Kidney/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 WaitlistSM. 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

<u>Name</u>: 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. This field is **required**. (<u>List of State codes</u>)

<u>Permanent Zip</u>: Enter the recipient's zip code, of their permanent address, at the time of transplant. This field is **required**.

Provider Information

<u>Recipient Center</u>: The recipient center will display. Verify that the transplant center name, center code, and the provider number, (6-character Medicare identification number of the hospital where the transplant recipient was transplanted) are correct.

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, formerly HCFA) assigned National Provider Identifier of the transplant physician. 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.

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

<u>Kidney Primary Diagnosis</u>: Select the primary diagnosis for the disease requiring a kidney transplant for this recipient. If the recipient has had a previous transplant for the same organ type, select 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. (List of Kidney Diagnosis codes)

<u>Pancreas Primary Diagnosis</u>: Select the primary diagnosis for the disease requiring a pancreas 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. (List of Pancreas Diagnosis codes)

Date: Last Seen Retransplanted or Death: 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**.

<u>Patient Status</u>: Select the appropriate status for this recipient. If **Dead** is selected, indicate the cause of death. This field is **required**. (List of Patient Status codes)

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 both the **Kidney Graft Status** and **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 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 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.

Was patient hospitalized during the last 90 days prior to the transplant admission? If the recipient was hospitalized during the last 90 days prior to transplant admission, select **Yes**. If not, select **No**. If unknown, select **UNK**.

<u>Medical Condition at time of transplant</u>: Select the choice that best describes the recipient's condition and location just prior to the time of transplant. This field is **required**. (List of Medical Condition codes)

In Intensive Care Unit Hospitalized Not in ICU Not Hospitalized

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

Note: The Karnofsky Index will display for recipients 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 Scale will display for recipients aged 1 to 17.

- 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>Physical Capacity</u>: (Complete for recipients older than 18 years of age.) Select the choice that best describes the recipient's physical capacity just prior to the time of transplant. If the recipient's **Medical Condition** indicates they are hospitalized, select **Not Applicable (hospitalized)**. (List of Physical Capacity codes)

No Limitations Limited Mobility Wheelchair bound or more limited Not Applicable (hospitalized) Unknown

Physical Capacity is the ability to perform bodily activities such as walking, dressing, bathing, grooming, etc.

<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

<u>Motor Development</u>: (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. (<u>List of Motor Development codes</u>)

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>Working for income</u>: (This field is **required** for recipients 19 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**.

If No, Not Working Due To: If No is selected, indicate the reason why the candidate is not working just prior to the time of transplant. (This field is optional for <u>adult</u> candidates only.) (<u>List of Not Work</u> <u>Reason codes</u>)

Disability - A physical or mental impairment that interferes with or prevents a candidate from working (e.g. arthritis, mental retardation, cerebral palsy, etc).

Demands of Treatment - An urgent medical treatment that prevents a candidate from working (e.g. dialysis).

Insurance Conflict - Any differences between a candidate and insurance company that prevents them from working.

Inability to Find Work - The lack of one's ability to find work (e.g. lack of transportation, work experience, over qualification, unavailable work, etc.).

Patient Choice - Homemaker - A candidate who chooses to manage their own household, instead of performing work for pay.

Patient Choice - Student Full Time/Part Time - A candidate who is enrolled and/or participating in college.

Patient Choice - Retired - A candidate who no longer has an active working life such as an occupation, business or office job.

Patient Choice - Other - Any reason not listed above that would prevent a candidate from working.

Not Applicable - Hospitalized - Select only if the patient's Medical Condition indicates they are in the hospital.

Unknown

If Yes: If Yes is selected, indicate the candidate's working status just prior to the time of transplant. (List of Working codes)

Working Full Time Working Part Time due to Demands of Treatment Working Part Time due to Disability Working Part Time due to Insurance Conflict Working Part Time due to Inability to Find Full Time Work Working Part Time due to Patient Choice Working Part Time Reason Unknown Working, Part Time vs. Full Time Unknown

<u>Academic Progress</u>: (This field is **required** for recipients less than 19 years of age.) Select the choice that best describes the recipient's academic progress just prior to the time of transplant. If the candidate is less than 5 years old or has graduated from high school, select **Not Applicable < 5 years old/High School graduate or GED**. (List of Academic Progress codes)

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 19 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**. (List of Academic Activity Level codes)

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

Kidney 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**. (List of Primary Insurance codes)

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 http://www.medicare.gov/Choices/Overview.asp.

