Intestine Transplant Recipient Follow Up 6 Month to 5 Year

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. Forms are generated by the age at transplant, not the age at listing. Pediatric follow-up records will continue to generate through the recipient's 25th birthday. The system will automatically update the next follow-up record to Adult as of the recipient's 26th birthday.

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 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.

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

The TRF record must be completed within 90 days from the record generation date. Click on OPTN
Policy and search for Data Submission Requirements for additional information.

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

Additional Resources: <u>History of Definition Changes</u>.

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>Birth Sex</u>: Verify recipient's sex (Male or Female), based on biologic and physiologic traits, at birth. If sex at birth is unknown, report sex at time of registration as reported by recipient or documented in medical record. The intent of this data collection field is to capture physiologic characteristics that may have an impact on recipient size matching or graft outcome. 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.

<u>Tx Date</u>: The recipient's transplant date, reported in the Recipient Feedback, will display. Verify that the displayed transplant date is correct. The transplant date is determined by the start of the organ anastomosis during transplant or the start of the islet infusion. Organ transplants include solid organ transplants and islet infusions. An organ transplant procedure is complete when any of the following occurs:

The chest or abdominal cavity is closed and the final skin stitch or staple is applied.

The transplant recipient leaves the operating room, even if the chest or abdominal cavity cannot be closed.

The islet infusion is complete.

<u>Previous Follow-up</u>: 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.

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.

<u>State of Permanent Residence</u>: 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. (<u>List of State codes</u>)

<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.

<u>Physician Name</u>: Enter the name of the physician who is following the patient. If the patient is being seen by a nurse practitioner or physician's assistant, enter the name of the practitioner providing care (e.g. physician, nurse practitioner, physician's assistant).

NPI #: Enter the 10-character CMS (Center for Medicare and Medicaid Services, formerly HCFA) assigned National Provider Identifier of the transplant physician or practitioner providing care (e.g. physician, nurse practitioner, physician's assistant). 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. This field is **required**.

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

<u>Date: Last Seen, Retransplanted or Death</u>: 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. This field is **required**.

<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>. Follow-up forms will no longer be generated for this patient. If <u>Dead</u> is selected, indicate the cause of death. If the recipient received another intestine from a different donor during the follow-up period, select <u>Retransplanted</u>. If the recipient was not seen during this follow-up period, select <u>Not Seen</u>; however, an annual follow-up form will be generated for this patient next year. This field is <u>required</u>.

Living Dead Retransplanted Not Seen

<u>Primary Cause of Death</u>: 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>List of Primary Cause of Death codes</u>)

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**. This field is **required**.

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. (<u>List of Cognitive Development codes</u>)

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.

If No, Not Working Due To: If No is selected, indicate the reason why the recipient was not working. (This field is optional for <u>adult</u> recipients only.) (<u>List of Not Work Reason codes</u>)

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

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

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

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

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

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

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

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

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

Unknown

If Yes: If **Yes** is selected, indicate the recipient's working status. (This field is optional for <u>adult</u> recipients only.) (<u>List of Working codes</u>)

Working Full Time

Working Part Time due to Demands of Treatment

Working Part Time due to Disability

Working Part Time due to Insurance Conflict

Working Part Time due to Inability to Find Full Time Work

Working Part Time due to Patient Choice

Working Part Time Reason Unknown

Working, Part Time vs. Full Time Unknown

<u>Academic Progress</u>: (This field is **required** for recipients less than 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

too young for school or has graduated from high school, select **Not Applicable, too young for school/High School graduate or GED**.

Within One Grade Level of Peers
Delayed Grade Level
Special Education
Not Applicable, too young for school/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 too young for school or has graduated from high school, select **Not Applicable**, too young for school/High School graduate or GED.

Full academic load Reduced academic load Unable to participate in academics due to disease or condition Not Applicable, too young for school/High School graduate or GED Status Unknown

<u>Primary Insurance at Follow-up</u>: Select the recipient's source of primary payment (largest contributor) during the follow-up period. (<u>List of Primary Insurance codes</u>). If the source of payment is not yet determined, select **Pending**. This field is **required**.

Private insurance (commercial Health insurance) refers to commercial insurance through an employer or affordable care act. 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 candidate. Includes Medicare part A, part B and part D. Medicare part A (hospital) must be in place to be considered primary payer. For additional information about Medicare, see http://www.medicare.gov/.

Public insurance - Medicare Part C or Medicare Advantage Original (Fee for Service) Medicare is assigned to a private plan insurer instead of the federal government. Payments are made based on a montly predetermined date. Sometimes a recipient may receive additional benefits such as prescription drugs. Medicare part A and B must be in place to sign up for Medicare part C or Medicare Advantage. 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.

Self Pay indicates that the candidate will pay for the cost of transplant.

Donation indicates that a company, institution, or individual(s) donated funds to pay for the transplant and care of the candidate.

Free Care (Charity Care) indicates that the transplant hospital will not charge candidate for the costs of the transplant operation.

Pending is used if the source of payment is not yet determined (Primary only).

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

Public Insurance -TRICARE Select this option if the patient has TRICARE health coverage.

Public Insurance - Indian Health Service Select this option if the patient has IHS health coverage.

Public Insurance - State Program select this option if the patient has health coverage through their state.

Clinical Information

<u>Height 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 was measured.

<u>Height</u>: (Complete for recipients younger than 18 years of age at transplant and younger than 26 years of age at follow-up.) 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**). (<u>List of Status codes</u>) UNet will generate and display calculated percentiles based on the 2000 CDC growth charts. This field is **required**.

