Pancreas Transplant Recipient Registration

Transplant Recipient Registration (TRR) records are generated and available immediately after a transplant event is reported through the recipient feedback process in WaitlistSM. Forms are generated by the age at transplant, not the age at listing. The TRR record is completed by the transplant center performing the transplant. The registration and hospital discharge follow-up information is combined in this record.

Complete the TRR at hospital discharge or six weeks post transplant, whichever is first. If the recipient is still hospitalized at six weeks post transplant, provide data regarding the recipient's progress consistent with the six-week time frame.

The TRR must be validated within 90 days of the record generation date. Example: If the recipient is removed as being transplanted on 10/1/XXXX, the TRR form will be due 90 days from that date, 12/30/XXXX. See <u>OPTN Policies</u> for additional information. Use the search feature to locate specific policy information on Data Submission Requirements.

To correct information that is already displayed on an electronic record, call the UNet[™] Help Desk at 1-800-978-4334.

Additional Resources: See History of Definition Changes.

Recipient Information

Name: Verify the last name, first name and middle initial of the transplant recipient is correct. If the information is incorrect, corrections may be made on the recipient's TCR record.

DOB: Verify the displayed date is the recipient's date of birth. If the information is incorrect, corrections may be made on the recipient's TCR record.

<u>SSN</u>: Verify the recipient's social security number is correct. If the information is incorrect, contact the Help Desk at 1-800-978-4334.

<u>Birth Sex</u>: Verify recipient's sex (Male or Female), based on biologic and physiologic traits at birth. If sex at birth is unknown, report sex at time of registration as reported by recipient or documented in medical record. The intent of this data collection field is to capture physiologic characteristics that may have an impact on recipient size matching or graft outcome. If the information is incorrect, corrections may be made on the recipient's TCR record.

<u>HIC</u>: Verify the 9 to 11 character Health Insurance Claim number for the recipient indicated on the recipient's most recently updated TCR record is correct. If the recipient does not have a HIC number, you may leave this field blank.

<u>Transplant Date</u>: Verify that the displayed transplant date is correct. The transplant date is determined by the start of the organ anastomosis during transplant or the start of the islet infusion. Organ transplants include solid organ transplants and islet infusions. An organ transplant procedure is complete when any of the following occurs:

The chest or abdominal cavity is closed and the final skin stitch or staple is applied.

The transplant recipient leaves the operating room, even if the chest or abdominal cavity cannot be closed.

The islet infusion is complete.

<u>State of Permanent Residence</u>: Select the name of the state of the recipient's permanent address at the time of transplant (location of full-time residence, not transplant center location). This field is **required**. (List of State codes)

<u>Permanent Zip Code</u>: Enter the recipient's permanent zip code at the time of transplant (location of full-time residence, not transplant center location). This field is **required**.

Provider Information

<u>Recipient</u> <u>Center</u>: The Recipient Center information reported in Waitlist displays. Verify that the center information is the hospital where the transplant operation was performed. The Provider Number is the 6-character Medicare identification number of the hospital. This is followed by the Center Code and Center Name.

Surgeon Name: Enter the name of the primary surgeon, who performed the transplant operation, and under whose name the transplant is billed. This field is **required**.

NPI #: Enter the 10-character CMS (Center for Medicare and Medicaid Services) assigned National Provider Identifier of the transplant surgeon. Your hospital billing office may be able to obtain this number for you. This field is **required**.

Donor Information

<u>UNOS Donor ID #</u>: The donor ID number, reported in the Recipient Feedback, will display. Each potential donor is assigned an identification number by the OPTN. This ID number corresponds to the date the donor information was entered into the OPTN computer system.

Recovering OPO: The Organ Procurement Organization (OPO) code will display. Verify the code is correct.

Donor Type: The donor type, reported in the Recipient Feedback, will display. Verify the recipient's donor type is correct. If the information is incorrect, contact the Help Desk at 1-800-978-4334.

Deceased indicates the donor was not living at the time of donation. **Living** indicates the donor was living at the time of donation.

Patient Status

Primary Diagnosis: Select the primary diagnosis for the disease requiring a transplant for this recipient. If the recipient has had a previous transplant for the same organ type, enter **Retransplant/Graft Failure** as the primary diagnosis for that organ. If **Other, Specify** is selected, enter the primary diagnosis in the space provided. The primary diagnosis should not be changed to concur with the pathology confirmed diagnosis. The primary diagnosis field

should reflect information known at the time of transplant. This field is **required**. (List of Pancreas Diagnosis codes)

Date: Last Seen, Retransplanted or Death: Complete at discharge (if discharged prior to six weeks from transplant date) or at six weeks from transplant date, whichever occurs first. Enter the date the hospital reported the recipient as living, retransplanted (when the data was obtained prior to the recipient's discharge) or the date of the recipient's death, using the standard 8-digit numeric format of MM/DD/YYYY. This field is **required**.

Patient Status: Complete at discharge (if discharged prior to six weeks from transplant date) or at six weeks from transplant date, whichever occurs first. Select the appropriate status for this recipient. If **Dead** is selected, indicate the cause of death. This field is **required**.

Living Dead Retransplanted

Primary Cause of Death: If the Patient Status is **Dead**, select the patient's cause of death. If an **Other** code is selected, enter the other cause of death in the space provided. (List of Primary Cause of Death codes)

Contributory Cause of Death: If the Patient Status is **Dead**, select the patient's contributory cause of death. Do not select the primary cause, since it cannot be both the primary and contributory cause of death. If an **Other** code is selected, enter the other cause of death in the space provided. (List of Contributory Cause of Death codes)

Contributory Cause of Death: If the Patient Status is **Dead**, select the patient's contributory cause of death. Do not select the primary cause, since it cannot be both the primary and contributory cause of death. If an **Other** code is selected, enter the other cause of death in the space provided. (List of Contributory Cause of Death codes)

Note: If the **Patient Status** is **Retransplanted**, then **Failed** must be selected for the **Pancreas Graft Status**.

Note: If the patient is being retransplanted, access the patient's last record for their previous transplant and select **Retransplanted** in the **Patient Status** field. This will stop the generation of TRF records associated with the previous transplant.

Transplant Hospitalization:

Date of Admission to Tx Center: Enter the date the recipient was admitted to the transplant center, using the standard 8-digit MM/DD/YYYY format. If the patient was admitted to the hospital before it was determined a transplant was needed, enter the date it was determined the patient needed a transplant. This field is **required**.

Date of Discharge from Tx Center: Enter the date the recipient was released to go home, using the standard 8-digit MM/DD/YYYY format. The recipient's hospital stay includes total time spent in different units of the hospital, including medical and rehab. This information is not required in the TRR record, but if entered here, it will automatically fill in the future TRF records. It is required in the TRF record.

Note: Leave this field blank if the recipient was removed from the waiting list with a code of 21, indicating the recipient died during the transplant procedure.

Clinical Information: PRETRANSPLANT

Functional Status: Select the choice that best describes the recipient's functional status just prior to the time of transplant. This field is **required**.

Note: The Karnofsky Index will display for adults aged 18 and older.

100% - Normal, no complaints, no evidence of disease

90% - Able to carry on normal activity: minor symptoms of disease

80% - Normal activity with effort: some symptoms of disease

70% - Cares for self: unable to carry on normal activity or active work

60% - Requires occasional assistance but is able to care for needs

50% - Requires considerable assistance and frequent medical care

40% - Disabled: requires special care and assistance

30% - Severely disabled: hospitalization is indicated, death not imminent

- 20% Very sick, hospitalization necessary: active treatment necessary
- 10% Moribund, fatal processes progressing rapidly

Note: The Lansky Score will display for pediatrics aged less than 18.

100% - Fully active, normal

90% - Minor restrictions in physically strenuous activity

80% - Active, but tires more quickly

70% - Both greater restriction of and less time spent in play activity

60% - Up and around, but minimal active play; keeps busy with quieter activities

50% - Can dress but lies around much of day; no active play; can take part in quiet play/activities

40% - Mostly in bed; participates in quiet activities

30% - In bed; needs assistance even for quiet play

20% - Often sleeping; play entirely limited to very passive activities

10% - No play; does not get out of bed

- Not Applicable (patient < 1 year old)
- Unknown

Note: This evaluation should be in comparison to the person's normal function, indicating how the patient's disease has affected their normal function.

<u>Cognitive Development</u>: (This field is **required** for recipients 18 years of age or younger.) Select the choice that best describes the recipient's cognitive development just prior to the time of transplant.

Definite Cognitive Delay/Impairment (verified by IQ score <70 or unambiguous behavioral observation)

Probable Cognitive Delay/Impairment (not verified or unambiguous but more likely than not, based on behavioral observation or other evidence)

Questionable Cognitive Delay/Impairment (not judged to be more likely than not, but with some indication of cognitive delay/impairment such as expressive/receptive language and/or learning difficulties)

No Cognitive Delay/Impairment (no obvious indicators of cognitive delay/impairment)

Not Assessed

Motor Development: (This field is **required** for recipients 18 years of age or younger.) Select the choice that best describes the recipient's motor development just prior to the time of transplant.

Definite Motor Delay/Impairment (verified by physical exam or unambiguous behavioral observation)

Probable Motor Delay/Impairment (not verified or unambiguous but more likely than not, based on behavioral observation or other evidence)

Questionable Motor Delay/Impairment (not judged to be more likely than not, but with some indication of motor delay/impairment)

No Motor Delay/Impairment (no obvious indicators of motor delay/impairment)

Not Assessed

<u>Academic Progress</u>: (This field is **required** for recipients less than 18 years of age.) Select the choice that best describes the recipient's academic progress just prior to the time of transplant. If the recipient is less than 5 years old or has graduated from high school, select **Not Applicable < 5 years old/High School graduate or GED**.

