Pancreas Transplant Recipient Registration (TRR) Record Field Descriptions

The Transplant Recipient Registration (TRR) records are generated and available immediately after a transplant event is reported through the recipient feedback process in Waitlist[™]. A TRR will also be generated in the case of a living donor transplant, where a recipient was added through the donor feedback process in Tiedi[®]. 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 the most recent information available regarding the recipient's progress.

The TRR record must be completed within 60 days from the record generation date. See <u>OPTN/UNOS</u> <u>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.

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.

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

<u>Gender</u>: Verify the recipient's gender is correct. 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 <u>most recently</u> updated TCR record is correct. If the recipient does not have a HIC number, you may leave this field blank.

<u>Tx Date</u>: Verify the displayed transplant date is the date of the beginning of the first anastomosis. If the operation started in the evening and the first anastomosis began early the next morning, the transplant date is the date that the first anastomosis began. The transplant is considered complete when the cavity is closed and the final skin stitch/staple is applied. The transplant date is indicated immediately after a transplant event is reported through the recipient feedback process in Waitlist and in the case of a living donor transplant, where a recipient was added through the donor feedback process in Tiedi.

<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**. (Appendix A)

<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 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 UNOS Donor ID number, reported in the Recipient Feedback, will display. Each potential donor is assigned an identification number by OPTN/UNOS. This ID number corresponds to the date the donor information was entered into the OPTN/UNOS 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. This field is **required**. (Appendix O) For definitions of the diagnosis codes, please see the <u>OPTN</u> website.

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. (<u>Appendix X</u>)

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. (Appendix X)

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. (Appendix X)

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

Working for income: (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:

Primary: Select as appropriate to indicate the recipient's source of primary payment (largest contributor) for the transplant. This field is **required**.

Private insurance refers to funds from agencies such as Blue Cross/Blue Shield, etc. 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 recipient. For additional information about Medicare, see <u>http://www.medicare.gov/</u>.

Public insurance - Medicare & Choice (also known as Medicare Managed Care) refers to funds from the government in which doctors and other health care providers are paid for each service provided to a recipient, along with additional benefits such as coordination of care or reducing-out-of-pocket expenses. Sometimes a recipient may receive additional benefits such as prescription drugs. 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.

Public insurance - Other government

Self indicates that the recipient 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 recipient.

Free Care indicates that the transplant hospital will not charge recipient for the costs of the transplant operation.

Foreign Government, Specify refers to funds provided by a foreign government (Primary only) Specify foreign country in the space provided. (<u>Appendix E</u>)

Unknown

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 and weight were 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**). 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</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**). 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.

Previous Transplants: 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).

<u>Average Daily Insulin Units</u>: Enter the recipient's average daily insulin in units. If the value is unavailable, select the appropriate status from the **ST** field (**Missing**, **Unknown**, **N/A**, **Not Done**, **Sliding Scale**). 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.

Definition: Human Immunodeficiency Virus - Any of several retroviruses and especially HIV-1 that infect and destroy helper T cells of the immune system causing the marked reduction in their numbers that is diagnostic of AIDS.

Nucleic Acid Testing (NAT) HIV- Select the NAT results from the list. This field is required

Positive
Negative
Not Done
UNK/Cannot Disclose

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.

Nucleic Acid Testing (NAT) HBV- Select the NAT results from the list. This field is required

Positive Negative Not Done UNK/Cannot Disclose

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.

Nucleic Acid Testing (NAT) HCV- Select the NAT results from the list. This field is required

Positive Negative Not Done UNK/Cannot Disclose

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

Positive	
Negative	
Not Done	
UNK/Cannot Disclos	e

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.

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

<u>Multiple Organ Recipient</u>: 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.

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**.

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.

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

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**.

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.

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)

Clinical Information: POST TRANSPLANT

Pancreas Graft Status: Select the status that best describes the pancreas graft status. This field is **required**.

Note: Select **Functioning** for the **Pancreas Graft Status** field if the patient was removed from the waiting list with a code 21, indicating the patient died during the transplant procedure.

Note: If death is indicated for the recipient, and the death was a result of some other factor unrelated to graft failure, select **Functioning**.

Functioning: The graft has sufficient function so that the recipient is **NOT** receiving any insulin or medication for blood sugar control.

Failed: The graft has totally failed and the patient is completely dependent upon insulin or oral medication for blood sugar control.

Patient using any method of blood sugar control? If the recipient is using any method of blood sugar control (i.e. insulin, oral medication, or diet) select Yes. If not, select No. If unknown, select UNK. This field is required.

Patient on Insulin? – If the recipient is currently on insulin then answer Yes. If the candidate is not on insulin answer No. If unknown, select UNK. This field is required

If Yes is entered, complete the following fields:

Date insulin resumed: Enter the date that the recipient resumed insulin treatment. This field is **required** if graft status is **Failed**.

Total insulin dosage units: Enter the total insulin dosage (long term dosage + short term dosage) post transplant. The dosage units must be entered in unit/kg/day. If the candidate's insulin dosage is unavailable, select the appropriate status from the **ST** field (**Missing**, **Unknown**, **N/A**, **Not Done**).

Insulin duration of use: Enter the total number of **days** that the candidate received insulin prior to listing. If the candidate's insulin duration is unavailable, select the appropriate status from the **ST** field (**Missing**, **Unknown**, **N/A**, **Not Done**).

Patient on oral medication to control blood sugar?: If the recipient is currently on oral medications to control blood sugar then answer **Yes.** If the candidate is not on oral medications to control blood sugar then answer **No**. If unknown, select **UNK.** This field is **required** if graft status is **Failed**.

Date oral medications resumed: Enter the date that the recipient began oral medications.

Patient using diet to control blood sugar: If the recipient is currently on using diet to control blood sugar levels then answer Yes. If the candidate is not answer No. If unknown, select UNK. This field is required if graft status is Failed.

If Failed is selected, complete the following fields:

Date of Graft Failure: Enter the date of graft failure using the standard 8-digit numeric format of MM/DD/YYYY.

Note: The date of failure and the date insulin/medication was resumed should be the same, unless the patient has a previous partial graft function reported.

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

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.

Did patient have any acute rejection episodes between transplant and discharge: If the recipient had any acute rejection episodes between transplant and discharge, select a **Yes** choice. If not, select **No**. If a **Yes** choice is selected, then indicate if a biopsy was done to confirm acute rejection. This field is **required**.

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

C-peptide Value: Enter the c-peptide value in ng/mL, range 0 - 15.00. If the value is unavailable, select the appropriate status from the **ST** field (**Missing**, **Unknown**, **N/A**, **Not Done**). For undetectable c-peptide values where the c-peptide value is reported as <X value, the threshold (i.e. X) is the acceptable value. For example, if c-peptide value is reported as <0.1 then the threshold is 0.1 and should be entered as "0.1" into the c-peptide value field. This field is **required**

Hba1c (%) – Enter the Hba1c percentage (0.0 – 99.9). If the value is unavailable, select the appropriate status from the **ST** field (**Missing**, **Unknown**, **N/A**, **Not Done**).

Immunosuppressive Information

<u>Are any medications given currently for maintenance or anti-rejection</u>: 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**.

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 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 <u>will not</u> be used long-term for immunosuppressive maintenance. Induction agents are usually polyclonal, monoclonal, or IL-2 receptor antibodies (e.g., Methylprednisolone, Atgam, Thymoglobulin, OKT3, Simulect, or Zenapax). Some of these drugs might be used for another finite period for rejection therapy and would be recorded as rejection therapy if used for this reason. For each induction medication indicated, enter the total number of days the drug was actually administered in the space provided. For example, if Simulect or Zenapax 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 for varying periods of time which may be either long-term or intermediate term with a tapering of the dosage until the drug is either eliminated or replaced by another long-term maintenance drug (e.g., Prednisone, Cyclosporine, Tacrolimus, Mycophenolate Mofetil, Azathioprine, or Rapamycin). 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 (e.g., Methylprednisolone, Atgam, OKT3, or Thymoglobulin). When switching maintenance drugs (e.g., 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.

Note: As further clarification, drugs that are used with the intention to maintain recipients longterm are medications such as Tacrolimus, Cyclosporine, Azathioprine, Mycophenolate Mofetil and Prednisone. These maintenance medications should not be listed as AR medications to treat acute rejection. When patients have a true acute rejection, they are given anti-rejection medication such as steroids, OKT3, ATG, Simulect and Zenapax, in addition to the maintenance medications. These are the medications that should be selected as anti-rejection.

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. <u>**Do not list non-**</u> **<u>immunosuppressive medications</u>**.

If the number of days is unavailable, select the appropriate status from the applicable **Status** field (**Missing**, **Unknown**, **N/A**, **Not Done**).

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, Decadron)

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, anti-CD52)

Cytoxan (cyclophosphamide)

Methotrexate (Folex PFS, Mexate-AQ, Rheumatrex)

OKT3 (Orthoclone, muromonab)

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:

- EON (generic cyclosporine)
- Gengraf (Abbott cyclosporine)
- Neoral (CyA-NOF)
- Other generic cyclosporine, specify brand:
- Sandimmune (cyclosporine A)
- Imuran (azathioprine, AZA)
- Leflunomide (LFL)

Mycophenolate acid, select from the following:

- CellCept (MMF)
- Generic MMF (generic CellCept)
- Myfortic (mycophenolate acid)
- Nulojix (belatacept)
- Rapamune (sirolimus, Rapamycin)

Tacrolimus, select from the following:

- Astagraf XL (extended release tacrolimus)
- Generic tacrolimus (generic Prograf)
- Prograf (FK506)
- Zortress (everolimus)

Other drugs

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