Kidney/Pancreas Transplant Recipient Follow-up (TRF) Record Field Descriptions

Transplant Recipient Follow-up (TRF) records are generated in Tiedi® at six months, one year and annually thereafter following transplantation, until either graft failure, recipient death or lost to follow-up is reported.

The Kidney/Pancreas Transplant Recipient Follow-up (TRF) record is to be completed by the transplant center responsible for follow-up of the recipient at intervals of six months, one year and annually thereafter. The record is to contain only the applicable patient information since the last follow-up period. It is not to contain information pertaining solely to the previous or next follow-up period. For example: the 6-month follow-up should contain information from the time after the TRR was completed to the 6-month transplant anniversary date; the 1-year follow-up should contain information from the day after the 6-month transplant anniversary date to the 1-year transplant anniversary date; the 2-year follow-up should contain information from the day after the 1-year transplant anniversary date to the 2-year anniversary date.

If the kidney/pancreas recipient dies or experiences a graft failure of both the kidney and pancreas between follow-up intervals, complete an Interim record containing the information pertinent to death or graft failure. The follow-up records are generated for two years post graft failure to track patient survival following graft failure, based on OPTN/UNOS Policy 7.1.3. The follow-up period for all transplant recipients is until death or retransplantation. However, if the recipient experiences graft failure of only one organ, then the graft failure must be reported on the next expected KPF record. It may also be reported on the last completed record for the failed organ if it occurred within 2 months of the record completion date.

TRF records generated before June 30, 2002 are forgiven except for the one-year, three-year, death/graft failure or most recently expected follow-up record. Amnesty records may be accessed by selecting the **Expected/Amnesty** and/or **Amnesty** option on the Search page. (For additional information, see Accessing Patient Records and Records Generation.)

If the patient is lost to follow-up, follow the steps for Reporting Lost to Follow-up.

View OPTN/UNOS Policy on Data Submission Requirements for additional information.

To correct information that is already displayed on an electronic record, call 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.

Gender: Verify the recipient's gender is correct. If the information is incorrect, corrections may be made on the recipient's TCR record.

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

Tx Date: The recipient's transplant date, reported in the Recipient Feedback, will display. Verify the 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.

Previous Follow-up: The recipient's follow-up status, reported in the previous TRF record, will display. Verify the recipient's previous follow-up status is correct.

Previous Px Stat Date: The recipient's patient status date, reported in the previous TRF record, will display. Verify the recipient's previous patient status date is correct.

Transplant Discharge Date: Enter the date the recipient was released to go home, or verify that the discharge date displayed is the date the recipient was released to go home. The patient's hospital stay includes total time spent in different units of the hospital, including medical and rehab. This is a required field.

> ***Note:*** The **Transplant Discharge Date** can only be edited on the patient's TRR, 6-month TRF and 1-year TRF. To correct this information on a follow-up that is after the 1-year TRF, access one of these three records and enter the correct date. The corrected information will automatically update on the other records.

State of Permanent Residence: Select the name of the state, of the recipient's permanent address, at the time of follow-up.

Zip Code: Enter the recipient's zip code, of their permanent address, at the time of follow-up.

Provider Information

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

Followup Center: The follow-up center, reported in the recipient's previous validated TRF record, will display. Verify the center name, center code and provider number for the center following the patient.

Physician Name: Enter the name of the physician who is following the patient.

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.

Follow-up Care Provided By: Indicate where the follow-up care was provided. If **Other Specify** is selected, specify the provider in the space provided.

Transplant Center
Non Transplant Center Specialty Physician
Primary Care Physician
Other Specify

Donor Information

UNOS Donor ID #: 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 (At Time Of Follow Up)

Date: Last Seen, Retransplanted or Death: Enter the date the patient was last seen, the date of death, or the date of retransplant for this recipient, using the standard 8-digit numeric format

of MM/DD/YYYY. The follow-up records (6-month, 1-year, 2-year, etc.) are to be completed within 30 days of the 6 month and yearly anniversaries of the transplant date. If the recipient died or the graft failed, and you have not completed an interim follow-up indicating these events, the 6-month and annual follow-ups should be completed indicating one of those two events.

Patient Status: If the recipient is living at the time of follow-up, select **Living**. If the recipient died during this follow-up period, select **Dead**. If the recipient received another kidney and/or pancreas from a different donor during the follow-up period, select **Retransplanted**. If **Dead** is selected, indicate the cause of death.

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.

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

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

Note: If the **Patient Status** is **Retransplanted** for the kidney(s), then the following fields are not applicable:

Kidney Graft Status
Most Recent Serum Creatinine
Kidney Date of Failure
Kidney Primary Cause of Graft Failure
Contributory causes of graft failure
Dialysis Since Last Follow-Up
Did patient have any kidney acute rejection episodes during the follow-up period

Note: If the **Patient Status** is **Retransplanted** for the pancreas, then the following fields are not applicable:

Pancreas Graft Status
Method of Blood Sugar Control
Pancreas Date of Failure
Pancreas Graft Removed
Pancreas Primary Causes of Graft Failure
Contributory Causes of Graft Failure
Conv. from Bladder to Enteric Drain Performed
Serum Amylase
Pancreas Transplant Complications (Not leading to graft failure)
Did patient have any pancreas acute rejection episodes during the follow-up period

Hospitalizations:

Has the patient been hospitalized since the last patient status date: If the recipient has been hospitalized since the last patient status report, regardless of patient status (living, dead, or retransplanted), select **Yes**. If not, select **No**. If unknown, select **UNK**. If **Yes** is selected, indicate the number of hospitalizations.

Note: Hospitalizations should ONLY include inpatient visits.

Number of hospitalizations: If the recipient was hospitalized, enter the number of hospitalizations. This field is optional.

Noncompliance:

Was there evidence of noncompliance with immunosuppression medication during this follow-up period that compromised the patient's recovery: If the recipient had been noncompliant during this follow-up period, select **Yes**. If not, select **No**. If unknown, select **UNK**. This field is optional.

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

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

10% - Moribund, fatal processes progressing rapidly
20% - Very sick, hospitalization necessary: active treatment necessary
30% - Severely disabled: hospitalization is indicated, death not imminent
40% - Disabled: requires special care and assistance
50% - Requires considerable assistance and frequent medical care
60% - Requires occasional assistance but is able to care for needs
70% - Cares for self: unable to carry on normal activity or active work
80% - Normal activity with effort: some symptoms of disease
90% - Able to carry on normal activity: minor symptoms of disease
100% - Normal, no complaints, no evidence of disease
Unknown

Note: The Lansky Scale will display for pediatrics aged 1 to 17.

10% - No play; does not get out of bed
20% - Often sleeping; play entirely limited to very passive activities
30% - In bed; needs assistance even for quiet play
40% - Mostly in bed; participates in quiet activities
50% - Can dress but lies around much of day; no active play; can take part in quiet play/activities
60% - Up and around, but minimal active play; keeps busy with quieter activities
70% - Both greater restriction of and less time spent in play activity
80% - Active, but tires more quickly
90% - Minor restrictions in physically strenuous activity
100% - Fully active, normal
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.

Physical Capacity: Select the choice that best describes the recipient's physical capacity at the time of listing. If the recipient's **Medical Condition** indicates they are hospitalized, select **Not Applicable (hospitalized)**. This field is optional for **adult** recipients only.

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.

Cognitive Development: (Complete for recipients younger than 18 years of age at transplant and younger than 26 years of age at follow-up.) Select the choice that best describes the recipient's cognitive development at the time of listing.

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: (Complete for recipients younger than 18 years of age at transplant and younger than 26 years of age at follow-up.) Select the choice that best describes the recipient's motor development at the time of listing.

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

Working for income: (Complete for recipients 19 years of age or older.) If the recipient was working for income at the time of follow-up, select **Yes**. If not, select **No**. If reporting the recipient's death, indicate if the recipient was working for income just prior to death.

If Yes: If **Yes** is selected, indicate the recipient's working status. (This field is optional for **adult** recipients only).

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

If No, Not Working Due To: If **No** is selected, indicate the reason why the recipient was not working. (This field is optional for **adult** recipients only).

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

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

Insurance Conflict - Any differences between a recipient 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 recipient who chooses to manage their own household, instead of performing work for pay.

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

Patient Choice - Retired - A recipient 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 recipient from working.

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

Unknown

Academic Progress: (Complete for recipients 18 years of age or younger.) Select the choice that best describes the recipient's academic progress at the time of follow-up. If reporting the recipient's death, select the choice that best describes the recipient's academic progress just prior to death.

Within One Grade Level of Peers
Delayed Grade Level
Special Education
Not Applicable < 5 years old
Status Unknown

Academic Activity Level: (Complete for recipients 18 years of age or younger.) Select the choice that best describes the recipient's academic activity level at the time of follow-up. If reporting the recipient's death, select the choice that best describes the recipient's academic level just prior to death.

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

Primary Insurance at Follow-up: Select the recipient's source of primary payment (largest contributor) during the follow-up period.

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 additional benefits (i.e., 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 cost of follow-up will be paid for by the recipient.

Donation indicates that a company, institution, or individual(s) donated funds to pay for the follow-up period and care of the recipient.

Free Care indicates that the transplant hospital will not charge recipient for the costs of the follow-up period.

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

Unknown

Clinical Information

Date of Measurement: (Complete for recipients younger than 18 years of age at transplant and younger than 26 years of age at follow-up.) 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 at the time of discharge in the appropriate space, in feet and inches or centimeters. If the recipient's height is unavailable, select the appropriate status from the **ST** field (**N/A**, **Not Done**, **Missing**, **Unknown**). For recipients 18 years old or younger at the time of listing, UNet will generate and display calculated percentiles based on the 2000 CDC growth charts. (This field is optional for **adult** recipients only).

Weight: Enter the weight of the recipient at the time of discharge in the appropriate space, in pounds or kilograms. If the recipient's weight is unavailable, select the appropriate status from the **ST** field (**N/A**, **Not Done**, **Missing**, **Unknown**). For recipients 18 years old or younger at the time of listing, UNet will generate and display calculated percentiles based on the 2000 CDC growth charts. (This field is optional for **adult** recipients only).

BMI (Body Mass Index)**:** For recipients 18 years old or younger during the follow-up period, 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/.

Is Growth Hormone Therapy Used During This Follow-up Period: (Complete for recipients younger than 18 years of age at transplant and younger than 26 years of age at follow-up.) If the recipient is undergoing growth hormone therapy during this follow-up period, select **Yes**. If not, select **No**. If unknown, select **UNK**.

Urine Protein Found By Any Method: If the recipient had urine protein, detected by any method, during the follow-up period, select **Yes**. If not, select **No**. If unknown, select **UNK**. This field is optional.

Bone Disease (check all that apply): (Complete for recipients younger than 18 years of age at transplant and younger than 26 years of age at follow-up.)

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**.

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

Spine-compression, #
Extremity, #
Other, #

AVN (avascular necrosis): If the recipient has AVN at the time of listing, select **Yes**. If not, select **No**. If unknown, select **UNK**.

Kidney Graft Status: If the kidney graft is functioning at the time of follow-up, select **Functioning**. If the kidney graft is not functioning at the time of follow-up, select **Failed**. If the **Patient Status** is **Retransplanted** for the kidney(s), this field is not applicable.

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

If **Functioning**, **Most Recent Serum Creatinine:** Enter the most recent serum creatinine available if the recipient's kidney graft was functioning at the time of follow-up. If unavailable, select the status from the **ST** field (**N/A**, **Not Done**, **Missing**, **Unknown**). If the **Patient Status** is **Retransplanted** for the kidney(s), this field is not applicable.

If **Failed**, provide the following information:

Kidney Date of Failure: Enter the date using the standard 8-digit numeric format of MM/DD/YYYY. If the **Patient Status** is **Retransplanted** for the kidney(s), this field is not applicable.

Kidney Primary Cause of Graft Failure: Select the cause of graft failure. If **Other, Specify** is selected, enter the cause of failure in the space provided. If the **Patient Status** is **Retransplanted** for the kidney(s), this field is not applicable.

Acute Rejection
Primary Failure
Graft Thrombosis
Infection
Urological Complications
Recurrent Disease
Chronic Rejection
BK (Polyoma) Virus
Other, Specify

Kidney 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 a primary and secondary cause of graft failure. If **Kidney Other Contributory Cause of Graft Failure** is selected, enter the cause of graft failure in the space provided. If the **Patient Status** is **Retransplanted** for the kidney(s), this field is not applicable. These fields are optional.

Kidney Acute Rejection
Kidney Chronic Rejection
Kidney Graft Thrombosis
Kidney Infection
Urological Complications
Patient Noncompliance
Recurrent Disease
BK (Polyoma) Virus
Kidney Other Contributory Cause of Graft Failure

Note: If the kidney/pancreas recipient experiences a graft failure of both the kidney and pancreas between follow-up intervals, complete an Interim record containing the information pertinent to death or graft failure. However, if the recipient experiences graft failure of only one organ, then the graft failure must be reported on the next expected KPF record. It may also be reported on the last completed record for the failed organ if it occurred within 2 months of the record completion date.

Dialysis Since Last Follow-up: If the recipient has received dialysis during the follow-up period, select **Yes**. If not, select **No**. If unknown, select **Unknown**. If a **Yes** choice was selected, enter the date the dialysis resumed and the dialysis provider. If the **Patient Status** is **Retransplanted** for the kidney(s), this field is not applicable.

No
Yes, Resumed Maintenance Dialysis
Yes, No Maintenance Resumption
Yes, Maintenance Resumption Unknown
Unknown

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

Select a Dialysis Provider: Select either **State** or **ESRD Network**, then click **Find a Center**. Click on the **Center Name** that is providing dialysis. The **Provider #** and **Provider Name** will be automatically entered. These fields are optional.

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

Note: If death is indicated for the recipient, 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 ≤ 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.

If **Partial Function** or **Failed** is selected, indicate **Method of blood sugar control:** Check all that apply. If the **Patient Status** is **Retransplanted** for the pancreas, this field is not applicable.

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:

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

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

Pancreas Graft Removed: Select **Yes** if the pancreas graft has totally failed, the recipient is completely dependent on insulin for blood glucose control, and the pancreas graft was removed. If not, select **No**. If unknown, select **Unknown**. If the **Patient Status** is **Retransplanted** for the pancreas, this field is not applicable. This field is optional.

Date Pancreas Graft Removed: If **Yes** is selected, enter the date the pancreas graft was removed using the standard 8-digit numeric format MM/DD/YYYY. This field is optional.

Pancreas Primary Causes of Graft Failure: Select the primary cause of graft failure. If **Other Specify** is selected, enter the cause of graft failure in the space provided. If the **Patient Status** is **Retransplanted** for the pancreas, this field is not applicable.

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

Contributory causes of graft failure: For each of the causes listed select **Yes**, **No**, or **Unk**nown to indicate whether each is a contributory cause of graft failure. Select **No** for the primary cause, since it cannot be both primary and secondary cause of graft failure. If **Other, Specify** is selected, specify the cause in the space provided. If the **Patient Status** is **Retransplanted** for the pancreas, this field is not applicable. This field is optional.

Pancreas Graft/Vascular Thrombosis
Pancreas Infection
Pancreas Bleeding
Anastomotic Leak
Pancreas Acute Rejection
Pancreas Chronic Rejection
Biopsy Proven Isletitis
Pancreatitis
Patient Noncompliance
Other, Specify

Note: If the kidney/pancreas recipient experiences a graft failure of both the kidney and pancreas between follow-up intervals, complete an Interim record containing the information pertinent to death or graft failure. However, if the recipient experiences graft failure of only one organ, then the graft failure must be reported on the next expected KPF record. It may also be reported on the last completed record for the failed organ if it occurred within 2 months of the record completion date.

Conv. From Bladder to Enteric Drain Performed: If the pancreas graft duct has been changed from bladder to enteric during this follow-up period, select **Yes**. If not, select **No**. If unknown, select **UNK**. If **Yes** is selected, indicate when the conversion occurred. On the recipient's TRR, if **Enteric w/Roux-En-Y** or **Enteric w/o Roux-En-Y** was selected for Duct Management, this question does not apply for this recipient and you must select **N/A**. If the **Patient Status** is **Retransplanted** for the pancreas, this field is not applicable.

Enteric Drain Date: If **Yes** is selected, enter the date of the conversion during this follow-up period using the standard 8-digit numeric format of MM/DD/YYYY.

Serum Amylase: Enter the last serum amylase level of this follow-up period in u/L. If the value is not available, select the status from the **ST** field (**N/A**, **Not Done**, **Missing**, **Unknown**). If the **Patient Status** is **Retransplanted** for the pancreas, this field is not applicable. This field is optional.

Pancreas Transplant Complications (Not leading to graft failure): For each of the complications listed, indicate if the complication occurred during this follow-up period. Do not select **Yes** if the complication contributed to failure of the pancreas graft. If the **Patient Status** is **Retransplanted** for the pancreas, this field is not applicable.

Pancreatitis: If the recipient was diagnosed as having pancreatitis, select **Yes**. If not, select **No**. If unknown, select **UNK**.

Anastomotic Leak: If the recipient exhibited signs and symptoms of an anastomotic leak during this follow-up period, select **Yes**. If not, select **No**. If unknown, select **UNK**.

Abscess or Local Infection: If the recipient exhibited signs and symptoms of abscess or local infection during this follow-up period, select **Yes**. If not, select **No**. If unknown, select **UNK**.

Other, Specify: If a complication other than those listed occurred during this follow-up period, select **Other, Specify** and enter the complication in the space provided.

Note: The **Serum Amylase**, **Serum Anionic Tripsinogen**, **Urinary Amylase**, **Glycosylated Hemoglobin** and **Pancreas Transplant Complications** since last follow-up fields will not display if a Pancreas retransplant was reported in a previous record.

Did patient have any kidney acute rejection episodes during the follow-up period: If the recipient experienced at least one episode during this follow-up period, select **Yes**. If not, select **No**. If unknown, select **Unknown**. If **Yes** is selected, indicate if a biopsy was done to confirm acute rejection. If the **Patient Status** is **Retransplanted** for the kidney(s), this field is not applicable.

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

Was Biopsy 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**. This field is optional.

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

Did patient have any pancreas acute rejection episodes during the follow-up period: If the recipient experienced at least one episode during this follow-up period, select **Yes**. If not, select **No**. If unknown, select **Unknown**. If **Yes** is selected, indicate if a biopsy was done to confirm acute rejection. If the **Patient Status** is **Retransplanted** for the pancreas, this field is not applicable.

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

Was Biopsy to confirm acute rejection: If the recipient had an acute pancreas 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**. This field is optional.

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

Viral Detection:

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

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.

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).

Postransplant Malignancy: If the recipient has been diagnosed with any malignant cancer since the last follow-up, select **Yes**. If not, select **No**. If unknown, select **UNK**. If **Yes** is selected, at least one of the fields listed below must be completed. A Post Transplant Malignancy record will generate when one or more of the fields listed below is selected. For additional information, see Post Transplant Malignancy Record Fields.

Donor Related: If the malignancy is donor related, select **Yes** . If not, select **No**. If unknown, select **UNK**. If **Yes** is selected, the Donor Related section will be displayed on the Post Transplant Malignancy record. For additional information, see Post Transplant Malignancy Record Fields - Donor Related.

Recurrence of Pre-Tx tumor: If a pre-transplant tumor has recurred, select **Yes**. If not, select **No**. If unknown, select **UNK**. If **Yes** is selected, the Recurrence of Pretransplant Malignancy section will be displayed on the Post Transplant Malignancy record. For additional information, see Post Transplant Malignancy Record Fields - Recurrence of Pretransplant Malignancy.

De Novo Solid Tumor: If the cancer was a De Novo solid tumor, select **Yes** If not, select **No**. If unknown, select **UNK**. If **Yes** is selected, the Post Transplant De Novo Solid Tumor section will be displayed on the Post Transplant Malignancy record. For additional information, see Post Transplant Malignancy Record Fields - Post Transplant De Novo Solid Tumor.

De Novo Lymphoproliferative disease and Lymphoma: If the cancer was post transplant lymphoproliferative disease or lymphoma, select **Yes** . If not, select **No**. If unknown, select **UNK**. If **Yes** is selected, the Post Tx Lymphoproliferative Disease and Lymphoma section will be displayed on the Post Transplant Malignancy record. For additional information, see Post Transplant Malignancy Record Fields - Post Tx Lymphoproliferative Disease and Lymphoma.

Note: Please report each type of malignancy only once in the follow-up process.

Note: When a patient has a tumor during one follow up period and the tumor continues into the next follow-up period without going away, the tumor should only be reported on that first follow-up record and not reported on the next follow-up record. The tumor should be reported on subsequent follow-up records ONLY if the tumor goes away and then returns in the next follow-up period.

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. These fields are optional.

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)
Valacyclovir (Valtrex)
Other, Specify

Treatment for BK (polyoma) virus: If recipient is receiving treatment, select **Yes**. If not, select **No**. If **Yes** is selected, check all that apply. If **Yes, Other, Specify** is selected, enter the treatment in the space provided. These fields are optional.

Yes, Immunosuppression reduction
Yes, Cidofavir
Yes, IVIG
Yes, Type Unknown
Yes, Other, Specify

Other Therapies: If the recipient received other therapies, select **Yes**. If not, select **No**. If **Yes** is selected, check all that apply: These fields are optional.

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

Previous Validated Maintenance Follow-up Medications: The follow-up Immunosuppression medication(s) indicated in the patient's most recently validated Transplant Recipient Registration (TRR) or Transplant Recipient Follow-up (TRF) record will be listed.

Note: If a drug cannot be indicated as **Maintenance** in the Transplant Recipient Registration (TRR), then it cannot be indicated as **Current Maintenance** or **Previous Maintenance** in the TRF. If the drug cannot be indicated as **Anti-rejection** in the TRR, then it cannot be indicated as **Anti-rejection** in the TRF.

Were any medications given during the follow-up period for maintenance: If there have been no changes in medications during this follow-up period, select **Yes same as previous validated report**. The immunosuppressive medications selected as Current on the previous validated report will automatically be checked off in the Previous and Current columns of this follow-up record. If there have been changes in medications during this follow-up period, select **Yes, but different than previous validated report**. Then select the appropriate Immunosuppressive Medications. If no medications were given during this follow-up period, select **None given**.

Note: If any medications were given during the 6-month follow-up period for maintenance, immunosuppression medications from the patient's validated TRR will be listed.

Did the physician discontinue all maintenance immunosuppressive medications: If the physician discontinued the patients immunosuppressive medications, select **Yes**. If the

patient stopped the medications themselves or they were stopped for some other reason, select **No**.

Did the patient participate in any clinical research protocol for immunosuppressive medications: If the recipient participated in clinical research, select **Yes**. If not, select **No**. If **Yes** is selected, enter the details in the space provided. This field is optional.

Immunosuppressive Medications

For each of the immunosuppressant medications listed, check **Previous Maintenance (Prev Maint)**, **Current Maintenance (Curr Maint)** or **Anti-rejection (AR)** to indicate all medications that were prescribed for the recipient during this follow-up period, and for what reason. If a medication was not given, leave the associated box(es) blank.

Previous Maintenance (Prev Maint) includes all immunosuppressive medications given during the report period, which covers the period from the last clinic visit to the current clinic visit, 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.

Current Maintenance (Curr Maint) includes all immunosuppressive medications given at the time of the current clinic visit to begin in the next report period 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.

Note: If the recipient was taking maintenance medications during the follow-up period but is now deceased, then select **Yes, but different than previous validated report**, and check-off all applicable medications in the **Previous** column only. Do not check-off any medications in the **Current** column.

Note: On Recipient Death (RD) records, any maintenance medications given during the follow-up period should be noted as **Previous**, and nothing should be noted in the **Current** column.

Anti-rejection (AR) immunosuppression includes all immunosuppressive medications given for the purpose of treating an acute rejection episode since the last clinic visit (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: The **Anti-rejection** field refers to any anti-rejection medications since the last clinic visit, not just at the time of the current clinic visit.

Note: As further clarification, drugs that are used with the intention to maintain recipients long-term 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 **Previous Maint**, or **Current Maint**, or **AR** next to **Other**

Immunosuppressive Medication field, and enter the full name of the medication in the space provided. **Do not list non-immunosuppressive medications**.

Other Immunosuppressive Medications

For each of the immunosuppressant medications listed, check **Previous Maintenance (Prev Maint)**, **Current Maintenance (Curr Maint)** or **Anti-rejection (AR)** to indicate all medications that were prescribed for the recipient during this follow-up period, and for what reason. If a medication was not given, leave the associated box(es) blank.

Previous Maintenance (Prev Maint) includes all immunosuppressive medications given during the report period, which covers the period from the last clinic visit to the current clinic visit, 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.

Current Maintenance (Curr Maint) includes all immunosuppressive medications given at the time of the current clinic visit to begin in the next report period 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.

Note: On Recipient Death (RD) records, any maintenance medications given during the follow-up period should be noted as **Previous**, and nothing should be noted in the **Current** column.

Anti-rejection (AR) immunosuppression includes all immunosuppressive medications given for the purpose of treating an acute rejection episode since the last clinic visit (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: The **Anti-rejection** field refers to any anti-rejection medications since the last clinic visit, not just at the time of the current clinic visit.

Note: As further clarification, drugs that are used with the intention to maintain recipients long-term 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 **Previous Maint**, or **Current Maint**, or **AR** next to **Other Immunosuppressive Medication** field, and enter the full name of the medication in the space provided. **Do not list non-immunosuppressive medications**.

Investigational Immunosuppressive Medications

For each of the immunosuppressant medications listed, check **Previous Maintenance (Prev Maint)**, **Current Maintenance (Curr Maint)** or **Anti-rejection (AR)** to indicate all medications that were prescribed for the recipient during this follow-up period, and for what reason. If a medication was not given, leave the associated box(es) blank.

Previous Maintenance (Prev Maint) includes all immunosuppressive medications given during the report period, which covers the period from the last clinic visit to the current clinic visit, 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.

Current Maintenance (Curr Maint) includes all immunosuppressive medications given at the time of the current clinic visit to begin in the next report period 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.

Note: On Recipient Death (RD) records, any maintenance medications given during this follow-up period should be noted as **Previous**, and nothing should be noted in the **Current** column.

Anti-rejection (AR) immunosuppression includes all immunosuppressive medications given for the purpose of treating an acute rejection episode since the last clinic visit (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: The **Anti-rejection** field refers to any anti-rejection medications since the last clinic visit, not just at the time of the current clinic visit.

Note: As further clarification, drugs that are used with the intention to maintain recipients long-term 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 **Previous Maint**, or **Current Maint**, or **AR** next to **Other Immunosuppressive Medication** field, and enter the full name of the medication in the space provided. **Do not list non-immunosuppressive medications**.

Drug Codes

Sandimmune (Cyclosporine A)
Neoral (CyA-NOF)
Tacrolimus (Prograf, FK506)
Sirolimus (RAPA, Rapamycin, Rapamune)
Leflunomide (LFL, Arava)
Azathioprine (AZA, Imuran)
Mycophenolate Mofetil (MMF, Cellcept, RS61443)
Cyclophosphamide (Cytoxan)
Methotrexate (Folex, PFS, Mexate-AQ, Rheumatrex)
Atgam (ATG)
OKT3 (Orthoclone, Muromonab)
Thymoglobulin
Zenapax - Daclizumab
Simulect - Basiliximab

Gengraf (Abbott Cyclosporine)
Everolimus (RAD, Certican)
EON (Generic Cyclosporine)
Myfortic (Mycophenolate Sodium)
Other generic Cyclosporine, specify brand:
Steroids (Prednisone,Methylprednisolone,Solumedrol,Medrol,Decadron)
Campath - Alemtuzumab (anti-CD52)
FTY 720
Rituximab
Modified Release Tacrolimus FK506E (MR4)
Other Immunosuppressive Medication, Specify
Other Immunosuppressive Medication, Specify