Within One Grade Level of Peers Delayed Grade Level Special Education Not Applicable <5 years old/High School graduate or GED Status Unknown

<u>Academic Activity Level</u>: (This field is **required** for recipients less than 18 years of age.) Select the choice that best describes the recipient's academic activity level just prior to the time of transplant. If the recipient is less than 5 years old or has graduated from high school, select **Not Applicable < 5 years old/High School graduate or GED**.

Full academic load Reduced academic load Unable to participate in academics due to disease or condition Not Applicable <5 years old/High School graduate or GED Status Unknown

<u>Working for income</u>: (This field is **required** for recipients 18 years of age or older.) If the recipient is working for income just prior to the time of transplant, select **Yes**. If not, select **No**. If unknown, select **UNK**.

Source of Payment:

<u>Primary</u>: Select as appropriate to indicate the candidate's source of primary payment (largest contributor) for the transplant. If the source of payment is not yet determined, select **Pending**. This field is **required**.

Private insurance (commercial Health insurance) refers to commercial insurance through an employer or affordable care act. It also refers to any worker's compensation that is covered by a private insurer.

Public insurance - Medicaid refers to state Medicaid funds.

Public insurance - Medicare FFS (Fee-for-Service) refers to funds from the government in which doctors and other health care providers are paid for each service provided to a candidate. Includes Medicare part A, part B and part D. Medicare part A (hospital) must be in place to be considered primary payer. For additional information about Medicare, see <u>http://www.medicare.gov/</u>.

Public insurance - Medicare Part C or Medicare Advantage Original (Fee for Service) Medicare is assigned to a private plan insurer instead of the federal government. Payments are made based on a montly predetermined date. Sometimes a recipient may receive additional benefits such as prescription drugs. Medicare part A and B must be in place to sign up for Medicare part C or Medicare Advantage. For additional information about Medicare, see http://www.medicare.gov/.

Public insurance - CHIP (Children's Health Insurance Program)

Public insurance - Department of VA refers to funds from the Veterans Administration.

Self Pay indicates that the candidate will pay for the cost of transplant.

Donation indicates that a company, institution, or individual(s) donated funds to pay for the transplant and care of the candidate.

Free Care (Charity Care) indicates that the transplant hospital will not charge candidate for the costs of the transplant operation.

Pending is used if the source of payment is not yet determined (Primary only).

Foreign Government, Specify refers to funds provided by a foreign government (Primary only) Specify the foreign country in the space provided.

Public Insurance -TRICARE Select this option if the patient has TRICARE health coverage.

Public Insurance - Indian Health Service Select this option if the patient has IHS health coverage.

Public Insurance - State Program select this option if the patient has health coverage through their state.

Height Date of Measurement: (Complete for recipients 18 years of age or younger.) Enter the date, using the 8-digit format of MM/DD/YYYY, the recipient's height was measured.

Height: Enter the height of the recipient, just prior to the time of transplant, in feet and inches or centimeters. If the recipient's height is unavailable, select the appropriate status from the **ST** field (**Missing**, **Unknown**, **N/A**, **Not Done**). (List of Status codes) For recipients 18 years old or younger at the time of transplant, UNet will generate and display calculated percentiles based on the 2000 CDC growth charts. This field is **required**.

<u>Weight Date of Measurement</u>: (Complete for recipients 18 years of age or younger.) Enter the date, using the 8-digit format of MM/DD/YYYY, the recipient's weight was measured.

<u>Weight</u>: Enter the weight of the recipient, just prior to the time of transplant, in pounds or kilograms. If the recipient's weight is unavailable, select the appropriate status from the **ST** field (**Missing**, **Unknown**, **N/A**, **Not Done**). (List of Status codes) For recipients 18 years old or younger at the time of transplant, UNet will generate and display calculated percentiles based on the 2000 CDC growth charts. This field is **required**.

<u>BMI (Body Mass Index)</u>: The recipient's BMI will display. For candidates less than 20 years of age at the time of transplant, UNet will generate and display calculated percentiles based on the 2000 CDC growth charts.

Percentiles are the most commonly used clinical indicator to assess the size and growth patterns of individual children in the United States. Percentiles rank the position of an individual by indicating what percent of the reference population the individual would equal or exceed (i.e. on the weight-for-age growth charts, a 5 year-old girl whose weight is at the 25th percentile, weighs the same or more than 25 percent of the reference population of 5-year-old girls, and weighs less than 75 percent of the 5-year-old girls in the reference population). For additional information about CDC growth charts, see http://www.cdc.gov/.

Note: Users who check the BMI percentiles against the CDC calculator may notice a discrepancy that is caused by the CDC calculator using 1 decimal place for height and weight and UNet using 4 decimal places for weight and 2 for height.

