current date. Require ability to enter multiple auto xm serum dates.				M	M
Auto T Cell		Invalid Negative Weak Positive Positive	Single selection list. Required for each auto xm serum date entered.				M	M
Auto B Cell		Invalid Negative Weak Positive Positive	Single selection list. Required for each auto xm serum date entered.				M	M
Allo XM Serum Date		Date	≤ current date Require ability to enter multiple allo xm serum dates.				M	M
Allo T Cell		Invalid Negative Weak Positive Positive	Single selection list. Required for each allo xm serum date entered.				M	M

Name	Description	Values	Data Rules	R	L	PR	PE	PO
Allo B Cell		Invalid Negative Weak Positive Positive	Single selection list. Required for each allo xm serum date entered.				M	M
Pronase		Yes No	Boolean Required for each auto or allo xm serum date entered.				M	M
Serum Treated		Yes No	Single selection list. Required for each auto or allo xm serum date entered.				O	O
Serum Treatment		DTT Heat EDTA Other	Single selection list. Required if serum treated = yes.				O	O
DSA in Sera		Yes No Predicted (No) Predicted (Yes) Indeterminate Not Tested	Single selection list. Required for each allo xm serum date entered. If DSA in Sera = yes or predicted (yes) then specify DSA details.				M	M
Surgical								
Surgical Details								
Date/Time of Admission to Hospital	Date and time of admission to hospital for transplant.	Date	≤ Current Date. Used to calculate days in hospital.				M	
Perioperative insulin use	Insulin usage in the first 24 hours of transplant	Yes: Hyperglycemia Yes: Program protocol No	Single selection list If Yes, then number of units				M	
Date/Time of Perfusion Fluid Use		Date/Time	≤ current date and time				M	
Preservation Fluid Used after Pancreas Removal	Preservation solution used to perfuse the graft for storage	UW HTK Celsior	Single selection list				M	

Name	Description	Values	Data Rules	R	L	PR	PE	PO
Preservation Fluid Dosage	Dosage of preservation fluid used	ml	≤ 9999				M	
Reflush after vascular reconstruction	Flag indicating if graft was flushed with preservation solution after vascular reconstruction	Yes No	If yes then specify type of preservation solution used – UW, HTK or Celsior				M	
Time on inotropes	Recipient time on inotropes	Time	≤ current date and time				M	
Surgical Procedure	Pancreas transplant surgical procedure type.	Kidney-Pancreas Pancreas Alone Pancreas after Kidney	Single selection list				M	
Graft weight	Weight of graft. Typically, 120 – 170 g.	g	≥ 0 and ≤ 500				O	
Surgical drains placed?	Flag indicating that surgical drain placed	Yes No	Single selection list If yes, then specify site and number				M	
Type of arterial reconstruction		Origin of harvested vessels Iliac Carotid	Single selection list				M	
Donor duodenal management		Enteric Drainage Bladder Drainage	Single selection list				M	
Venous Vascular Management		Portal Systemic (vena cavae)	Single selection list				M	
Venous Extension		None Venous extension to portal vein Venous extension to systemic Other specify	Single selection list				M	
Graft placement		Right side of pelvis Left side of pelvis	Single selection list				M	
Pancreas Volume	Length, width and thickness of graft	cm^3	≤ 9999				M	

Name	Description	Values	Data Rules	R	L	PR	PE	PO
Transplant Date/Time	Date and time of transplant. AKA Recipient Vascular Clamp Release or Clamp Off Time or End Cold Time or Reperfusion Time.	Date	≤ current date. ≥ Donor Cross Clamp Date/Time.				M	
Donor Cross Clamp Date/ Time	Date/Time of aortic cross clamping in deceased donor.	Time	Hr:mm (24-hour time). ≤ current date.				M	
Preservation start time		Time	Hr:mm (24-hour time). ≤ current date. > Cross clamp time.				M	
Preservation end time		Time	Hr:mm (24-hour time). ≤ current date. > Preservation start time.				M	
Reperfusion time		Time	Hr:mm (24-hour time). ≤ current date. > Preservation end time.				M	
Cold Ischemia Time	Time from start to end of preservation.	Duration (hours)	Preservation end time minus start time.				C	
Warm Ischemia Time	Time from end of preservation to reperfusion in recipient.	Duration (minutes)	Reperfusion time minus preservation end time.				C	
Total Ischemia Time		Duration (hours)	Preservation end time minus cross clamp time.				C	
Organ Transplanted	Transplant state of donor's organ after organ recovery	Transplanted Not Transplanted	When transplant date/time recorded then data derived by Registry.				M	

	Name	Description	Values	Data Rules	R	L	PR	PE	PO
●	Reason organ not transplanted	Reason organ not transplanted.	Lack of recipient hospital resources No suitable recipient Organ medically unsuitable for transplant Prolonged cold ischemia time Prolonged warm ischemia time Recipient died Recipient medically unsuitable Storage and preservation problems Technical problem in OR Transportation logistics	If not transplanted is selected, then reason required.				M	
●	Recipient Intended	Flag indicating if recipient was the intended.	Yes No	Single selection list				M	
●	Recipient Not Intended Reason	Reason not intended recipient received organ.	Recipient medically unsuitable Recipient died Positive actual cross match result Recipient unable to travel Recipient refused Organ not as described, Organ test results unacceptable	If not intended recipient, then reason required.				M	
●	Transplant Centre at Time of Transplant	Transplant Centre where transplant took place.	List of Transplant Centres	Single selection list				C	
Peri. and Post-Transplant Complications									
●	Clavien Score		Grade I: Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic and radiological interventions. Allowed therapeutic regimens are: drugs as antiemetics, antipyretics, analgetics, diuretics and electrolytes and physiotherapy. This grade also includes wound infections opened at the bedside. Grade II: Requiring pharmacological treatment with drugs other than such allowed for grade I complications. Blood transfusions and total parenteral nutrition are also included.	Single selection list				M	

Name	Description	Values	Data Rules	R	L	PR	PE	PO
		Grade III: Requiring surgical, endoscopic or radiological intervention Grade III-a: Intervention not under general anesthesia Grade III-b: Intervention under general anesthesia Grade IV: Life-threatening complication (including CNS complications: brain haemorrhage, ischaemic stroke, subarachnoid bleeding, but excluding transient ischaemic attacks) requiring IC/ICU management. Grade IV-a: Single organ dysfunction (including dialysis) Grade IV-b: Multi-organ dysfunction Grade V: Death of a patient Suffix 'd': If the patient suffers from a complication at the time of discharge, the suffix “d” (for ‘disability’) is added to the respective grade of complication. This label indicates the need for a follow-up to fully evaluate the complication.					
Surgical Complication	Clavien score >3B		If clavien score >= 3B then infection details required				M	
Date of Infection		Date	≤ current date.			O	M	M
Infection		Yes No	n/a			O	M	M
Infection Type		Bacterial Viral Fungal Unknown	Multiple selection list			O	M	M

Name	Description	Values	Data Rules	R	L	PR	PE	PO
Infection Location		Pulmonary Gastro-intestinal Urine Soft tissue Line-related Ophthalmologic Other	Multiple selection list			O	M	M
Infection Treated		Yes No	n/a			O	M	M
Anastomotic Leak	aka duodenal leak	Yes No	If yes, then provide date of leak				M	
Date of Anastomotic Leak		Date	≤ current date.				O	
Surgical Re-exploration	Need to take patient back to OR to explore pancreas transplant at any time during transplant admission.	Yes No	Single selection list				M	
Pancreatitis		Yes No	If yes, then provide a date.				M	
Date of Pancreatitis		Date	≤ current date.				O	
Arterial Vascular Thrombosis		Yes No	If yes, then provide a date.				M	
Date of Arterial Vascular Thrombosis		Date	≤ current date.				O	
Venous Vascular Thrombosis		Yes No	If yes, then provide a date.				M	
Date of Venous Vascular Thrombosis		Date	≤ current date.				O	
Major cardiovascular event		Yes No	n/a				M	

Name	Description	Values	Data Rules	R	L	PR	PE	PO
Outcome								
Graft Function								
Morning blood sugar	Transplant hospitalization	mmol/L	Data collection at date of discharge then at 1wk, 1 month, 6 months and annually				M	M
Number of insulin used per day		Units	Data collection at date of discharge then at 1wk, 1 month, 6 months and annually				M	M
Oral hypoglycemic use		Units	Data collection at date of discharge then at 1wk, 1 month, 6 months and annually				M	M
Conv. From Bladder to Enteric Drain Performed Date	This would have to post transplant	Date	< Current date				M	M
Graft Rejection								
Date of pancreas biopsy		Date	≤ current date					M
Biopsy test number	ID number used for biopsies at centre where biopsy was taken.	Identifier	n/a					M
Biopsy Result	Overview of biopsy result.	Normal Intermediate Acute T-Cell mediated rejection Grade I/mild Grade II/moderate Grade III/severe Antibody-mediated rejection Chronic allograft arteriopathy Chronic allograft rejection/graft fibrosis StageI/mild Stage II/moderate Stage III/severe Islet pathology Recurrent autoimmune diabetes	Patient can have more than one diagnosis from a biopsy, apart from “Normal” and “Treated for rejection without biopsy”.					M

Name	Description	Values	Data Rules	R	L	PR	PE	PO
		mellitus Islet amyloid deposition Other – please specify Treated with rejection without biopsy						
Recipient Transplant Biopsy Data Collection Form	For each biopsy recorded an attachment of biopsy data.	Attachment document	For each date of biopsy entered an attachment is required.					M
Date of Rejection		Date	If date provided, then at least one rejection is required (e.g. provide AMR)					M
Acute T cell mediated Rejection	Grade of Acute T cell mediated rejection	Grade I / Mild Grade II / Moderate Grade III / Severe	Single selection list					M
Antibody Mediated Rejection		1 Confirmed circulating DSA 2 Morphological evidence of tissue injury 3 C4d positivity in interacinar capillaries	Multiple selection list					M
Chronic Allograft Rejection	Stage of Chronic Allograft Rejection	Stage I (mild graft fibrosis) Stage II (moderate graft fibrosis) Stage III (sever graft fibrosis)	Single selection list					M
Amylase at time of rejection		U/L	≥ 0 and ≤ 9999					M
Lipase at time of rejection		U/L	≥ 0 and ≤ 9999					M
Treatment at time of rejection		Solumedrol ATG IVIG Plasma Exchange Rituximab Other specify	Multiple selection list					M
Amylase post treatment		U/L	≥ 0 and ≤ 9999					M
Lipase post treatment		U/L	≥ 0 and ≤ 9999					M

	Name	Description	Values	Data Rules	R	L	PR	PE	PO
●	Did rejection lead to graft failure?		Yes No	n/a					M
	Graft Failure								
●	Graft Failure Cause	Cause of graft failure.	Anastamotic/duodenal leak Biopsy-proven isletitis Bleeding Diabetes mellitus type II Infection – bacterial Infection - fungal Infection – viral Infection – CMV Infection - other Pancreatic artery thrombosis Pancreatic vein thrombosis Pancreatitis Recurrent autoimmune diabetes mellitus Rejection – hyperacute Rejection – acute cellular Rejection – acute antibody-mediated Rejection – mixed cellular and antibody-mediated Rejection – chronic Other (free text)					M	M
●	Graft Failure Date		Date	≤ current date If applicable, record at time of discharge.				M	M
●	Date Graft Removed		Date	≤ current date If applicable, record at time of discharge.				M	M
●	Date Insulin Resumed		Date	≤ current date				M	M
●	Date Oral Hypoglycemic started		Date	≤ current date				M	M
●	Patient Pancreatectomy at Graft Failure	Surgical removal of the graft at time of graft failure	Yes No	If applicable, record at time of discharge.				M	M

Name	Description	Values	Data Rules	R	L	PR	PE	PO
Immunological Regimen								
Immunosuppressive Medication - Induction	Induction immunosuppressive regimen patient has been prescribed at time of transplant	Interleukin-2 receptor blocker (e.g., Simulect) Corticosteroids (relevant for rapid corticosteroid withdrawal protocols) Rabbit anti-thymocyte globulin (rATG) Intravenous immunoglobulin (IVIg) Anti-CD20 antibody (e.g., rituximab) Proteosome inhibitor (e.g., bortezomib) C5 inhibitor (e.g., eculizumab) Plasmapheresis (PLEX) Cyclophosphamide Immunoabsorption (e.g., Glycosorb column) Alemtuzumab (i.e., Campath)	Multiple selection list. If applicable, record at time of discharge and post-transplant follow-up. Require ability to capture multiple time points over time. Only at time of transplant				M	M
Immunosuppressive Medication – Maintenance at discharge	Maintenance immunosuppressive regimen patient has been prescribed at discharge	Prograf Advagraf Tacrolimus immediate-release (generic) Tacrolimus extended-release (generic) Neoral Cyclosporine (generic) Sirolimus Everolimus mTOR inhibitor (generic) Cellcept Mycophenolate mofetil (generic) Myfortic Mycophenolate sodium (generic) Azathioprine Oral corticosteroids Leflunomide CTLA-4 costimulation blocker (e.g., belatacept) Other specify	Multiple selection list. If applicable, record at time of discharge and post-transplant follow-up. Require ability to capture multiple time points over time.				M	M
Discharge								
Date of hospital discharge		Date	≤ current date. Used to calculate days in hospital.					M

Name	Description	Values	Data Rules	R	L	PR	PE	PO
Days in ICU		Number	≥ 0 and ≤ 365				M	
Days in Hospital	Number of days a patient in the hospital for transplant (from time of admission to discharge).	Number	Calculated based on date of hospital discharge and date of hospital admission for transplant.					C
Death								
Date of Death		Date	≤ current date. ≥ Date of Birth.			M	M	M
Cause of Death	Primary cause of death.	Accident related to treatment Accident unrelated to treatment Motor vehicle accident Heart Failure Myocardial ischemia and infarction Aortic aneurysm Arterial embolism Cardiac arrest Cardiogenic shock Myocarditis Arrhythmia - specify Brain anoxia Degenerative brain disease Hemorrhage (non-stroke) Stroke Other specify Acute gastroenteritis with dehydration Gastro-intestinal haemorrhage Gastro-intestinal tumour with or without perforation Mesenteric infarction Pancreatitis Perforation of colon/small bowel Perforation of peptic ulcer Sclerosing (or adhesive) peritoneal disease Cause of death, uncertain, not determined Graft infection Non-Specific	Single selection list.			O	O	M

Name	Description	Values	Data Rules	R	L	PR	PE	PO
		Primary failure Recurrent disease Rejection - Acute Antibody-Mediated Rejection - Acute Cellular Rejection - Acute Mixed (Cellular and Antibody-Mediated) Rejection- Chronic Rejection- Hyperacute Technical Bone marrow depression Non-Immuno drug related - hematologic Thrombocytopenia Other specify Thrombosis - specify Disseminated intravas coagulation Gastrointestinal Haemorrhage from vascular access or dialysis circuit Hemorrhagic pericarditis Intraoperative Other specify Post-Operative Respiratory Haemorrhage from graft site - specify Hemorrhage from surgery (not hemorrhage from graft site or vascular access or dialysis) — specify Hemorrhage from vascular access or dialysis circuit Immunosuppressive drug related - hematologic Immunosuppressive drug related - non-hematologic Bacterial pneumonia Bacterial septicemia Bacterial- other specify Cytomegalovirus Epstein Barr Virus						

Name	Description	Values	Data Rules	R	L	PR	PE	PO
		Generalized viral infection - specify viral agent						
		Infection (bacterial) - specify site and pathogen						
		Infection (fungal)- specify site and pathogen						
		Infection (viral) - specify site and pathogen						
		Infections elsewhere (except viral hepatitis)						
		Mixed other specify						
		Other specify						
		Peritonitis						
		Peritonitis (not sclerosing or adhesive peritoneal disease)						
		Pneumocystic carinii pneumonia (PCP)						
		Protozoal/parasitic infection (includes toxoplasmosis)						
		Septicemia/sepsis-specify source						
		Tuberculosis (elsewhere)						
		Tuberculosis (lung)						
		Viral hepatitis looks like a duplicate of Infection (viral) - specify site						
		Viral septicemia						
		Viral- other specify						
		Wound infection – specify site						
		Biliary Strictures						
		Alcoholic Cirrhosis						
		Cirrhosis, not viral						
		Cystic liver disease						
		Liver Failure						
		Liver, due to hepatitis B virus						
		Liver, due to hepatitis C virus						
		Liver, other viral hepatitis						
		Liver, drug toxicity - specify drug						
		Lymphoma						
		Post-Tx lymphoproliferative disorder						
		Malignant disease except malignant disease possibly induced by immunosuppressive therapy—specify primary source						
		Metastatic - other specify						
		Primary - other specify						
		Skin malignancy - other specify						

Name	Description	Values	Data Rules	R	L	PR	PE	PO
		Drug-related toxicity - specify drug						
		Acid/Base Disorder						
		Amyloidosis						
		Cachexia						
		Dementia						
		Diabetes Mellitus						
		Diabetic keto acidosis (DKA)						
		Fluid/Electrolyte Disorder						
		Hypertension						
		Multiple Organ Failure						
		Non-Immuno - Non-Hematologic, Specify Drug						
		Unknown						
		Intraop: Not Hemorrhage - Other Specify						
		Other identified causes of death - specify						
		Trauma - specify						
		Status epilepticus						
		Drug neurotoxicity - specify drug						
		Neurologic infection - specify infectious agent						
		Acute Respiratory Distress Disease						
		Bronchiolitis obliterans						
		Dehiscencepulm: Bronchiolitis						
		Primary pulmonary hypertension						
		Pulmonary embolus						
		Pulmonary infection (bacterial)						
		Pulmonary infection (fungal)						
		Pulmonary infection (viral)						
		Other specify						
		Acute kidney injury						
		Chronic kidney disease						
		Uraemia caused by kidney transplant failure						
		Alcohol abuse						
		Drug abuse (excludes alcohol abuse)						
		Non-Compliance						
		Patient refused further treatment						
		Suicide						
		Therapy ceased for any other reason						
		Pulmonary vein stenosis						
		Ruptured vascular aneurysm						

Name	Description	Values	Data Rules	R	L	PR	PE	PO
		Stent/balloon complication Arterial thrombosis Venous thrombosis						
Graft state at time of death		Died with a functioning graft Died after graft failure	Single selection list			M		M

Appendix D – Deceased Donor Data for Pancreas Community

	Name	Description	Values	Data Rules	Mandatory
	Registration				
	Identifiers				
●	National Donor ID	National donor identifier generated by registry.	Identifier	Calculated by system when record created.	Required to create record
●	Local Donor ID	Local donor identifier entered by OPO.	Identifier	≤ 50 characters	Required to create record
●	Date of Birth	Date of birth of donor.	YYYY-MM-DD	≤ current date	Required to create record
	Demographics				
●	Gender	Gender of donor.	Male Female Other Unknown	Single selection list	Required to create record
●	Height (cm)	Height of donor in cm.	cm	≥ 0.0 and ≤ 300.0	Required to create record
●	Weight (kg)	Weight of donor in kg.	kg	≥ 0.0 and ≤ 700.0	Required to create record
●	ABO	Blood type of donor.	A B O AB unknown	Single selection list	Required for VXM and offer
●	Confirm ABO	Confirm blood group by re-entering blood group.	Free-text	≤ 4 characters	Required for VXM and offer

	Name	Description	Values	Data Rules	Mandatory
●	Ethnicity	Ethnicity of donor.	Aboriginal Asian Black Caucasian Indian subcontinent Latin American Middle Eastern/Arabian Pacific Islander Other/Multicultural	Single selection list	Required for VXM and offer
	Facility				
●	OPO	Organ Procurement Organization responsible for donor.	Abbreviated and full name of OPO	Single selection list	Required to create record
●	HLA lab	HLA lab responsible for providing HLA typing.	Abbreviated and full name of HLA	Derived by system based on associated Transplant Centre.	Required to create record
●	Referral Hospital	Hospital where potential deceased donor is identified.	Hospital name with city	n/a	Required to create record
●	Retrieval Hospital	Hospital where the deceased donor organ procurement surgery takes place.	Hospital name with city	Single selection list	Required to close donor case
	Consent				
●	Pancreas Consent State	Consent state of pancreas.	Consented Not Consented Not Participating	Single selection list	Required for VXM
	Declaration of Death				
	Death				
●	Type of Declaration of Death	Declaration of death could be neurological determination of death (NDD) or donor after cardio circulatory death (DCD).	NDD DCD	Single selection list	Required for VXM

	Name	Description	Values	Data Rules	Mandatory
●	Cause of Death	Deceased donor cause of death.	Encephalitis Anoxia/Hypoxia Arteriovenous malformation Cerebral abscess Cerebral oedema Cerebrovascular accident (stroke) Diabetic ketoacidosis Drug Overdose-Barbiturate Drug Overdose-Benzodiazepine Drug Overdose-Carbon monoxide Drug Overdose-Opiate Fall Gunshot Hepatic failure Hydrocephalus Hyponatremia Inborn error of metabolism Meningitis Motor vehicle collision Primary CNS tumour Ruptured cerebral aneurysm Subarachnoid hemorrhage Unknown Other-comment required	Single selection list	Required for VXM
	DCD				
●	Withdrawal of Life Support Date/Time	Date/Time life support was withdrawn.	Date and time	≤ current date/time and ≥ date of birth of donor. Mandatory for DCD only.	Required to close donor case
●	DCD Declaration Start Date/Time	Start of lack of spontaneous circulation.	Date and time	≤ current date/time and ≥ withdrawal of life support date/time. ≤ DCD Declaration End Date/Time. Mandatory for DCD only.	Required to close donor case
●	DCD Declaration End Date/Time	Confirmation of lack of spontaneous circulation and actual death date/time.	Date and time	≤ current date/time and ≥ withdrawal of life support date/time.	Required to close donor case

	Name	Description	Values	Data Rules	Mandatory
				≥ DCD Declaration Start Date/Time. Mandatory for DCD only.	
	Assessment				
●	Diabetes History	Flag indicating if patient has a history of diabetes.	Yes No Unknown	Single selection list	Required for offer
	Exceptional Distribution				
●	Exceptional Distribution	Flag indicating if donor is exceptional distribution.	Yes No	Single selection list	Required for offer
●	Exceptional Distribution flags	Selectable list of exceptional distribution reasons.	List of exceptional distribution reasons	Multiple selection list	Select reason if Exceptional Distribution = Yes
●	Exceptional Distribution Comments	Comments related to exceptional distribution.	Details	≤ 1024 characters for each comment added	Optional
	HLA				
●	A_1	HLA typing of donor.	Molecular allele	≤ 20 characters	Required for VXM
●	A_2	HLA typing of donor.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM
●	B_1	HLA typing of donor.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM
●	B_2	HLA typing of donor.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM
●	C_1	HLA typing of donor.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM
●	C_2	HLA typing of donor.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM
●	DRB1_1	HLA typing of donor.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM
●	DRB1_2	HLA typing of donor.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM

Name	Description	Values	Data Rules	Mandatory
DRB3_1	HLA typing of donor.	Molecular allele	See rules in A_1 molecular. Of the six text-entry fields which are available for the locus DRB3, DRB4, and DRB5, a maximum of two values may be entered, and a minimum of one value must be entered.	Required for VXM
DRB3_2	HLA typing of donor.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM
DRB4_1	HLA typing of donor.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM
DRB4_2	HLA typing of donor.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM
DRB5_1	HLA typing of donor.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM
DRB5_2	HLA typing of donor.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM
DRB 3/4/5 Tested, but not present	Flag indicating if DRB3, DRB4 and DRB5 tested but not present.	Yes No	When no values are entered for DRB3, DRB4, and DRB5, and the HLA typing is to be considered complete, then indicate that DRB3, DRB4, and DRB5 were “Tested, but not present”.	Required for VXM
DPA1_1	HLA typing of donor.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM
DPA1_2	HLA typing of donor.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM
DPB1_1	HLA typing of donor.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM
DPB1_2	HLA typing of donor.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM

	Name	Description	Values	Data Rules	Mandatory
●	DQA1_1	HLA typing of donor.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM
●	DQA1_2	HLA typing of donor.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM
●	DQB1_1	HLA typing of donor.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM
●	DQB1_2	HLA typing of donor.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM
●	HLA Typing Confirmed	User confirms HLA Typing.	Yes No	Default = blank	Required for VXM
	Serology – For each serology - multiple time points can be captured - a test type must be recorded for each serology result - sample drawn date/time recorded for each result				
●	Sample Drawn Date/Time	Date/Time serology (blood) sample is drawn.	Date and time	≤ current date/time and Must be greater than date of birth of donor. Required for any serology test result entered in registry.	Required for any serology test result entered in registry
●	Sample Dilution	Flag indicating if serology sample is diluted or undiluted.	Diluted Undiluted	n/a	Required for any serology test result entered in the registry
●	Serology Source	Flag indicating source of serology sample drawn.	Mother Donor	Defaulted to Donor	Required for any serology test result entered in the registry
●	CMV	CMV result based on IgG test.	Positive Negative Pending Not Tested Indeterminate	At least one result is required.	Required for offer

Name	Description	Values	Data Rules	Mandatory
EBV	EBV result based on any of the following tests: IgG (VCA) or IgG (EBNA), IgM.	Positive Negative Pending Not Tested Indeterminate	At least one result is required.	Required for offer
Hepatitis B Core Antibody	HBV result based on Anti-HBc (HBcAb) test.	Positive Negative Pending Not Tested Indeterminate	At least one result is required.	Required for offer
Hepatitis B Surface Antibody	HBV result based on Anti-HBs (HBsAb) test.	Positive Negative Pending Not Tested Indeterminate	At least one result is required	Required for offer
Hepatitis B Surface Antigen	HBV result based on the following test; HBsAG test, NAT.	Positive Negative Pending Not Tested Indeterminate	At least one result is required.	Required for offer
Hepatitis C Antibody	HCV result based on IgG test.	Positive Negative Pending Not Tested Indeterminate	At least one result is required.	Required for offer
Hepatitis C NAT	HCV result based on the following tests: HCV RNA NAT, Double NAT (HIV, HCV), Triple NAT (HIV, HCV, HBV).	Positive Negative Pending Not Tested	At least one result is required.	Required for offer
HIV I and II Antibody	HIV I and II result based on any of the following tests: IgG, Antibody/ p24antigen.	Positive Negative Pending Not Tested Indeterminate	At least one result is required.	Required for offer

	Name	Description	Values	Data Rules	Mandatory
	HIV I and II NAT	HIV I and II result based on any of the following tests: HIV NAT (HIV DNA, HIV Single NAT), Double NAT (HIV, HCV), and Triple NAT (HIV, HCV, and HBV).	Positive Negative Pending Not Tested	At least one result is required.	Required for offer
	HTLV I and II	HTLV I and II result based on IgG test.	Positive Negative Pending Not Tested Indeterminate	At least one result is required.	Required for offer
	Syphilis	Syphilis result based on the following tests: EIA, RPR, VDRL, FTA-ABS.	Positive Negative Pending Not Tested Indeterminate	At least one result is required.	Required for offer
	West Nile	West Nile result based on IgG, IgM, NAT.	Positive Negative Pending Not Tested Indeterminate	At least one result is required.	Required for offer
	Chemistry– For each chemistry - multiple time points can be captured -				
	Date/Time of Collection		Date and time	≤ current date/time and must be greater than date of birth of donor.	Required for any Chemistry entered in the registry
	Amylase (U/L)	Amylase	Numeric	≥ 0 and ≤ 9999	Required for offer
	Lipase (U/L)	Amylase	Numeric	≥ 0 and ≤ 9999	Required for offer

	Name	Description	Values	Data Rules	Mandatory
	Offer				
●	Offer Sate	For each organ offer, state of organ being offered	Proposed Accepted Declined Withdrawn Cancelled Acceptance	Single selection list	Required for offer
●	Offer State Reason	For each organ offer that was declined, withdrawn or cancelled acceptance, the reason for the decline.	CTR reason list	Multiple selection list	Required for offer
	Recovery				
	Disposition				
●	Cross Clamp Date/ Time	Date and time organs were recovered and flushed with a specially prepared, ice-cold solution.	Date and time	≤ current date/time and Must be greater than first brain death date/time for NDD Donor or DCD Declaration End Date/Time for DCD Donor If organ recovered for transplant, then cross clamp date/time required	Required to close donor case
●	Pancreas Recovered State	Recovered state of organ.	Recovered Not recovered	If organ consented, then recovery details required.	Required to close donor case
●	Not Recovered Reason	Not recovered reason for each organ.	Coroner / medical examiner decline No suitable recipient (size/ABO) Storage and preservation problems No recipient located No recovery team available Medically unsuitable pre OR Medically unsuitable intra OR Unable to maintain donor pre OR Technical problem in OR Transportation logistics Problem with recipient All offers declined	Single selection list	Required if not recovered selected

Name	Description	Values	Data Rules	Mandatory
		DCD did not die within acceptable time High inotrope requirement Inadequate perfusion of organ (thrombosis) Infection/sepsis Organ damaged during recovery Unable to maintain donor intra OR		
Recovered for Reason	Recovered for a specific medical use, for each organ.	Transplant Research Medical Education Tissue Not Used Not Applicable Pathology	Single selection list	Required if recovered selected
Pancreas Transplanted State	Transplanted state of organ.	Transplanted Not Transplanted	If organ consented, then transplant details required.	Required to close donor case
Not Transplanted Reason	Not transplanted reason for each organ.	Lack of recipient hospital resources No suitable recipient Organ medically unsuitable for transplant Prolonged cold ischemia time Prolonged warm ischemia time Recipient died Recipient medically unsuitable Storage and preservation problems Technical problem in OR Transportation logistics	Single selection list	Required if not transplanted selected
Not Transplanted Disposition	Specify disposition of not transplanted organ.	Medical Education Not Used Pathology Research Tissue	Single selection list	Required if not transplanted selected

Appendix E – Deceased Donor and Islet Processing Data

	Name	Description	Values	Data Rules	Mandatory
	Registration				
	Identifiers				
●	National Donor ID	National donor identifier generated by registry.	Identifier	Calculated by system when record created.	Required to create record
●	Local Donor ID	Local donor identifier entered by OPO.	Identifier	≤ 50 characters	Required to create record
●	Date of Birth	Date of birth of donor.	YYYY-MM-DD	≤ current date If date of birth is unknown, enter donor's age at time of infusion – a deceased donor record cannot be created without a date of birth	Required to create record
●	Donor Case	State of donor case e.g. open or closed	Open Close	Default = Open	Required to create record
●	Date and Time of Hospital Admission		YYYY-MM-DD HH:MM	≤ current date and time	Optional
	Demographics				
●	Gender	Gender of donor.	Male Female Other Unknown	Single selection list	Required to create record
●	Height (cm)	Height of donor in cm.	cm	≥ 0.0 and ≤ 300.0	Required to create record
●	Weight (kg)	Weight of donor in kg.	kg	≥ 0.0 and ≤ 700.0	Required to create record
●	BMI	Body mass index of patient	Numeric	BMI = weight (kg)/ (height (m) * height (m)).	Calculated by system

	Name	Description	Values	Data Rules	Mandatory
●	ABO	Blood type of donor.	A B O AB unknown	Single selection list	Required for VXM and offer
	Facility				
●	OPO	Organ Procurement Organization responsible for donor.	Abbreviated and full name of OPO	Single selection list	Required to create record
●	Referral Hospital	Hospital where potential deceased donor is identified.	Hospital name with city	n/a	Required to create record
●	Retrieval Hospital	Hospital where the deceased donor organ procurement surgery takes place.	Hospital name with city	Single selection list	Required to close donor case
	Consent				
●	Pancreas Consent State	Consent state of pancreas.	Consented Not Consented Not Participating	Single selection list	Required for VXM
	Declaration of Death				
	Death				
●	Type of Declaration of Death	Declaration of death could be neurological determination of death (NDD) or donor after cardio circulatory death (DCD).	NDD DCD	Single selection list	Required for VXM
●	Cause of Death	Deceased donor cause of death.	Anoxia/Hypoxia Head trauma Cerebrovascular/stroke CNS tumour Other-comment required	Single selection list	Required for VXM
●	Mechanism of Death		Asphyxiation Blunt injury Cardiovascular Death from natural causes Drowning Drug intoxication Gunshot wound	Single selection list	Required to close donor case

	Name	Description	Values	Data Rules	Mandatory
			Intracranial hemorrhage/stroke Seizure Stab Sudden infant death Other – comment required		
●	Circumstances of Death		Motor vehicle accident Alleged suicide Alleged homicide Alleged child abuse Non-motor vehicle Death from natural causes Other-comment required	Single selection list	Required to close donor case
	DCD				
●	Withdrawal of Life Support Date/Time	Date/Time life support was withdrawn.	Date and time	≤ current date/time and ≥ date of birth of donor. Mandatory for DCD only.	Required to close donor case
●	DCD Declaration Start Date/Time	Start of lack of spontaneous circulation.	Date and time	≤ current date/time and ≥ withdrawal of life support date/time. ≤ DCD Declaration End Date/Time. Mandatory for DCD only.	Required to close donor case
●	DCD Declaration End Date/Time	Confirmation of lack of spontaneous circulation and actual death date/time. When does the cold ischemia time begin?	Date and time	≤ current date/time and ≥ withdrawal of life support date/time. ≥ DCD Declaration Start Date/Time. Mandatory for DCD only.	Required to close donor case
	Assessment				
●	History of Hypertension		Yes No Unknown	If yes, then specify duration	Required for offer
●	Duration	Hypertension duration	0-5 years 6-10 years > 10 years Unknown	Required if history of hypertension = yes Single selection list	Optional

Name	Description	Values	Data Rules	Mandatory
Method of Control	Hypertension method of control	Diet Diuretics Other hypertensive medication	Required if history of hypertension = yes Multiple selection list	Optional
History of alcohol dependency		Yes No Unknown	If yes, then specify continued use in the past six months	Required for offer
Continued use in the past six months		Yes No Unknown	Required if history of alcohol dependency = yes Single selection list	Optional
History of diabetes		Yes No Unknown	If yes, the specify duration Single selection list	Required for offer
Duration	Diabetes duration	0-5 years 6-10 years > 10 years Unknown	Required if history of diabetes = yes Single selection list	Optional
Insulin Dependent		Yes No Unknown	Required if history of diabetes = yes If insulin dependent = yes, then provide number of years' donor has been taking insulin Single selection list	Optional
Number of years' donor has been taking insulin		0-5 years 6-10 years > 10 years Unknown	Required if insulin dependent = yes	Optional
Cardio Respiratory Arrest		Yes No Unknown	If yes, then specify duration	Required for offer
Duration of cardiac arrest		Minutes	≥ 0 minutes Required if cardio respiratory arrest = yes	Optional
Other Risks		Yes No Unknown	If other risks = yes or unknown, then risk details are required	Optional

	Name	Description	Values	Data Rules	Mandatory
●	Other Risk Details		Text	≤ 2000 characters Required if other risks = yes or unknown	Optional
	Exceptional Distribution				
●	Exceptional Distribution	Flag indicating if donor is exceptional distribution.	Yes No	Single selection list	Required for offer
●	Exceptional Distribution flags	Selectable list of exceptional distribution reasons.	List of exceptional distribution reasons	Multiple selection list	Select reason if Exceptional Distribution = Yes
●	Exceptional Distribution Comments	Comments related to exceptional distribution.	Details	≤ 1024 characters for each comment added	Optional
	Medication – For each medication - multiple time points can be captured - infusion date/time recorded for each result - a unit must be recorded for each medication - maximum dosage must be recorded for each medication				
●	Were vasopressors used		Yes No Unknown	Single selection list If yes, then specify each vasopressor used and the dose	Required for offer
●	Unit	Unit of measure for medication given to patient.	Grams Nanograms per kilo per minute Miliequivalent Micrograms per kilo per minute Microgram per minute Micrograms per hour Miligram per kilo per minute Miligram per hour Miligrams Units per minute Units per hour Microgram Micrograms per kilo per hour Miligram per kilo per hour	For each vasopressor used then unit is required	Optional

Name	Description	Values	Data Rules	Mandatory
		Milliunit per kilo per minute Units per kilo per minute miligram per kilo micrograms per kilo		
Epinephrine hydrochloride (Adrenaline)		Maximum Dosage and Unit	≥ 0.000 and ≤ 999.9999. For each vasopressor used then maximum dosage is required	Optional
Dobutamine hydrochloride (Dobutrex)		Maximum Dosage and Unit	≥ 0.000 and ≤ 999.9999. For each vasopressor used then maximum dosage is required	Optional
Dopamine hydrochloride (Inatropin)		Maximum Dosage and Unit	≥ 0.000 and ≤ 999.9999. For each vasopressor used then maximum dosage is required	Optional
Metaraminol bitartrate (Aramine)		Maximum Dosage and Unit	≥ 0.000 and ≤ 999.9999. For each vasopressor used then maximum dosage is required	Optional
Midodrine hydrochloride (ProAmatine)		Maximum Dosage and Unit	≥ 0.000 and ≤ 999.9999. For each vasopressor used then maximum dosage is required	Optional
Norephinephrine Bitartrate (Noaradrenaline, Levophed)		Maximum Dosage and Unit	≥ 0.000 and ≤ 999.9999. For each vasopressor used then maximum dosage is required	Optional
Phenylephrine hydrochloride (Neo-Synephrine, Metasympatol)		Maximum Dosage and Unit	≥ 0.000 and ≤ 999.9999. For each vasopressor used then maximum dosage is required	Optional
Other vasopressor		Maximum Dosage and Unit	≥ 0.000 and ≤ 999.9999. For each vasopressor used then maximum dosage is required	Optional

	Name	Description	Values	Data Rules	Mandatory
	From time of admission, was insulin given		Yes No Unknown	Single selection list	Required for offer
	HLA Typing – Conditional mandatory rules - Required for virtual crossmatch				
	A_1	HLA typing of donor.	Molecular allele	≤ 20 characters	Required for VXM
	A_2	HLA typing of donor.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM
	B_1	HLA typing of donor.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM
	B_2	HLA typing of donor.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM
	C_1	HLA typing of donor.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM
	C_2	HLA typing of donor.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM
	DRB1_1	HLA typing of donor.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM
	DRB1_2	HLA typing of donor.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM
	DRB3_1	HLA typing of donor.	Molecular allele	See rules in A_1 molecular. Of the six text-entry fields which are available for the locus DRB3, DRB4, and DRB5, a maximum of two values may be entered, and a minimum of one value must be entered.	Required for VXM
	DRB3_2	HLA typing of donor.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM
	DRB4_1	HLA typing of donor.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM

Name	Description	Values	Data Rules	Mandatory
DRB4_2	HLA typing of donor.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM
DRB5_1	HLA typing of donor.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM
DRB5_2	HLA typing of donor.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM
DRB 3/4/5 Tested, but not present	Flag indicating if DRB3, DRB4 and DRB5 tested but not present.	Yes No	When no values are entered for DRB3, DRB4, and DRB5, and the HLA typing is to be considered complete, then indicate that DRB3, DRB4, and DRB5 were “Tested, but not present”.	Required for VXM
DPA1_1	HLA typing of donor.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM
DPA1_2	HLA typing of donor.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM
DPB1_1	HLA typing of donor.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM
DPB1_2	HLA typing of donor.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM
DQA1_1	HLA typing of donor.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM
DQA1_2	HLA typing of donor.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM
DQB1_1	HLA typing of donor.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM
DQB1_2	HLA typing of donor.	Molecular allele	See rules in A_1 molecular allele.	Required for VXM
HLA Typing Confirmed	User confirms HLA Typing.	Yes No	Default = blank	Required for VXM

	Name	Description	Values	Data Rules	Mandatory
	Serology – For each serology - multiple time points can be captured - a test type must be recorded for each serology result - sample drawn date/time recorded for each result				
●	Sample Drawn Date/Time	Date/Time serology (blood) sample is drawn.	Date and time	≤ current date/time and Must be greater than date of birth of donor. Required for any serology test result entered in registry.	Required for any serology test result entered in registry
●	Sample Dilution	Flag indicating if serology sample is diluted or undiluted.	Diluted Undiluted	n/a	Required for any serology test result entered in the registry
●	Serology Source	Flag indicating source of serology sample drawn.	Mother Donor	Defaulted to Donor	Required for any serology test result entered in the registry
●	CMV	CMV result based on IgG test.	Positive Negative Pending Not Tested Indeterminate	At least one result is required.	Required for offer
●	EBV	EBV result based on any of the following tests: IgG (VCA) or IgG (EBNA), IgM.	Positive Negative Pending Not Tested Indeterminate	At least one result is required.	Required for offer
●	Hepatitis B Core Antibody	HBV result based on Anti-HBc (HBcAb) test.	Positive Negative Pending Not Tested Indeterminate	At least one result is required.	Required for offer

Name	Description	Values	Data Rules	Mandatory
Hepatitis B Surface Antibody	HBV result based on Anti-HBs (HBsAb) test.	Positive Negative Pending Not Tested Indeterminate	At least one result is required	Required for offer
Hepatitis B Surface Antigen	HBV result based on the following test; HBsAG test, NAT.	Positive Negative Pending Not Tested Indeterminate	At least one result is required.	Required for offer
Hepatitis C Antibody	HCV result based on IgG test.	Positive Negative Pending Not Tested Indeterminate	At least one result is required.	Required for offer
Hepatitis C NAT	HCV result based on the following tests: HCV RNA NAT, Double NAT (HIV, HCV), Triple NAT (HIV, HCV, HBV).	Positive Negative Pending Not Tested	At least one result is required.	Required for offer
HIV I and II Antibody	HIV I and II result based on any of the following tests: IgG, Antibody/ p24antigen.	Positive Negative Pending Not Tested Indeterminate	At least one result is required.	Required for offer
HIV I and II NAT	HIV I and II result based on any of the following tests: HIV NAT (HIV DNA, HIV Single NAT), Double NAT (HIV, HCV), and Triple NAT (HIV, HCV, and HBV).	Positive Negative Pending Not Tested	At least one result is required.	Required for offer
HTLV I and II	HTLV I and II result based on IgG test.	Positive Negative Pending Not Tested Indeterminate	At least one result is required.	Required for offer

	Name	Description	Values	Data Rules	Mandatory
	Syphilis	Syphilis result based on the following tests: EIA, RPR, VDRL, FTA-ABS.	Positive Negative Pending Not Tested Indeterminate	At least one result is required.	Required for offer
	West Nile	West Nile result based on IgG, IgM, NAT.	Positive Negative Pending Not Tested Indeterminate	At least one result is required.	Required for offer
	Chemistry– For each chemistry - multiple time points can be captured				
	Date/Time of Collection		Date and time	≤ current date/time and must be greater than date of birth of donor.	Required for any Chemistry entered in the registry
	T Bili (µmol/L)		Normal values 0-300	≥ 0 and ≤ 999.	Optional for offer
	ALT (U/L)		Normal values <50	≥ 0 and ≤ 99999.	Optional for offer
	AST (U/L)		Normal values <140	≥ 0 and ≤ 99999.	Optional for offer
	Amylase (U/L)	Amylase	Numeric	≥ 0 and ≤ 9999.	Required for offer
	Lipase (U/L)	Amylase	Numeric	≥ 0 and ≤ 9999.	Required for offer
	Electrolytes– For each electrolytes - multiple time points can be captured				
	Date/Time of Collection		Date and time	≤ current date/time and must be greater than date of birth of donor.	Required for any Chemistry entered in the registry
	BUN	Blood Urea Nitrogen			Optional for offer
	Creatinine	Serum Creatinine	Normal values 46-110 (umol/L)	≥ 0 and ≤ 9999.	Optional for offer

Name	Description	Values	Data Rules	Mandatory
Recovery				
Pancreas Procurement Team		Unrelated to processing/infusion team Related to processing/infusion team Unknown	Single selection list	Required to close donor case
Cross Clamp Date/ Time	Date and time organs were recovered and flushed with a specially prepared, ice-cold solution.	Date and time	≤ current date/time and Must be greater than first brain death date/time for NDD Donor or DCD Declaration End Date/Time for DCD Donor If organ recovered for transplant, then cross clamp date/time required	Required to close donor case
Indicate all solutions used for pancreas preservation		UW HTK Other specify		Required to close donor case
Pancreas Recovered State	Recovered state of organ.	Recovered Not recovered	If organ consented, then recovery details required.	Required to close donor case
Not Recovered Reason	Not recovered reason for each organ.	Coroner / medical examiner decline No suitable recipient (size/ABO) Storage and preservation problems No recipient located No recovery team available Medically unsuitable pre OR Medically unsuitable intra OR Unable to maintain donor pre OR Technical problem in OR Transportation logistics Problem with recipient All offers declined DCD did not die within acceptable time High inotrope requirement Inadequate perfusion of organ (thrombosis) Infection/sepsis Organ damaged during recovery Unable to maintain donor intra OR	Single selection list Required if not recovered selected	Required to close donor case

	Name	Description	Values	Data Rules	Mandatory
●	Recovered for Reason	Recovered for a specific medical use, for each organ.	Transplant Research Medical Education Tissue Not Used Not Applicable Pathology	Single selection list Required if recovered selected	Required to close donor case
	Islet Processing Information				
●	Islet Processing and Testing Centre		Toronto General Hospital University of Alberta McGill University Health Centre	Single selection list	Required
●	Time removed from container		HH:MM Time Zone	≤ time	Required
●	Weight of pancreas after trimming		gm		Required
●	Undigested Tissue		Yes No	If yes, then specify amount of undigested tissue	Required
●	Amount of undigested tissue		gm		Required
	Digestion				
●	End (Switch) Time		HH:MM Time Zone	≤ time	Required
●	Enzymes Used		Liberase HI Serva GMP collagenase Serva premium collagenase Serva neutral protease GMP Serva neutral protease Premium Collagenase P Sigma blend NB1 Thermolysin Unknown Other specify	Multiple selection list	Required
●	Enzyme Type Lot 1		Liberase HI Serva GMP collagenase Serva premium collagenase	Single selection list	Required

Name	Description	Values	Data Rules	Mandatory
		Serva neutral protease GMP Serva neutral protease Premium Collagenase P Sigma blend NB1 Thermolysin Unknown Other specify		
Lot 1 Number		Text	≤ 20 characters	Required
Enzyme Type Lot 2		Liberase HI Serva GMP collagenase Serva premium collagenase Serva neutral protease GMP Serva neutral protease Premium Collagenase P Sigma blend NB1 Thermolysin Unknown Other specify	Single selection list	Required
Lot 2 Number		Text	≤ 20 characters	Required
Enzyme Type Lot 3		Liberase HI Serva GMP collagenase Serva premium collagenase Serva neutral protease GMP Serva neutral protease Premium Collagenase P Sigma blend NB1 Thermolysin Unknown Other specify	Single selection list	Required
Lot 3 Number		Text	≤ 20 characters	Required

	Name	Description	Values	Data Rules	Mandatory
●	Was Pulmozyme used during processing?		Yes No Unknown	Single selection list	Required
	Islet Purification				
●	Total pellet (packed) volume		ml		Required
●	Total number of islet		Numeric		Required
●	Total IEQ		IEQ		Required
●	IEQ/g (whole pancreas)		IEQ/g		Required
●	IEQ/g (digested pancreas)		IEQ/g		Required
	Islet Pretreatment and Product Characterization				
●	Islet Cultured		Yes No	If yes, then indicate the duration and temperature	Required
●	Duration	Islet cultured duration	Hours and minutes		Required
●	Temperature	Islet cultured temperature	Celsius		Required
●	Total packed cell volume		ml		Required
●	Percent trapped islets		%	≤ 100	Required
●	Total islet count				Required
●	Total number of Islet Equivalents		IEQ		Required
●	Total number of beta cells		X 10^6		Required
●	Total DNA content		µg		Required

Name	Description	Values	Data Rules	Mandatory
Islet Microbiology Results				
Gram stain		No organism seen Positive Unknown Missing	If positive, then specify: Gram negative Gram positive Unknown	Required
Aerobic culture		No Growth Positive Unknown Not Done	If positive, then specify details (≤ 2000 characters)	Required
Anaerobic culture		No Growth Positive Unknown Not Done	If positive, then specify details (≤ 2000 characters)	Required
Fungal culture		No Growth Positive Unknown Not Done	If positive, then specify details (≤ 2000 characters)	Required
Mycoplasma		No Growth Positive Unknown Not Done	If positive, then specify details (≤ 2000 characters)	Required
Percent dithizone positive cells		%	≤ 100	Required
Percent beta cells		%	≤ 100	Required
Islet viability test		Fluorescei Diacetate/Propidium Iodide Equivalent fluorochromes Trypan Blue Syto Green 13 Fluorescein Diacetate/Ethidium Bromide Other specify	Single selection list	Required
Islet viability test result		%	≤ 100	Required
Islet potency stimulation index		Numeric		Required

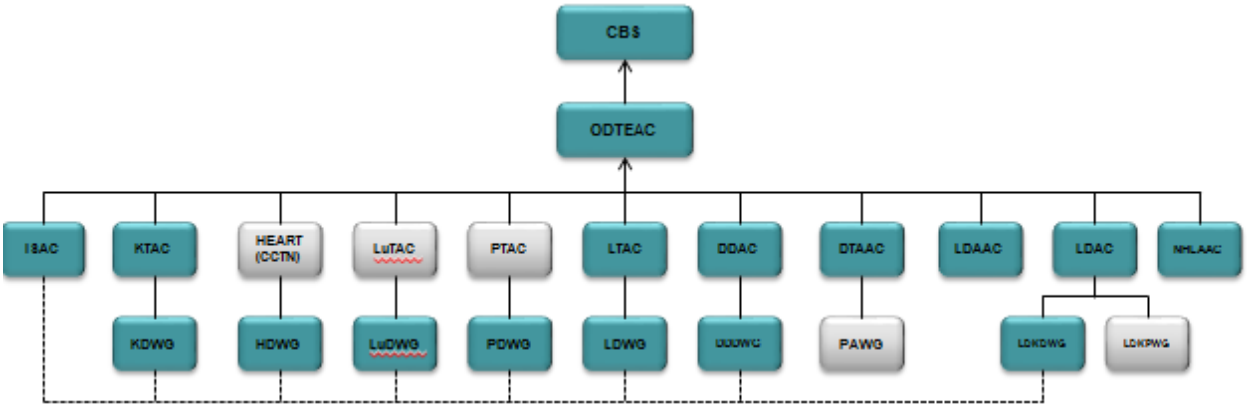
Name	Description	Values	Data Rules	Mandatory
Disposition				
Pancreas Transplanted State	Transplanted state of organ.	Pancreas Transplanted Islet Transplanted Pancreas Not Transplanted	If organ consented, then transplant details required. Single selection list	Required to close donor case

Appendix F – Sample Data Scan

Data Element	HDWG ..	HDWG R	HDWG Pr	HDWG Pe	HDWG Po	CORR H	UNOS H	NHSBT H	ISHLT	IMACS
Registration	14	4	4	0	0	16	19	29	6	
Identifying Information	2	0	2	0	0	3	3	5	2	
Date of Birth						M	M	M	M	●
First Name						M	M	M	O	●
Middle Name									O	●
Last Name						M	M	M	O	●
Former Last Name										
LDPE ID										
Local Recipient ID									M	
National Recipient ID								M		
Provincial Health Number (PHN)	M		M			O	O	M		
PHN/Home Prov	M		M			O				
Registered On LDPE										
Contact Information	2	0	2	0	0	3	2	4	0	
Contact Relationship										
Order of contact										
Address								M		
City						M				
Email										
Postal Code	M		M			M	M	M		
Province	M		M			M	M	M		
Telephone-Home								M		
Telephone-Mobile										
Telephone-Work										
Patient Waiting in Permanent ZIP Code							O			
Demographics	5	4	0	0	0	5	8	9	3	
Body Metrics	3	4	0	0	0	4	3	6	3	
Age									M	
Advanced Age										●
Gender	M					M	M	M	M	●
Height (cm)	M					M	M	M	O	●
Weight (kg)	M					M	M	M	O	●
BMI							C			
Body Surface Area (Peds)		C						M		
ABO		M				M	O	M	M	●
Confirm ABO		M								
RH		M						M		
Confirm RH		M								
In-utero										

Appendix G – Terms of Reference

Organ Donation & Transplantation Committees



CBS: Canadian Blood Services
ODTEAC: Organ Donation & Transplantation Expert Advisory Committee
ISAC: Information Strategy Advisory Committee (In development)
KTAC: Kidney Transplant Advisory Committee
Heart: proposed as a subset of the Canadian Cardiac Transplantation Network (In development)
LuTAC: Lung Transplant Advisory Committee (TBD)
PTAC: Pancreas-Islets Advisory Committee (TBD)
LTAC: Liver Transplant Advisory Committee
DDAC: Deceased Donation Advisory Committee
DTAAC: Donation and Transplant Administrators Advisory Committee
LDAAC: Living Donation Administrators Advisory Committee
LDAC: Living Donation Advisory Committee
NHLAAC: National Human Leukocyte Antigen Advisory Committee
KDWG: Kidney Data Working Group
HDWG: Heart Data Working Group
LuDWG: Lung Data Working Group
PDWG: Pancreas-Islets Data Working Group
LDWG: Liver Data Working Group
DDDWG: Deceased Donation Data Working Group
PAWG: Public Awareness Working Group (TBD)
LDKDWG: Living Donation Kidney Data Working Group (In development)
LDKAWG: Living Donation Kidney Administrators Working Group
LDKPWG: Living Donation Kidney Protocols Working Group (TBD)

Mandate / Scope

The Working Group's scope encompasses matters related to inter-provincial pancreas-islets transplant practices, including documentation of listing and allocation practices, donor and recipient information, and pancreas-islets transplant outcomes in support of the CTR. To contribute to the data needs that will inform

clinical decisions and support clinical research with respect to pancreas-islets transplantation and outcomes reporting, the Working Group will:

- identify data points along the pancreas-islets donation, allocation and transplant critical path
- identify the availability and gaps in current data and the comparability of data amongst pancreas-islets transplant programs
- develop a minimum data set for pancreas-islets transplantation with regards to pancreas-islets waitlist outcomes, pancreas-islets transplant activity and pancreas-islets transplant outcomes to support clinical decisions and research
- recommend a quality control strategy to assess the quality and completeness of data submissions to the registry

Authority

The Pancreas-Islets Data Working Group shall function under the current mandate and authority of Canadian Blood Services until such time that a formal governance and accountability structure is approved by the FPT Deputy Ministers of Health. The Chair of the Working Group committee shall be appointed by Canadian Blood Services.

Reporting

The Pancreas-Islets Data Working Group will report to the Information Strategy Advisory Committee (ISAC) and the Organ Donation and Transplantation Expert Advisory Committee (ODTEAC). Activities may also be reported to an interprovincial government committee, the Provincial and Territorial Blood Liaison Committee, as part of the performance reporting requirements for Canadian Blood Services as set out by governments.

Composition of the Pancreas-Islets Data Working Group

Membership in the Pancreas-Islets Data Working Group will include 3 – 5 individuals with relevant professional knowledge and experience in pancreas-islets transplantation. Members will also have a deep appreciation and interest in the use of pancreas-islets data to advance pancreas-islets donation and transplantation in Canada.

Canadian Blood Services, with the concurrence of the Chair, has the ability to request the appointment of new members as the need is identified.

Membership will balance and encompass representation from pancreas-islets transplantation programs across Canada. Subject matter experts may be invited to attend specific Working Group meetings as required. Membership participation is required at two out of every three meetings scheduled.

Chair

The Chair of the Committee shall be appointed by Canadian Blood Services, and shall serve a two-year term. Upon completion of this term Canadian Blood Services may extend the appointment. The Chair of the Committee is responsible for ensuring that the Committee functions within these Terms of Reference and will provide regular updates to the ISAC on the activities of the Pancreas-Islets Data Working Group.

Processes and Timeframes

- The day and time for teleconferences will be set based on agreed membership preference
- Materials will be circulated to members 5 business days in advance of the teleconference

Quorum

- A majority of the voting members of the Committee shall constitute a quorum.
- Ordinarily, decisions and recommendations of the Committee will be achieved by consensus.

Meetings

- Canadian Blood Services will provide the Secretariat to the Committee meetings.
- Meetings will be held on <timing>, or at the call of the Chair.
- Attendance is expected at 2 of every 3 meetings.
- Members shall not send delegates to meetings, unless approved by the Chair.

Confidentiality

All materials used in support of committee business must be treated as confidential Pancreas-Islets Data Working Group business and should not be distributed without the approval of Canadian Blood Services.

Evaluation

Prior to the final teleconference of the Pancreas-Islets Data Working Group an evaluation of the performance of the working group will be undertaken and the results will be shared with members.