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 <u>additional benefits</u> 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/Choices/Overview.asp.

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>List of Foreign Country codes</u>)

Secondary: Select check as appropriate to indicate the recipient's source of secondary payment. (List of Secondary Insurance codes)

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 http://www.medicare.gov/Choices/Overview.asp.

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

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 the recipient for the costs of the transplant operation.

None - Select if the recipient does not have a secondary source of payment.

Pancreas 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**. (List of Primary Insurance codes)

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 http://www.medicare.gov/Choices/Overview.asp.

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 <u>additional benefits</u> 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/Choices/Overview.asp.

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.

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

Secondary: Select check as appropriate to indicate the recipient's source of secondary payment. (List of Secondary Insurance codes)

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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 the recipient for the costs of the transplant operation.

None - Select if the recipient does not have a secondary source of payment.

Clinical Information: PRETRANSPLANT

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.

<u>Height</u>: 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**). (<u>List of Status codes</u>) 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**.

Weight: 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 UNetsm 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 First Dialyzed: If the recipient was on maintenance dialysis before transplant, enter the date that the recipient first began 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 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**). This field is **required**. (<u>List of Status codes</u>)

<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**. (<u>List of Status codes</u>)

Viral Detection:

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

Positive Negative Not Done UNK/Cannot Disclose

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.

CMV IgG: Select the serology results from the drop-down list. 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).

CMV IgM: Select the serology results from the drop-down list. This field is required.

Positive	
Negative	
Not Done	
UNK/Cannot Dis	sclose

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 Core Antibody: Select the serology results from the drop-down 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 drop-down 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 drop-down 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 drop-down list. 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.

<u>Was preimplantation kidney biopsy performed at the transplant center</u>: If a pre-implantation kidney biopsy was performed, select **Yes**. If not, select **No**. If unknown, select **UNK**.

<u>Did patient receive any pretransplant blood transfusions</u>: If the recipient received any pretransplant blood transfusions between listing and transplant, select **Yes**. If not, select **No**. If unknown, select **UNK**. This field is **required**.

<u>Any tolerance induction technique used</u>: If the recipient used any tolerance induction technique, select **Yes**. If not, select **No**. If unknown, select **UNK**.

Tolerance Induction: Before a transplant occurs the immune system can be prepared for the upcoming graft by attempting to induce graft tolerance. This can be achieved through a variety of protocols. The following are examples of tolerance induction protocols from the <u>Primer on</u> <u>Transplantation 1-4</u>)*:

Administration of moAbs (monoclonal antibodies) targeting cell surface molecules such as CD4, CD8, CD25, LFA-1, or the TCR (T-cell receptor)

Blockade of the costimulation pathways of T cell activation

Institution of pharmacological drug including steroids, rapamycin, cyclosporine

Donor specific transfusion

Combinations of immunosuppressive drugs and plasmaphoresis to decrease the recipient PRA in living donor transplants (member example)

* Norman, Douglas J., Turka, Laurence A. Primer on Transplantation, Second Edition page 40, American Society of Transplantation 2001

<u>Previous Pregnancies</u>: (This field will not display for male recipients.) For female recipients, select the number of previous pregnancies. Previous pregnancies include pregnancies, which may not have resulted in live births. If the information is unknown, select **Unknown**. (This field is optional for <u>pediatric</u> recipients only.) This field is **required**. (List of Pregnancy codes)

No Previous Pregnancy 1 Previous Pregnancy 2 Previous Pregnancies 3 Previous Pregnancies 4 Previous Pregnancies 5 Previous Pregnancies More than 5 Previous Pregnancies Not Applicable: < 10 years old Unknown

<u>Malignancies between listing and transplant</u>: 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 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**. (List of Malignancy codes)

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.

Bone Disease (check all that apply): (Complete for recipients 18 years of age or younger.)

Fracture in the past year: If the recipient had any fractures in the past year, select Yes. If not, select No. If unknown, select UNK. This field is required.

If Yes is selected, specify the location and number of fractures

Spine-compression fracture:	#of fractures:
Extremity:	# of fractures:
Other:	# of fractures:

AVN (avascular necrosis): If the recipient has AVN at the time of transplant, select **Yes**. If not, select **No**. If unknown, select **UNK**. This field is **required**.

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 tx 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 Waitlist Removal displays.

Note: 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. (List of Procedure Type codes)

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 / left kidney Whole pancreas with duodenal patch / right kidney Whole pancreas with duodenal patch / en-bloc kidneys Pancreas with duodenal patch / en-bloc kidneys Pancreas with duodenal patch / en-bloc kidneys Whole pancreas / left kidney Whole pancreas / right kidney Whole pancreas / right kidney Whole pancreas / en-bloc kidneys Whole pancreas / en-bloc kidneys

Surgical Information:

Was the Pancreas revascularized before or after other organs? Indicate if the pancreas was revascularized. If this surgery did not include a simultaneous transplant with another organ, select Not Applicable. (List of Revascularized codes)

Before Simultaneous After Not Applicable

Surgical Incision: Indicate the surgical incision type. (List of Surgical Incision codes)

Iliac Fossa PA left/KI right: A transverse, lower abdominal incision Iliac Fossa PA right/KI left: A transverse, lower abdominal incision Left Midline: Incision follows the midline of the abdomen. Right

Graft Placement: Indicate where the graft was placed during the transplant operation. This field is **required**. (List of Graft Placement codes)

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 retro-peritoneally with the peritoneum then opened.

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

Simultaneous Kidney-Pancreas: The recipient received a simultaneous kidney pancreas. **Cluster:** The recipient received a pancreas with at 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.

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.

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 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**.

Kidney and Pancreas Preservation Information:

Note: When entering time in hours, 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)

Total Cold Ischemia Time <u>Right KI</u> (OR EN-BLOC): (if pumped, include pump time): If the recipient's Procedure Type is **Right Kidney**, **En-Bloc**, or **Sequential**, enter the **Total Cold Ischemia Time** for the right kidney or both kidneys, in hours, (if pumped, include pump time). If the time is unavailable, select the status from the **ST** field (**Missing**, **Unknown**, **N/A**, **Not Done**). This field is **required**. (List of Status codes)

-OR-

Total Cold Ischemia Time Left KI (OR EN-BLOC): (if pumped, include pump time): If the recipient's Procedure Type is Single Left, or Sequential, enter the Total Cold Ischemia Time for the left kidney, in hours, (if pumped, include pump time). If the time is unavailable, select the status from the ST field (Missing, Unknown, N/A, Not Done). This field is required. (List of Status codes)

Total Cold Ischemia Time is the number of hours between the time preservation of the organ begins and the time the organ was removed from cold storage.

Total Warm Ischemia Time <u>Right KI (OR EN-BLOC)</u>: (include anastomotic time): If the recipient's Procedure Type is **Right Kidney**, En-Bloc, or Sequential, enter the Warm Ischemia

Time for the right kidney or both kidneys, in minutes, (include anastomotic time) for the <u>right or en-bloc kidneys</u>. (This field is optional for <u>adult</u> recipients only.) If the time is unavailable, select the status from the **ST** field (**Missing**, **Unknown**, **N/A**, **Not Done**). This field is **required**. (<u>List of Status codes</u>)

-OR-

Total Warm Ischemia Time Left KI (OR EN-BLOC): (include anastomotic time): If the recipient's Procedure Type is Single Left, or Sequential, enter the Warm Ischemia Time for the left kidney, in minutes, (include anastomotic time) for the <u>right or en-bloc kidneys</u>. (This field is optional for <u>adult</u> recipients only.) If the time is unavailable, select the status from the ST field (Missing, Unknown, N/A, Not Done). This field is required. (List of Status codes)

Total Pancreas Preservation Time (include cold, warm, anastomotic time): The preservation information for the pancreas procedure type is displayed for the recipient. This is the time between cessation of blood flow in the donor and revascularization of the pancreas in the recipient. Enter the time in hours. 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)

<u>Kidney(s) received on</u>: Indicate whether the transplanted organs were received on **Ice** or **Pump**. For recipients of a living donor transplant, **N/A** is also an option. If received on ice, indicate whether the organ(s) **Stayed on ice** or were **Put on pump**. If received on pump, indicate whether the organ(s) **Stayed on pump** or were **Put on ice**. This field is **required**. (List of Kidneys Received On codes)

Note: Select **N/A** from the **ST** field for all Preservation Information if the recipient was removed from the waiting list with a code 21, indicating the recipient died during the transplant procedure.

If put on pump or stayed on pump: If the organs were pumped, indicate the Final resistance at transplant and Final flow rate at transplant in the spaces provided. This field will not display if transplanted organs were received on Ice and Stayed on ice. If final resistance is unavailable, select the appropriate status from the ST field (Missing, Unknown, N/A, Not Done).

Incidental Tumor found at time of Transplant: If an incidental tumor was found at the time of transplant in an organ that was removed from the recipient, select Yes. If not, select No. If unknown, select UNK. If Yes is selected, specify the tumor type. If Other Primary Kidney Tumor, Specify is selected, enter the name in the space provided. (Missing, Unknown, N/A, Not Done). (List of Tumor codes)

Oncocytoma Renal Cell Carcinoma Carcinoid Adenoma Transitional Cell Carcinoma Other Primary Kidney Tumor, Specify

Clinical Information: Post Transplant

<u>Kidney Graft Status</u>: If the kidney graft is functioning, select **Functioning**. If the graft is not functioning at the time of hospital discharge or time of report, select **Failed**. If Failed, complete the remainder of this section. This field is **required**.

- *Note:* Select **Functioning** if the recipient was removed from the waiting list with a code 21, indicating the recipient 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**.

Resumed Maintenance dialysis: If the recipient returned to maintenance dialysis, select **Yes**. If not, select **No**.

Date Maintenance Dialysis Resumed: If the recipient returned to maintenance dialysis, enter the date using the standard 8-digit numeric format of MM/DD/YYYY.

Select a Dialysis Provider:

Provider #: If the recipient returned to maintenance dialysis, enter the provider.

Provider Name: Enter the name of the dialysis provider.

Note: You may re-sort your Provider or Center results by clicking the designated red drop-down arrow.

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

Kidney 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 Cause** and enter the primary cause of graft failure in the space provided. (List of Graft Failure codes)

Hyperacute Rejection Acute Rejection Primary Failure Graft Thrombosis Infection Surgical Complications Urological Complications Recurrent Disease Other Specify Cause

Contributory causes of graft failure: For each of the causes listed, select **YES**, **NO**, or **UNK** to indicate if 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 a cause other than those listed contributed to the graft failure, enter the contributory cause of graft failure in the **Other** space provided.

Kidney Acute Rejection Kidney Graft Thrombosis Kidney Infection Surgical Complications Urological Complications Recurrent Disease Other, Specify:

Did patient have any acute kidney 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. (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

Was Biopsy done to confirm acute rejection: If the recipient had an acute kidney rejection episode, indicate whether biopsy confirmed acute rejection by selecting Yes. If a biopsy was not done, select Biopsy not done. If unknown, select Unknown. (List of Biopsy Confirmed codes)

Biopsy not done Yes, rejection confirmed Yes, rejection not confirmed

Is growth hormone therapy used between listing and transplant: If growth hormone therapy was used select YES. If not, select NO. If unknown, select UNK. This field is required.

<u>Most Recent Serum Creatinine Prior to Discharge</u>: Enter the most recent serum creatinine value in mg/dl available prior to the recipient's discharge from the hospital. Enter a number between 0.1 and 25.0. If the value is unavailable, select the appropriate status from the **ST** field (**Missing**, **Unknown**, **N/A**, **Not Done**). This field is **required**. (List of Status codes)

<u>Kidney Produced > 40 ml of Urine in First 24 hours:</u> If the kidney graft produced at least 40 ml of urine within the first 24 hours following the transplant operation, select **Yes**. If not, select **No**.

<u>Patient Need dialysis within First Week:</u> If the recipient required any dialysis within the first 7 days following the transplant operation, select **Yes**. If not, select **No**. This field is **required**.

<u>Creatinine decline by 25% or more in first 24 hours on 2 separate samples</u>: If creatinine value declined by 25% or more in the first 24 hours post transplant on 2 separate samples, select **Yes**. If not, select **No**.

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.

Partial Function: The patient is taking some insulin, but \leq 50% of the usual amount taken before transplant, or C-Peptide is present.

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

Method of blood sugar control: If Partial Function or Failed is selected, check all that apply. (List of Blood Sugar Control codes)

Insulin Oral medication Diet No Treatment

Date Insulin/Medication Resumed: If **Insulin** or **Oral medication** is selected, enter the date using the standard 8 digit numeric format of MM/DD/YYYY.

If Failed is selected, complete the following fields:

Date of Graft Failure Pancreas: If the pancreas graft failed, enter the date of the failure.