<u>Previous Transplants</u>: The three most recent transplant(s), indicated on the recipient's validated Transplant Recipient Registration (TRR) record(s), will display. Verify all previous transplants listed by organ type, transplant date and graft failure date.

Note: The three most recent transplants on record for this recipient will be displayed for verification. If there are any prior transplants that are not listed here, contact the UNet Help Desk at 1-800-978-4334 or <u>unethelpdesk@unos.org</u> to determine if the transplant event is in the database.

<u>Pretransplant Dialysis</u>: If the recipient was on maintenance dialysis before transplant, select **Yes**. If not, select **No**. If unknown, select **UNK**. This field is **required**.

If Yes, Date of Most Recent Initiation of Chronic Maintenance Dialysis: If the recipient was on maintenance dialysis before transplant, enter the date of most recent initiation of chronic maintenance dialysis. If the date is unavailable, select the appropriate status from the ST field (Missing, Unknown, N/A, Not Done). (List of Status codes)

<u>Average Daily Insulin Units</u>: Enter the average daily total insulin dosage units in the space provided. Average daily insulin dose should be a total including all insulin administered in any form per day (short term, long term, by pump, subcutaneous). The insulin dosage units must be between 1 and 1000. If the value is unavailable, select the appropriate status from the ST field (Missing, Unknown, N/A, Not Done). This field is required.

<u>Serum Creatinine at Time of TX</u>: Enter the serum creatinine at the time of transplant in mg/dl. If the value is unavailable, select the appropriate status from the **ST** field (**Missing**, **Unknown**, **N/A**, **Not Done**). This field is **required**.

Viral Detection:

HIV Serostatus: Select the serology results from the list. This field is required.

Positive Negative Not Done UNK/Cannot Disclose

Definition: (Human Immunodeficiency Virus) - The virus that causes AIDS, which is the most advanced stage of HIV infection. HIV is a retrovirus that occurs as two types: HIV-1 and HIV-2. Both types are transmitted through direct contact with HIV-infected

body fluids, such as blood, semen, and genital secretions, or from an HIV-infected mother to her child during pregnancy, birth, or breastfeeding (through breast milk).

CMV Status: Select the serology results from the list. If there is a positive CMV IgG or positive CMV Total Antibody result then CMV Status should be reported as positive. This field is **required**.

Positive Negative Not Done UNK/Cannot Disclose

Definition: Cytomegalovirus - A herpesvirus (genus Cytomegalovirus) that causes cellular enlargement and formation of eosinophilic inclusion bodies especially in the nucleus and that acts as an opportunistic infectious agent in immunosuppressed conditions (as AIDS).

HBV Surface Antibody Total: Select the serology results from the list. This field is **required**.

Positive Negative Not Done UNK/Cannot Disclose

HBV Core Antibody: Select the serology results from the list. This field is required.

Positive Negative Not Done UNK/Cannot Disclose

Definition: Hepatitis B Virus - A sometimes fatal hepatitis caused by a double-stranded DNA virus (genus Orthohepadnavirus of the family Hepadnaviridae) that tends to persist in the blood serum and is transmitted especially by contact with infected blood (as by transfusion or by sharing contaminated needles in illicit intravenous drug use) or by contact with other infected bodily fluids (as during sexual intercourse) -- also called serum hepatitis.

HBV Surface Antigen: Select the serology results from the list. This field is required.

Positive Negative Not Done UNK/Cannot Disclose

Definition: Hepatitis B Virus - A sometimes fatal hepatitis caused by a double-stranded DNA virus (genus Orthohepadnavirus of the family Hepadnaviridae) that tends to persist in the blood serum and is transmitted especially by contact with infected blood (as by transfusion or by sharing contaminated needles in illicit intravenous drug use) or by contact with other infected bodily fluids (as during sexual intercourse) -- also called serum hepatitis.

HCV Serostatus: Select the serology results from the list. This field is required.

Positive Negative Not Done UNK/Cannot Disclose

Definition: Hepatitis C Virus - A disease caused by a flavivirus that is usually transmitted by parenteral means (as injection of an illicit drug, blood transfusion, or exposure to blood or blood products) and that accounts for most cases of non-A, non-B hepatitis.

EBV Serostatus: Select the serology results from the list. If there is a positive EBV IgG or positive EBV Total Antibody result then EBV Serostatus should be reported as positive. This field is **required**.

Positive Negative Not Done UNK/Cannot Disclose

Definition: (Epstein-Barr Virus) - A herpesvirus (genus Lymphocryptovirus) that causes infectious mononucleosis and is associated with Burkitt's lymphoma and nasopharyngeal carcinoma -- abbreviation EBV; called also EB virus.

NAT (Nucleic Acid Test) Results:

HIV NAT: Select the NAT results from the list. This field is required.

Positive Negative Not Done UNK/Cannot Disclose

Definition: (Human Immunodeficiency Virus) - The virus that causes AIDS, which is the most advanced stage of HIV infection. HIV is a retrovirus that occurs as two types: HIV-1 and HIV-2. Both types are transmitted through direct contact with HIV-infected body fluids, such as blood, semen, and genital secretions, or from an HIV-infected mother to her child during pregnancy, birth, or breastfeeding (through breast milk).

HBV NAT: Select the NAT results from the list. This field is required.

Positive Negative Not Done UNK/Cannot Disclose

Definition: (Hepatitis B Virus) - A virus which primarily causes inflammation of the liver. The hepatitis B virus can be transmitted in several ways including blood transfusion, needle sticks, body piercing and tattooing using unsterile instruments, dialysis, sexual and even less intimate close contact, and childbirth. Symptoms include fatigue, jaundice, nausea, vomiting, dark urine, and light stools.

HCV NAT: Select the NAT results from the list. This field is required.

Positive Negative Not Done UNK/Cannot Disclose Definition: (Hepatitis C Virus) - Inflammation of the liver due to the hepatitis C virus which is usually spread via blood transfusion (rare), hemodialysis, and needle sticks. The damage hepatitis C does to the liver can lead to cirrhosis and its complications as well as cancer. Transmission of the virus by sexual contact is rare. At least half of hepatitis C patients develop chronic hepatitis C infection. Diagnosis is made by blood test. Treatment and probably cure is via antiviral drugs and is effective in over 90% of patients. Chronic hepatitis C was frequently treated with injectable interferon, in combination with antiviral oral medications, but now is most often treated with oral antivirals alone.

Note: For an equivocal (or indeterminate) result that changes to either positive or negative, change the result to the newer more specific value even though it may be a different test date. For a result that was originally equivocal (or indeterminate) or remains equivocal (or indeterminate) after repeated testing, record as "UNK/cannot disclose".

Malignancies between listing and transplant: If recipient had any malignancies between listing and transplant, select **Yes**. If the recipient has not had any malignancies, select **No**. If **Yes** is selected, indicate type of malignancy. If unknown, select **UNK**. If the recipient had a malignancy, but the type of malignancy is not listed, select **Other, specify** and enter the name of the malignancy in the space provided. This field is **required**.

Skin Melanoma Skin Non-Melanoma CNS Tumor Genitourinary Breast Thyroid Tongue/Throat/Larynx Lung Leukemia/Lymphoma Liver Other, specify

Note: This question is NOT applicable for patients receiving living donor transplants who were never on the waiting list.

Clinical Information: TRANSPLANT PROCEDURE

Multiple Organ Recipient: If the recipient received other organs, reported on the Recipient Feedback, they will display. If the recipient didn't receive any other organs at this time, **None** is displayed. Verify the other organs, transplanted at this time, are correct. If incorrect, contact the Help Desk.

<u>Were extra vessels used in the transplant procedure</u>: If extra vessels (vascular allografts) were used in the transplant procedure, as indicated on the Waitlist Removal, **YES** displays.

Vessel Donor ID: The **Donor ID** entered on the WaitlistSM Removal displays. Donor IDs entered for this question must be from deceased donors. All deceased donor extra vessels must be monitored due to the potential for disease transmission.

Note: If the extra vessels used in a transplant procedure are procured from a tissue processing organization, they are not reported in UNet.

Procedure Type: The procedure type, reported in the Recipient Feedback, will display. Verify the information displayed in the Procedure Type field is correct.

LEFT KIDNEY **RIGHT KIDNEY EN-BLOC** Sequential Kidney **Pancreas Segment** Whole Pancreas with Duodenum Whole Pancreas with Duodenal Patch Whole Pancreas Pancreas segment / Kidney Right Pancreas segment / Kidney Left Pancreas segment / En-bloc Kidney Pancreas Segment/Sequential Kidney Whole pancreas with duodenum / left kidney Whole pancreas with duodenum / right kidney Whole pancreas with duodenum / en-bloc kidneys Pancreas with duodenum/sequential kidney Whole pancreas with duodenal patch / left kidney Whole pancreas with duodenal patch / right kidney Whole pancreas with duodenal patch / en-bloc kidneys Pancreas with duodenal patch/sequential kidney Whole pancreas / left kidney Whole pancreas / right kidney Whole pancreas / en-bloc kidneys Whole pancreas/sequential kidney

Surgical Information:

Graft Placement: Indicate where the graft was placed during the transplant operation. This field is **required**.

Intra-Peritoneal: Pancreas graft placed totally within the peritoneal cavity. **Retro-Peritoneal:** Pancreas graft placed totally behind the peritoneum (extra peritoneal).

Partial Intra/Retro-Peritoneal: Pancreas placed retroperitoneally with the peritoneum then opened.

Operative Technique: Indicate the type of pancreas transplant. This field is **required**. (List of Operative Technique codes)

Pancreas Alone: The recipient only received a pancreas.

Cluster: The recipient received a pancreas with a least a whole liver. Other organs could also have been transplanted.

Multi-Organ Non-Cluster: The recipient received a pancreas with any other organ(s) excluding kidney and liver.

Pancreas After Kidney: The recipient received a pancreas after having a kidney transplant in the past.

Pancreas with Kidney Different Donor: The recipient received a deceased donor pancreas in addition to a living donor kidney at the same time.

Duct Management: Indicate the type of duct management used to manage the exocrine pancreatic functions. This field is **required**. (List of Duct Management codes)

Enteric with Roux-En-Y: The pancreatic duct is allowed to drain into the small intestine using a Roux-En-Y.

Enteric without Roux-En-Y: The pancreatic duct is allowed to drain into the small intestine without using a Roux-En-Y.

Cystostomy: The pancreatic duct is allowed to drain into the bladder.

Duct Injection Immediate: A synthetic polymer is injected directly into the pancreatic duct immediately after surgical revascularization.

Duct Injection Delayed: The duct is left open for a period up to 30 days before a synthetic polymer is injected directly into the pancreatic duct.

Other Specify: If a type of duct management used is not listed, select **Other** and enter the type of duct management in the space provided.

Note: If it is a multi-visceral transplant, select Enteric with Roux-En-Y or Enteric without Roux-En-Y. Only when either of these is selected will you have the N/A option on the Pancreas Transplant Recipient Follow-up (TRF) Record for Conv. From Bladder to Enteric Drain Performed.

Venous Vascular Management: Indicate which venous system (systemic or portal) was used to attach the pancreas. This field is required. (List of Vascular Management codes)

Systemic System (Iliac:Cava) Portal System (Portal or Tributaries) NA/Multi-organ cluster

Arterial Reconstruction: Indicate the type of arterial reconstruction used in the transplant operation. This field is **required**. (List of Arterial Reconstruction codes)

Celiac Axis with Pancreas: The celiac axis remained attached to the pancreas and reconstruction of the artery was not necessary.

Y-Graft to SpA and SMA: The splenic artery (SpA) and the superior mesenteric artery (SMA) were attached via an arterial graft.

SpA to SMA Direct: The splenic artery was anastomosed end-to-side to the superior mesenteric artery.

SpA to SMA with Interposition: The splenic artery was attached to the superior mesenteric artery with an interposition graft.

SpA Alone: The splenic artery alone.

Other Specify: If the type of arterial reconstruction is not listed, select **Other** and enter the type of reconstruction used in the space provided.

Venous Extension Graft: If a venous extension graft was used to lengthen the portal or splenic vein of the pancreas graft, select **Yes**. If not, select **No**. This field is **required**.

Preservation Information:

The preservation information for the pancreas procedure type is displayed for the recipient. Enter the **Total Pancreas Preservation Time**, in hours, for the pancreas procedure.

Total Pancreas Preservation Time (include cold, warm and anastomotic time) is the time between cessation of blood flow in the donor and revascularization of the pancreas in the recipient. If the time is unavailable, select the appropriate status from the **ST** field (**Missing, Unknown, N/A, Not Done**). This field is **required**. (List of Status codes)

Note: Enter the time in hours and decimal parts of an hour. For example, 1 hour should be entered as "1", "1.0" or "1.00"; 1 hour and 30 minutes should be entered as "1.5" or "1.50" not "1.30". To report the minutes, divide the number of minutes into 60 and record 2 decimal places. Example: 7hrs 19 minutes = 7.32 (60 divided by 19 =.32)

<u>Organ Check-In Date</u>: Enter the date (MM/DD/YYYY) the organ arrives at the transplant hospital (prior to opening the organ's external transport container).

<u>Check-In Time</u>: Enter the time the organ arrives at the transplant hospital (prior to opening the organ's external transport container).

Note: Time should be in 24-hour format.

Clinical Information: POST TRANSPLANT

Pancreas Graft Status: Select the status that best describes the pancreas graft status. If the **Patient Status** is **Retransplanted** for the pancreas, this field is not applicable.

Note: If death is indicated for the recipient, report graft status up until the instance of death.

Functioning: The graft has sufficient function so that the recipient is **NOT** receiving a level of insulin for blood sugar control that constitutes a failed graft (0.5 kg of insulin a day for 90 consecutive days).

Failed: The graft has failed when ANY of the following occurs:

- A recipient's transplanted pancreas is removed
- A recipient re-registers for a pancreas
- A recipient registers for an islet transplant after receiving a pancreas transplant
- A recipient's insulin use is greater than or equal to 0.5 units/kg/day for a consecutive 90 days
- · A recipient dies

If Failed is selected, complete the following fields:

Pancreas Date of Failure: Enter the date of failure using the standard 8 digit numeric format of MM/DD/YYYY. If the **Patient Status** is **Retransplanted** for the pancreas, this field is not applicable.

Pancreas Graft Removed: If the pancreas graft had been removed, select **Yes**. If not, select **No**. If unknown, select **UNK**.

If Yes, Date Pancreas Graft Removed: If the pancreas graft had been removed, enter the date of removal.

