

# Records ?

## Pediatric Liver 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<sup>B</sup> 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<sup>B</sup> 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/m<sup>2</sup> %ile

Pathology confirmed liver diagnosis at hospital discharge:

Specify:

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.

Date of Failure:

Contributory causes of graft failure:

Primary Graft Failure

- YES
- NO
- UNK

Vascular Thrombosis

- YES
- NO
- UNK

Hepatic arterial thrombosis

- YES
- NO
- UNK

Hepatic outflow obstruction

- YES
- NO
- UNK

Portal vein thrombosis

- YES
- NO
- UNK

Biliary Tract Complication:

- YES
- NO
- UNK

Denovo Hepatitis

- YES
- NO
- UNK

Recurrent Hepatitis:

- YES
- NO
- UNK

Recurrent Disease:

- YES
- NO
- UNK

Acute Rejection:

- YES
- NO
- UNK

Chronic Rejection:  YES  NO  UNK

Infection:  YES  NO  UNK

Patient Noncompliance:  YES  NO  UNK

Other, Specify:

Discharge Lab Data:

Lab Date:

Total Bilirubin:  mg/dl St=

SGPT/ALT:  U/L St=

Serum Albumin:  g/dl St=

Serum Creatinine:  mg/dl St=

INR (ratio):  St=

Most Recent Lab Data:

Lab Date: \*

Total Bilirubin: \*  mg/dl St=

SGPT/ALT:  U/L St=

Serum Albumin:  g/dl St=

Serum Creatinine: \*  mg/dl St=

INR (ratio):  St=

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

Insulin dependent:  YES  NO  UNK

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

Acyclovir (Zovirax)

Cytogam (CMV)

Gamimune

If Yes, check all that apply:

- 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

Photopheresis

Plasmapheresis

Total Lymphoid Irradiation (TLI)

If Yes, check all that apply:

### 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="text"/>	<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 (Cytosan)	<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="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other Immunosuppressive Medication, Specify <input type="text"/>	<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"/>