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. (List of Graft Failure codes)

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

Did patient have any acute pancreas 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**. (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

Was Biopsy done to confirm acute rejection: If the answer to the previous question was YES, recipient had an acute kidney rejection episode, indicate whether biopsy confirmed acute rejection by selecting Yes. If a biopsy was not done, select Biopsy not done. If unknown, select Unknown. (List of Biopsy Confirmed codes)

Biopsy not done Yes, rejection confirmed Yes, rejection not confirmed

<u>Pancreas Transplant Complications</u>: (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.

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

<u>Weight Post Transplant</u>: Enter the recipient's weight, at the time of discharge, in pounds or kilograms. If the recipient's weight is not available, select the appropriate status from the **ST** field (**Missing**, **Unknown, N/A**, **Not Done**). This field is **required**.

Treatment

Biological or Anti-viral Therapy: If biological or anti-viral therapy is being administered to the recipient, select **Yes**. If not, select **No**. If unknown or can't disclose, select **Unknown/Cannot Disclose**. If **Yes** is selected, check all that apply. If a therapy, other than those listed, was administered, select **Other, Specify** and enter the therapy in the space provided. (List of Anti-viral Treatment codes)

Acyclovir (Zovirax) Cytogam (CMV) Gamimune Gammagard Ganciclovir (Cytovene) Valgancyclovir (Valcyte) HBIG (Hepatitis B Immune Globulin) Flu Vaccine (Influenza Virus) Lamivudine (Epivir) (for treatment of Hepatitis B) Other, Specify Valacyclovir (Valtrex)

<u>Other Therapies</u>: If the recipient received other therapies, select **Yes**. If not, select **No**. If **Yes** is selected, check all that apply. (<u>List of Other Therapies codes</u>)

Photopheresis Plasmapheresis Total Lymphoid Irradiation (TLI)

Note: If the recipient was removed from the waiting list with a code 21, indicating the recipient died during the transplant procedure, select **No** for all Biologicals or Anti-viral.

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**.

<u>Did the recipient participate in any clinical research protocol for immunosuppressive</u> <u>medications</u>: If the recipient participated in clinical research for immunosuppressive medications, select **Yes**. If not, select **No**. If **Yes**, specify in the space provided.

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 <u>total number of days the drug was actually administered</u> 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 <u>should not</u> be listed under AR immunosuppression, but <u>should be</u> 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**). (<u>List of Status codes</u>)

Other 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 <u>total number of days the drug was actually administered</u> 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 <u>should not</u> be listed under AR immunosuppression, but <u>should be</u> 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**). (<u>List of Status codes</u>)

Investigational 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 (example: 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 <u>total number of days the drug was actually administered</u> 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 (example: Methylprednisolone, Atgam, OKT3, or Thymoglobulin). When switching maintenance drugs (example: from Tacrolimus to Cyclosporine; or from Mycophenolate Mofetil to Azathioprine) because of rejection, the drugs <u>should not</u> be listed under AR immunosuppression, but <u>should be</u> 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**). (<u>List of Status codes</u>)

Drug Codes (List of Drug Codes)

Immunosuppressive Medications

Steroids (Prednisone, Methylprednisolone, Solumedrol, Medrol, Decadron) Atgam (ATG) OKT3 (Orthoclone, Muromonab) Thymoglobulin Simulect - Basiliximab Zenapax - Daclizumab Azathioprine (AZA, Imuran) EON (Generic Cyclosporine) Gengraf (Abbott Cyclosporine) Other generic Cyclosporine, specify brand: Neoral (CyA-NOF) Sandimmune (Cyclosporine A) CellCept (Mycophenolate Mofetil; MMF) Generic MMF (Generic CellCept) Prograf (Tacrolimus, FK506) Generic Tacrolimus (Generic Prograf) Modified Release Tacrolimus FK506E (MR4) Sirolimus (RAPA, Rapamycin, Rapamune) Myfortic (Mycophenolate Sodium) **Other Immunosuppressive Medications** Campath - Alemtuzumab (anti-CD52) Cyclophosphamide (Cytoxan) Leflunomide (LFL, Arava) Methotrexate (Folex, PFS, Mexate-AQ, Rheumatrex) Other Immunosuppressive Medication, Specify Rituximab

Investigational Immunosuppressive Medications

Everolimus (RAD, Certican) Other Immunosuppressive Medication, Specify