Pancreas Primary Cause of Graft Failure: Select the primary cause of graft failure. If the primary cause of graft failure is not listed, select **Other Specify** and enter the primary cause of graft failure in the space provided.

Graft/Vascular Thrombosis Infection Bleeding Anastomotic Leak Primary Non-Function Acute Rejection Hyperacute Rejection Biopsy Proven Isletitis Pancreatitis Other Specify

Contributory causes of graft failure: For each of the causes listed, select **Yes**, **No**, or **UNK** to indicate whether each is a contributory cause of graft failure. Select **NO** for the primary cause, since it cannot be both the primary and secondary cause of graft failure. If **Other** is selected, specify the cause in the space provided.

Pancreas Graft/Vascular Thrombosis Pancreas Infection Bleeding Anastomotic Leak Hyperacute Rejection Pancreas Acute Rejection Biopsy Proven Isletits Pancreatitis Other Specify

Patient using either oral medication or diet for blood sugar control: Answer whether the patient is using diet or medication for blood sugar control, **not including insulin**. *This includes injectable, non-insulin medications.* Select **Yes**, **No**, or **UNK** to indicate whether the patient is using any method of blood sugar control. This field is **required**.

Note: The intent of this field is to collect data on prescribed blood sugar maintenance. Extraneous methods sought out by a recipient outside of the prescribed regimen should not be taken into account when reporting on known methods of blood sugar control. For example, if it is known that a recipient is not on oral medication for blood sugar control, but it is unknown whether a recipient is using a diet not prescribed by the center (extraneous to the treatment plan), the user should enter No.

If Yes, complete the following fields:

Patient on oral medication to control blood sugar?: Select Yes, No, or UNK to indicate whether the patient is on oral medication to control blood sugar. This field is **required**.

Date of medications resumed: Enter the date medications resumed using the standard 8-digit numeric format of MM/DD/YYYY. Date must be after date of birth and before and/or equal to today's date. If unavailable, select the status from the **ST** field (**N/A**, **Not Done**, **Missing**, **Unknown**). This field is **required**.

Patient using diet to control blood sugar: Select Yes, No, or UNK to indicate whether the patient is using diet to control blood sugar. This field is required.

Patient on insulin? Select **Yes**, **No**, or **UNK** to indicate whether the patient is currently on insulin as of the patient status date. This field is **required**.

If Yes, complete the following fields:

Date insulin resumed: Enter the date insulin resumed using the standard 8-digit numeric format of MM/DD/YYYY. Date must be after date of birth and before and/or equal to today's date. If unavailable, select the appropriate status from the **ST** field (**N/A**, **Not Done**, **Missing**, **Unknown**). This field is **required**.

Average total insulin dosage per day: Enter the average daily total insulin dosage units (units/kg/day) in the space provided. Average daily insulin dose should be a total including all insulin administered in any form per day (short term, long term, by pump, subcutaneous). The insulin dosage units must be between 1 and 1000. If the value is unavailable, select the appropriate status from the ST field (N/A, Not Done, Missing, Unknown). This field is required.

Insulin duration of use: Enter the insulin duration of use (days) for the current dosage in the space provided. If unavailable, select the appropriate status from the **ST** field (**N/A**, **Not Done**, **Missing**, **Unknown**). This field is **required**.

<u>C-peptide value</u>: Enter the c-peptide value in ng/mL. The value must be between 0.00 and 99.90. If unavailable, select the status from the **ST** field (**N/A**, **Not Done**, **Missing**, **Unknown**).

Pancreas Transplant Complications: (Not leading to graft failure.)

For each of the complications listed, indicate if the complication occurred prior to the recipient's hospital discharge. Do not select **Yes** if the complication contributed to failure of the pancreas graft.

Pancreatitis: If the recipient has been diagnosed as having pancreatitis, select **Yes**. If not, select **No**. If unknown, select **UNK**. This field is **required**.

Anastomotic Leak: If the recipient exhibits signs and symptoms of an anastomotic leak, select Yes. If not, select No. If unknown, select UNK. This field is required.

Abscess or Local Infection: If the recipient exhibits signs and symptoms of abscess or local infection, select Yes. If not, select No. If unknown, select UNK. This field is required.

Pancreas Transplant Complications: Other: If a complication other than those listed occurred, specify the complication in the space provided.

<u>Did patient have any acute rejection episodes between transplant and discharge</u>: If the recipient had any acute rejection episodes between transplant and discharge, select a **Yes** choice. If not, select **No**. This field is **required**. (List of Any Acute Rejection Episodes codes)

Yes, at least one episode treated with anti-rejection agent Yes, none treated with additional anti-rejection agent No

Immunosuppressive Information

Are any medications given currently for maintenance or anti-rejection: If medications have been given to the recipient for maintenance or anti-rejection during the time between transplant and hospital discharge, or 6 weeks post-transplant if the recipient has not been discharged, select **Yes**. If not, select **No**. If **Yes**, complete the sections below. This field is required.

