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 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 recipient dies or experiences a graft failure between follow-up intervals, complete an interim record containing the information pertinent to death or graft failure.

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 <u>Appendix T</u> and <u>Appendix U</u>.)

If the patient is lost to follow-up, follow the steps for <u>Appendix V</u>.

The TRF record must be completed within 30 days from the record generation date. See OPTN/UNOS Policies 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 UNetSM 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.

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

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

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 <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</u> <u>Date</u>: 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.

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.

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 (location of full-time residence, not follow-up center location). This field is required. (Appendix A)

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

Provider Information

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

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.

<u>Follow-up Care Provided By</u>: 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

Date: Last Seen, Retransplanted or Death: Enter the date the patient was last seen, or the date of death, or 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.

<u>Patient Status</u>: If the recipient is living at the time of follow-up, select <u>Living</u>. If the recipient died during this follow-up period, select <u>Dead</u>. If the recipient received another kidney from a different donor during the follow-up period, select <u>Retransplanted</u>. If <u>Dead</u> 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. (<u>Appendix X</u>)

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. (Appendix X)

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. (Appendix X)

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. This field is required.

Note: Hospitalizations should ONLY include inpatient visits.

Functional Status: Select the choice that best describes the recipient's functional status at the time of follow-up. This field is required.

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

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

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

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

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

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

50% - Requires considerable assistance and frequent medical care

40% - Disabled: requires special care and assistance

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

20% - Very sick, hospitalization necessary: active treatment necessary

10% - Moribund, fatal processes progressing rapidly

Unknown

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

100% - Fully active, normal

90% - Minor restrictions in physically strenuous activity

80% - Active, but tires more quickly

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

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

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

40% - Mostly in bed; participates in quiet activities

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

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

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

Not Applicable (patient < 1 year old)

Unknown

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

<u>Cognitive Development</u>: (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 follow-up.

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>: (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 follow-up.

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 18 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 unknown, select **UNK**. If reporting the recipient's death, indicate if the recipient was working for income just prior to death.

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 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 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

Academic Progress: (This field is required for recipients less than 18 years of age.) 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 progress just prior to death. If the recipient is less than 5 years old or has graduated from high school, select **Not Applicable** < 5 **years old/High School graduate or GED**.

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

Academic Activity Level: (This field is required for recipients less than 18 years of age.) 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 activity just prior to death. If the recipient is less than 5 years old or has graduated from high school, select **Not Applicable < 5 years old/High School graduate or GED**.

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

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/.

Public insurance - Medicare & Choice refers to funds from the government in which doctors and other health care providers are paid for each service provided to a recipient, along with additional benefits such as coordination of care or reducing-out-of-pocket expenses. Sometimes a recipient may receive additional benefits such as prescription drugs. For additional information about Medicare, see http://www.medicare.gov/.

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

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

Public insurance - Other government

Self indicates that the 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 Specify refers to funds provided by foreign government (Primary only). Specify foreign country in the space provided. (<u>Appendix E</u>)

Unknown

Clinical Information

<u>Date of Measurement</u>: (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. This field is required.

Height: Enter the height of the recipient at the time of follow-up 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 follow-up, UNet will generate and display calculated percentiles based on the 2000 CDC growth charts. This field is required for pediatric recipients only.

Weight: Enter the weight of the recipient at the time of follow-up 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 follow-up, UNet will generate and display calculated percentiles based on the 2000 CDC growth charts. This field is required.

BMI (Body Mass Index): For candidates less than 20 years of age 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/.

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

Graft Status: Select the status that best describes the pancreas graft status.

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 oral medication for blood sugar control.

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

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

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

If **Yes** is entered, complete the following fields:

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

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

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

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

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

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

If **Failed** is selected, complete the following fields:

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

Pancreas Graft Removed: If the pancreas graft has totally failed, the recipient is completely dependent on insulin for blood glucose control, and the pancreas graft was removed, select **Yes**. If not, select **No**. If unknown, select **Unknown**. 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.

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.

Graft/Vascular Thrombosis

Infection

Bleeding

Anastomotic Leak

Primary Non-Function (Graft Never Functioned Post-Transplant)

Acute Rejection

Chronic Rejection

Hyperacute Rejection

Biopsy Proven Isletitis

Pancreatitis Other, Specify

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.

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 primary and secondary cause of graft failure. If **Other**, **Specify** is selected, specify the cause in the space provided.

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

<u>Conv. From Bladder to Enteric Drain Performed</u>: 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**. This field is required.

If Yes, Enteric Drainage 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.

Most Recent Serum Creatinine: Enter the most recent serum creatinine, in mg/dl, available. If unavailable, select the status from the **ST** field (N/A, Not Done, Missing, Unknown). This field is required.

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

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

<u>Pancreas Transplant Complications (Not leading to graft failure)</u>: 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.

Pancreatitis: If the recipient was diagnosed during this follow-up period 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 Complications: If a complication other than those listed occurred during this follow-up period, enter the complication in the space provided.

Did patient have any 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. This field is required.

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

Unknown

<u>Viral Detection:</u> The following fields will be required on 6-month and 1-year TRFs if the recipient received an organ from a donor that was classified as "CDC High Risk" on the DDR

HIV Serology: Select the results from the drop-down list.

Positive Negative

UKN/Cannot Disclose

Not Done

HIV NAT: Select the results from the drop-down list.

Positive Negative

UKN/Cannot Disclose

Not Done

HbsAg: Select the results from the drop-down list.

Positive Negative

UKN/Cannot Disclose

Note Done

HBV DNA: Select the results from the drop-down list.

Positive Negative

UKN/Cannot Disclose

Not Done

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

Positive Negative

UKN/Cannot Disclose

Not Done

HCV Serology: Select the results from the drop-down list.

Positive Negative

UKN/Cannot Disclose

Not Done

HCV NAT: Select the results from the drop-down list.

Positive Negative UKN/Cannot Disclose Not Done

Post Transplant 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

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

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 Pre-transplant Malignancy section will be displayed on the Post Transplant Malignancy record. For additional information, see

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

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

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.

Immunosuppressive Information

<u>Previous Validated Maintenance Follow-up Medications</u>: 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: (<u>List of Changes to Maintenance Medications codes</u>)

If there were immunosuppressive medications during this follow-up period, select Yes, same as validated TRR form. The drugs on the previously validated TRR will pre-populate.

If there have been changes in medications during this follow-up period, select Yes, but different than validated TRR form. Then select the appropriate Immunosuppressive Medications by placing a checkmark in the Current Maint or AR column.

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.

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 <u>should not</u> be listed under AR immunosuppression, but <u>should be</u> 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 used for induction, acute rejection, or maintenance

Steroids (prednisone, methylprednisolone, Solumedrol, Medrol, Decadron)

Drugs used for induction or acute rejection

Atgam

Campath (alemtuzumab, anti-CD52)

Cytoxan (cyclophosphamide)

Methotrexate (Folex PFS, Mexate-AQ, Rheumatrex)

OKT3 (Orthoclone, muromonab)

Rituxan (rituximab)

Simulect (basiliximab)

Thymoglobulin

Drugs primarily used for maintenance

Cyclosporine, select from the following:

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

Mycophenolate acid, select from the following:

- CellCept (MMF)
- Generic MMF (generic CellCept)

- Myfortic (mycophenolate acid)
- Nulojix (belatacept)
- Rapamune (sirolimus, Rapamycin)

Tacrolimus, select from the following:

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

Other drugs

Other immunosuppressive medication, specify: