

Records

Pediatric Intestine Transplant Recipient Follow-Up Worksheet

The revised worksheet sample is for reference purposes only and is pending OMB approval.

Note: These worksheets are provided to function as a guide to what data will be required in the online TIEDI^B application. Currently in the worksheet, a red asterisk is displayed by fields that are required, independent of what other data may be provided. Based on data provided through the online TIEDI^B application, additional fields that are dependent on responses provided in these required fields may become required as well. However, since those fields are not required in every case, they are not marked with a red asterisk.

| Recipient Information | |
|---|---|
| Name: | DOB: |
| SSN: | Gender: |
| HIC: | Tx Date: |
| Previous Follow-Up: | Previous Px Stat Date: |
| Transplant Discharge Date: | <input type="text"/> |
| State of Permanent Residence: * | <input type="text"/> |
| Zip Code: * | <input type="text"/> - <input type="text"/> |
| Provider Information | |
| Recipient Center: | |
| Followup Center: | |
| Physician Name: * | <input type="text"/> |
| NPI: * | <input type="text"/> |
| Follow-up Care Provided By: * | <input type="radio"/> Transplant Center <input type="radio"/> Non Transplant Center Specialty Physician <input type="radio"/> Primary Care Physician <input type="radio"/> Other Specify |
| Specify: | <input type="text"/> |
| Donor Information | |
| UNOS Donor ID #: | |
| Donor Type: | |
| Patient Status | |
| Date: Last Seen, Retransplanted or Death * | <input type="text"/> |
| Patient Status: * | <input type="radio"/> LIVING <input type="radio"/> DEAD <input type="radio"/> RETRANSPLANTED |
| Primary Cause of Death: | <input type="text"/> |
| Specify: | <input type="text"/> |
| Contributory Cause of Death: | <input type="text"/> |
| Specify: | <input type="text"/> |
| Contributory Cause of Death: | <input type="text"/> |
| Specify: | <input type="text"/> |
| Hospitalizations: | |
| Has the patient been hospitalized since the last patient status date: * | <input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> UNK |
| Number of Hospitalizations: | <input type="text"/> St= <input type="text"/> |
| Noncompliance: | |
| Was there evidence of noncompliance with immunosuppression medication during this follow-up period that compromised the patient's recovery: | <input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> UNK |
| Functional Status: * | <input type="text"/> |
| Cognitive Development: * | <input type="radio"/> Definite Cognitive delay/impairment (verified by IQ score <70 or unambiguous behavioral observation) <input type="radio"/> Probable Cognitive delay/impairment (not verified or unambiguous but more likely than not, based on behavioral observation or other evidence) |

- Questionable Cognitive delay/impairment (not judged to be more likely than not, but with some indication of cognitive delay/impairment such as expressive/receptive language and/or learning difficulties)
- No Cognitive delay/impairment (no obvious indicators of cognitive delay/impairment)
- Not Assessed

Motor Development: *

- 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 indications of motor delay/impairment)
- No Motor delay/impairment (no obvious indicators of motor delay/impairment)
- Not Assessed

Academic Progress *

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

Academic Activity Level *

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

Primary Insurance at Follow-up: *

Specify:

Clinical Information

Date of Measurement: *

Height: *

 ft. in. cm %ile St=

Weight: *

 lbs. kg %ile St=

BMI:

 kg/m² %ile

Graft Status: *

- Functioning
- Failed

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

TPN Dependent:

- YES
- NO

IV Dependent:

- YES
- NO

Oral Feeding:

- YES
- NO

Tube Feeding:

- YES
- NO

Date of Failure:

Primary Cause of Failure:

- RECURRENT TUMOR
- ACUTE REJECTION
- CHRONIC REJECTION
- TECHNICAL PROBLEMS
- INFECTION
- LYMPHOPROLIFERATIVE DISEASE
- GVHD (Graft Versus Host Disease)
- Ischemia / NEC (Necrotizing Enterocolitis) Like Syndrome
- PATIENT NONCOMPLIANCE
- OTHER SPECIFY