<u>Weight 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 weight was measured.

<u>Weight</u>: (Complete for recipients younger than 18 years of age at of age at transplant and younger than 26 years of age at follow-up.) 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**). (<u>List of Status codes</u>) 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 at the time of follow-up, 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 weightfor-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 field is **required**.

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:

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

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

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 the last follow-up to the current follow-up: The intent of this field is to capture NEW post-transplant diabetes onset since last follow-up period.

Select Yes:

- If the recipient developed post-transplant diabetes since the last follow-up
- If previous post-transplant diabetes was reported, later resolved, and has been re-diagnosed during the most recent follow-up period

Select No:

- If no new diabetes diagnosis since previous follow-up
- If onset of post-transplant diabetes has been documented on a previous follow-up and has not resolved

Select UNK, if unknown.

Note: A patient should not be considered as having developed diabetes based on gestational diabetes only.

If yes, insulin dependent: If the recipient is insulin dependent, select Yes. If not, select No. If unknown, select UNK.

Most Recent Lab data:

Lab Date: 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.

Total Bilirubin: Enter the lab value for total serum bilirubin in mg/dl taken closest to the time of follow-up.

Serum Creatinine: 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**. This field is **required**. (<u>List of Any Acute Rejection Episodes codes</u>)

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

Viral Detection:

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 list.

Positive Negative UKN/Cannot Disclose Not Done

HIV NAT (Nucleic Acid Testing): PCR or NAT testing can be used to submit response. Select the results from the drop-down list.

Positive Negative UKN/Cannot Disclose Not Done

HbsAg: Select the results from the list.

Positive Negative UKN/Cannot Disclose Note Done

HBV DNA: PCR or NAT testing can be used to submit response. Select the results from the drop-down list.

Positive Negative UKN/Cannot Disclose Not Done

HBV Core Antibody: Select the results from the list.

Positive Negative UKN/Cannot Disclose Not Done

HCV Serology: Select the results from the list.

Positive Negative UKN/Cannot Disclose Not Done

HCV NAT: PCR or NAT testing can be used to submit response. Select the results from the list.

Positive Negative UKN/Cannot Disclose Not Done

<u>Post Transplant 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 <u>Post Transplant Malignancy Record Fields</u>.

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 <u>Post Transplant Malignancy Record Fields - Post Transplant De Novo Solid Tumor</u>.

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: 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 Informaion

<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.

Definitions of Immunosuppressive Follow-up 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, with the intention to maintain them long-term (example: prednisone, cyclosporine, tacrolimus, mycophenolate mofetil, azathioprine, or Rapamune). 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, with the intention to maintain them long-term (example: prednisone, cyclosporine, tacrolimus, mycophenolate mofetil, azathioprine, or Rapamune). This does not include any immunosuppressive medications given to treat rejection episodes.

Anti-rejection (AR) immunosuppression includes all immunosuppressive medications given for the purpose of treating an acute rejection episode since the last clinic visit (example: methylprednisolone or Thymoglobulin). When switching maintenance drugs (example: 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.

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. **Note:** Do not list non-immunosuppressive medications.

Drugs used for induction, acute rejection, or maintenance

Steroids (prednisone, methylprednisolone, Solumedrol, Medrol)

Drugs used for induction or acute rejection

Atgam

Campath (alemtuzumab)

Cytoxan (cyclophosphamide)

Methotrexate (Folex PFS, Mexate-AQ, Rheumatrex)

Rituxan (rituximab)

Simulect (basiliximab)

Thymoglobulin

Drugs primarily used for maintenance

Cyclosporine, select from the following:

- Gengraf
- Neoral
- Sandimmune
- · Generic cyclosporine
- Imuran (azathioprine, AZA)
- Leflunomide (LFL)

Mycophenolic acid, select from the following:

- CellCept (MMF)
- Generic MMF (generic CellCept)
- Myfortic (mycophenolic acid)
- Generic Myfortic (generic mycophenolic acid)

mTOR inhibitors, select from the following:

- Rapamune (sirolimus)
- Generic sirolimus
- Zortress (everolimus)
- Nulojix (belatacept)

Tacrolimus, select from the following:

- Astagraf XL (extended release tacrolimus)
- Envarsus XR (tacrolimus XR)
- Prograf (tacrolimus)
- Generic tacrolimus (generic Prograf)

Other drugs

Other immunosuppressive medication, specify:

Public Burden Statement: The private, non-profit Organ Procurement and Transplantation Network (OPTN) collects this information in order to perform the following OPTN functions: to assess whether applicants meet OPTN Bylaw requirements for membership in the OPTN; and to monitor compliance of member organizations with OPTN Obligations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0915-0157 and it is valid until XX/XX/202X. This information collection is required to obtain or retain a benefit per 42 CFR §121.11(b) (2). All data collected will be subject to Privacy Act protection (Privacy Act System of Records #09-15-0055). Data collected by the private non-profit OPTN also are well protected by a number of the Contractor's security features. The Contractor's security system meets or exceeds the requirements as prescribed by OMB Circular A-130, Appendix III, Security of Federal Automated Information Systems, and the Departments Automated Information Systems Security Program Handbook. The public reporting burden for this collection of information is estimated to average 0.27 hours per response, including the time for reviewing instructions, searching existing data sources, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to HRSA Information Collection Clearance Officer, 5600 Fishers Lane, Room 14N39, Rockville, Maryland, 20857 or paperwork@hrsa.gov.