Definition of Immunosuppressive Medications

For each of the immunosuppressive medications listed, select Ind (Induction), Maint (Maintenance) or AR (Anti-rejection) to indicate all medications that were prescribed for the recipient during the initial transplant hospitalization period, and for what reason. If a medication was not given, leave the associated box(es) blank.

Induction (Ind) immunosuppression includes all medications given for a short finite period in the perioperative period for the purpose of preventing acute rejection. Though the drugs may be continued after discharge for the first 30 days after transplant, it will not be used long-term for immunosuppressive maintenance. Induction agents are usually polyclonal, monoclonal, or IL-2 receptor antibodies (example: methylprednisolone, Campath, Thymoglobulin, or Simulect). Some of these drugs might be used for another finite period for rejection therapy and would be recorded as anti-rejection therapy if used for this reason. For each induction medication indicated, write the total number of days the drug was actually administered in the space provided. For example, if Simulect was given in 2 doses a week apart then the total number of days would be 2, even if the second dose was given after the patient was discharged.

Maintenance (Maint) includes all immunosuppressive medications given before, during or after transplant with the intention to maintain them long-term (example: prednisone, cyclosporine, tacrolimus, mycophenolate mofetil, azathioprine, or Rapamune). This does not include any immunosuppressive medications given to treat rejection episodes, or for induction.

Anti-rejection (AR) immunosuppression includes all immunosuppressive medications given for the purpose of treating an acute rejection episode during the initial post-transplant period or during a specific follow-up period, usually up to 30 days after the diagnosis of acute rejection (example: methylprednisolone, or Thymoglobulin). When switching maintenance drugs (example: from tacrolimus to cyclosporine; or from mycophenolate mofetil to azathioprine) because of rejection, the drugs should not be listed under AR immunosuppression, but should be listed under maintenance immunosuppression. If an immunosuppressive medication other than those listed is being administered (e.g., new monoclonal antibodies), select Ind, Maint, or AR next to Other Immunosuppressive Medication field, and enter the full name of the medication in the space provided. *Note:* Do not list non-immunosuppressive medications.

Drug used for induction, acute rejection, or maintenance

Select the appropriate status from the applicable **Status** field (**Missing, Unknown, N/A, Not Done**).

Steroids (prednisone, methylprednisolone, Solumedrol, Medrol)

Drugs used for induction or acute rejection

Select the appropriate status from the applicable **Status** field (**Missing, Unknown, N/A, Not Done**).

Atgam

Campath (alemtuzumab)

Cytoxan (cyclophosphamide)

Methotrexate (Folex PFS, Mexate-AQ, Rheumatrex)

Rituxan (rituximab)

Simulect (basiliximab)

Thymoglobulin

Drugs primarily used for maintenance

Select the appropriate status from the applicable **Status** field (**Missing, Unknown, N/A, Not Done**).

Cyclosporine, select from the following:

- Gengraf
- Neoral
- Sandimmune
- Generic cyclosporine
- Imuran (azathioprine, AZA)
- Leflunomide (LFL)

Mycophenolic acid, select from the following:

- CellCept (MMF)
- Generic MMF (generic CellCept)
- Myfortic (mycophenolic acid)
- Generic Myfortic (generic mycophenolic acid)

mTOR inhibitors, select from the following:

- Rapamune (sirolimus)
- Generic sirolimus
- Zortress (everolimus)
- Nulojix (belatacept)

Tacrolimus, select from the following:

- Astagraf XL (extended release tacrolimus)
- Envarsus XR (tacrolimus XR)
- Prograf (tacrolimus)
- Generic tacrolimus (generic Prograf)

Other drugs

Select the appropriate status from the applicable **Status** field (**Missing, Unknown, N/A, Not Done**).

Other immunosuppressive medication, specify:

Public Burden Statement: The private, non-profit Organ Procurement and Transplantation Network (OPTN) collects this information in order to perform the following OPTN functions: to assess whether applicants meet OPTN Bylaw requirements for membership in the OPTN; and to monitor compliance of member organizations with OPTN Obligations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0915-0157 and it is valid until XX/XX/202X. This information collection is required to obtain or retain a benefit per 42 CFR §121.11(b) (2). All data collected will be subject to Privacy Act protection (Privacy Act System of Records #09-15-0055). Data collected by the private non-profit OPTN also are well protected by a number of the Contractor's security features. The Contractor's security system meets or exceeds the requirements as prescribed by OMB Circular A-130, Appendix III, Security of Federal Automated Information Systems, and the Departments Automated Information Systems Security Program Handbook. The public reporting burden for this collection of information is estimated to average 0.27 hours per response, including the time for reviewing instructions, searching existing data sources, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to HRSA Information Collection

Clearance Officer, 5600 Fishers Lane, Room 14N39, Rockville, Maryland, 20857 or paperwork@hrsa.gov.