Intestine 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, but no later than the date of death or graft failure. 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 the patient no later than the date of death or graft failure. For example: an interim graft failure is reported with a graft failure date of March 10. The patient status date should also be March 10 and the information collected on the form should be based on patient evaluation no later than March 10.

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 **Searching for Patient Records – <u>Appendix T</u>** and **Records Generation –** See <u>Appendix U</u>.) If the patient is lost to follow-up, follow the steps for **Reporting Lost to Follow-up – See <u>Appendix V</u>**.

The TRF record must be completed within 30 days from the record generation date. Click on OPTN Policy on Data Submission Requirements for additional information.

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

Recipient Information

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

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

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

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

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

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.

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

<u>Transplant Discharge Date</u>: 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 (location of full-time residence, not follow-up center location). This field is required. (**List of State codes – Appendix A**)

<u>Permanent 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.

<u>NPI #</u>: 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

<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 (At Time of Follow-up)

<u>Date: Last Seen, Retransplanted, Graft Failure, or Death</u>: Enter the date the patient was last seen, the date of death, the date of graft failure, 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. This is a <u>required</u> field.

<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. This is a <u>required</u> field. ()

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)

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..

Note: Hospitalizations should ONLY include inpatient visits.

<u>Functional Status</u>: 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

<u>Working for income</u>: (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 reporting the recipient's death, indicate if the recipient was working for income just prior to death.

<u>Academic Progress</u>: (This field is required for recipients less than 18 years of age.) Select the choice that best describes the recipient's academic progress 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/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 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. (**List of Foreign Country codes –** <u>Appendix E</u>)

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. This is a <u>required</u> field.

Height: (Complete for recipients younger than 18 years of age of age at transplant.) 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). UNet will generate and display calculated percentiles based on the 2000 CDC growth charts. This is a <u>required</u> field.

Weight: (Complete for recipients younger than 18 years of age at of age at transplant) 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). UNet will generate and display calculated percentiles based on the 2000 CDC growth charts. This is a required field.

BMI (Body Mass Index): For candidates less than 20 years of age at the time of follow-up, UNet will generate and display calculated percentiles based on the 2000 CDC growth charts. This is a required field

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: If the graft is functioning at the time of follow-up, select **Functioning**. If the graft is not functioning at the time of follow-up, select **Failed**. This is a <u>required</u> field.

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**, select **Yes** or **No** for each of the following fields:

TPN Dependent: If the recipient is dependent on total parenteral nutrition, select Yes. If not, select No.

IV Dependent: If the recipient is dependent on intravenous fluids, select Yes. If not, select No.

Oral Feeding: If the recipient is dependent on oral nutrition, select Yes. If not, select No.

Tube Feeding: If the recipient is receiving nutrition via any gastric tube, select Yes. If not, select No.

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

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

<u>Primary Cause of Failure</u>: Select the cause of graft failure. If **Other Specify** is selected, enter the cause of graft failure in the space provided.

Recurrent Tumor Acute Rejection Chronic Rejection
Technical Problems
Infection
Lymphoproliferative Disease
Patient Noncompliance
GVHD (Graft vs. Host Disease)
Ischemia/NEC (Necrotizing Enterocolitis Like Syndrome)
Other Specify

New diabetes onset between last follow-up to the current follow-up: New diabetes onset between last follow-up to the current follow-up: If the recipient has been newly diagnosed as having diabetes during this follow-up period, select Yes. If new onset of diabetes was already reported on last follow-up, do not report it again on current follow-up. If not, select No. If unknown, select Unk. If the patient is not newly diagnosed with diabetes but has newly become insulin dependent for their diabetes, then answer Yes to this question. This field is optional.

Note: If this is a 1-year follow-up, then report any new signs or symptoms since transplant.

Diabetes: If yes, Insulin Dependent: If the recipient has started insulin since the last follow-up, select **Yes**. If not, select **No**. If unknown, select **Unk**.

Note: The **Diabetes:** If **Yes, Insulin Dependent** field can only be edited on the patient's 1-year TRF. To correct this information on a 1-year TRF, access this record and enter the correct date. The corrected information will automatically update on the subsequent records.

Most Recent Lab data:

<u>Lab Date</u>: Enter date, using the standard 8-digit numeric format of MM/DD/YYYY, when samples were drawn and laboratory tests were performed closest to the end of this current follow-up period. If any lab values are entered, then this is a required field.

<u>Serum Creatinine</u>: Enter the lab value for the serum creatinine value in mg/dl taken closest to the time of follow-up. If the value is unavailable, select the status from the **ST** field (N/A, Not Done, Missing, Unknown).

<u>Did patient have any acute rejection episodes during the follow-up period:</u> 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.

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._For each of the tests listed, select the results from the drop-down list (**Positive, Negative, Not Done, Unknown/Cannot Disclose**).

HIV Serology
HIV NAT
HbsAg
HBV DNA
HBV Core Antibody
HCV Serology
HCV NAT

<u>Postransplant Malignancy</u>: 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.

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 TRF.

Were any medications given during the follow-up period for maintenance:

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 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 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**.

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 <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**.

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 <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 Codes

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

Zortress (Everolimus)

EON (Generic Cyclosporine)

Myfortic (Mycophenolate Sodium)

Other generic Cyclosporine, specify brand:

Steroids (Prednisone, Methylprednisolone, Solumedrol, Medrol, Decadron)

Campath - Alemtuzumab (anti-CD52)

FTY 720

Rituximab

Astagraf XL (Extended Release Tacrolimus)

Generic Tacrolimus (Generic Prograf)

Nulojix (Belatacept)

Generic MMF (Generic CellCept)

Other Immunosuppressive Medication, Specify

Other Immunosuppressive Medication, Specify