Other, Specify:

Diabetes onset during the follow-up period: * YES NO UNK

Insulin dependent: YES NO UNK

Most Recent Lab date: *

Total Bilirubin: * mg/dl St=

Serum Albumin: mg/dl St=

Serum Creatinine: * mg/dl St=

Did patient have any acute rejection episodes during the follow-up period: * Yes, at least one episode treated with anti-rejection agent

Yes, none treated with additional anti-rejection agent

No

Unknown

Was biopsy done to confirm acute rejection: Biopsy not done

Yes, rejection confirmed

Yes, rejection not confirmed

Unknown

Postransplant Malignancy: * YES NO UNK

Donor Related: YES NO UNK

Recurrence of Pre-Tx Tumor: YES NO UNK

De Novo Solid Tumor: YES NO UNK

De Novo Lymphoproliferative disease and Lymphoma: YES NO UNK

Treatment

Biological or Anti-viral therapy: YES NO Unknown/Cannot disclose

If Yes, check all that apply:

Acyclovir (Zovirax)

Cytogam (CMV)

Gamimune

Gammagard

Ganciclovir (Cytovene)

Valgancyclovir (Valcyte)

HBIG (Hepatitis B Immune Globulin)

Flu Vaccine (Influenza Virus)

Lamivudine (Epivir) (for treatment of Hepatitis B)

Valacyclovir (Valtrex)

Other, Specify

Specify:

Specify:

Other therapies: YES NO

If Yes, check all that apply:

Photopheresis

Plasmapheresis

Total Lymphoid Irradiation (TLI)

Immunosuppressive Information

Previous Validated Maintenance Follow-Up Medications:

Were any medications given during the follow-up period for maintenance: * Yes, same as previous validated report

Yes, but different than previous validated report

None given

Did the physician discontinue all maintenance immunosuppressive medications:

YES NO

Did the patient participate in any clinical research protocol for immunosuppressive medications:

YES NO

Specify:

Immunosuppressive Medications

[View Immunosuppressive Medications](#)

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, *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* (example: 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 current clinic visit to begin in the next report *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* (example: Prednisone, Cyclosporine, Tacrolimus, Mycophenolate Mofetil, Azathioprine, or Rapamycin). 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, Atgam, OKT3, 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. **Do not list non-immunosuppressive medications.**

| | Prev Maint | Curr Maint | AR |
|---|-------------------------------------|-------------------------------------|-------------------------------------|
| Steroids (Prednisone, Methylprednisolone, Solumedrol, Medrol, Decadron) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Atgam (ATG) | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| OKT3 (Orthoclone, Muromonab) | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Thymoglobulin | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Simulect - Basiliximab | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Zenapax - Daclizumab | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Azathioprine (AZA, Imuran) | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| EON (Generic Cyclosporine) | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| Gengraf (Abbott Cyclosporine) | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| Other generic Cyclosporine, specify brand: | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| Neoral (CyA-NOF) | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| Sandimmune (Cyclosporine A) | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| Mycophenolate Mofetil (MMF, Cellcept, RS61443) | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| Tacrolimus (Prograf, FK506) | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| Modified Release Tacrolimus FK506E (MR4) | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| Sirolimus (RAPA, Rapamycin, Rapamune) | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| Myfortic (Mycophenolate Sodium) | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |

Other Immunosuppressive Medications

| | Prev Maint | Curr Maint | AR |
|--|-------------------------------------|-------------------------------------|-------------------------------------|
| Campath - Alemtuzumab (anti-CD52) | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Cyclophosphamide (Cytoxan) | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Leflunomide (LFL, Arava) | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| Methotrexate (Folex, PFS, Mexate-AQ, Rheumatrex) | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Other Immunosuppressive Medication, Specify | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Other Immunosuppressive Medication, Specify | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Rituximab | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |

Investigational Immunosuppressive Medications

| | Prev Maint | Curr Maint | AR |
|----------------------------|--------------------------|--------------------------|-------------------------------------|
| Everolimus (RAD, Certican) | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| FTY 720 | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |