

# Records

## Pediatric Kidney-Pancreas Transplant Recipient Follow-Up Worksheet

FORM APPROVED: O.M.B. NO. 0915-0157 Expiration Date: 10/31/2010

Note: These worksheets are provided to function as a guide to what data will be required in the online TIEDI<sup>®</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>®</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	
<b>Name:</b>	<b>DOB:</b>
<b>SSN:</b>	<b>Gender:</b>
<b>HIC:</b>	<b>Tx Date:</b>
<b>Previous Follow-Up:</b>	<b>Previous Px Stat Date:</b>
<b>Transplant Discharge Date:</b>	<input type="text"/>
<b>State of Permanent Residence:</b> *	<input type="text"/>
<b>Zip Code:</b> *	<input type="text"/> - <input type="text"/>

Provider Information	
<b>Recipient Center:</b>	
<b>Followup Center:</b>	
<b>Physician Name:</b> *	<input type="text"/>
<b>NPI#:</b> *	<input type="text"/>
<b>Follow-up Care Provided By:</b> *	<input type="radio"/> Transplant Center <input type="radio"/> Non Transplant Center Specialty Physician <input type="radio"/> Primary Care Physician <input type="radio"/> Other Specify
<b>Specify:</b>	<input type="text"/>

Donor Information	
<b>UNOS Donor ID #:</b>	
<b>Donor Type:</b>	

Patient Status	
<b>Date: Last Seen, Retransplanted or Death</b> *	<input type="text"/>
<b>Patient Status:</b> *	<input type="radio"/> LIVING <input type="radio"/> DEAD <input type="radio"/> RETRANSPLANTED
<b>If Retransplanted, choose organ(s):</b>	<input type="radio"/> Kidney <input type="radio"/> Pancreas <input type="radio"/> Kidney/Pancreas
<b>Primary Cause of Death:</b>	<input type="text"/>
<b>Specify:</b>	<input type="text"/>
<b>Contributory Cause of Death:</b>	<input type="text"/>
<b>Specify:</b>	<input type="text"/>
<b>Contributory Cause of Death:</b>	<input type="text"/>
<b>Specify:</b>	<input type="text"/>

Hospitalizations:

Has the patient been hospitalized since the last patient status date: \*

YES  NO  UNK

Number of Hospitalizations:

St=

Noncompliance:

Was there evidence of noncompliance with immunosuppression medication during this follow-up period that compromised the patient's recovery:

YES  NO  UNK

Functional Status: \*

Cognitive Development:

- Definite Cognitive delay/impairment
- Probable Cognitive delay/impairment
- Questionable Cognitive delay/impairment
- No Cognitive delay/impairment
- Not Assessed

Motor Development:

- Definite Motor delay/impairment
- Probable Motor delay/impairment
- Questionable Motor delay/impairment
- No Motor delay/impairment
- Not Assessed

Academic Progress: \*

- 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: \*

- 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: \*

Specify:

### Clinical Information

Date of Measurement:

Height: \*

 ft.  in.  cm %ile St= 

Weight: \*

 lbs.  kg %ile St= 

BMI:

 kg/m<sup>2</sup> %ile

Urine Protein Found By Any Method:

YES  NO  UNK

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

If yes, insulin dependent:  YES  NO  UNK

Kidney 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.

Kidney Date of Failure:

Kidney Primary Cause of Graft Failure:

Specify

Contributory causes of graft failure:

Kidney Acute Rejection  YES  NO  UNK

Kidney Chronic Rejection  YES  NO  UNK

Kidney Graft Thrombosis  YES  NO  UNK

Kidney Infection  YES  NO  UNK

Urological Complications  YES  NO  UNK

Patient Noncompliance  YES  NO  UNK

Recurrent Disease:  YES  NO  UNK

BK (Polyoma) Virus  YES  NO  UNK

Kidney Other Contributory Cause of Graft Failure

If Functioning, Most Recent Serum Creatinine:  mg/dl St=

NO

YES, RESUMED MAINTENANCE DIALYSIS

Dialysis Since Last Follow-Up:  YES, NO MAINTENANCE RESUMPTION

YES, MAINTENANCE RESUMPTION UNKNOWN

UNKNOWN

Date Maintenance Dialysis Resumed:

Select a Dialysis Provider:

Provider #:

Provider Name:

Pancreas Graft Status:\*  Functioning  Partial Function  Failed

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

Insulin

Method of blood sugar control:  Oral medication

Diet

No Treatment

Date insulin/medication resumed:

Pancreas Date of Failure

Pancreas Graft Removed:  YES  NO  UNK

Date Pancreas Removed:

Pancreas Primary Causes of Graft Failure

Specify:

Contributory causes of graft failure:

Pancreas Graft/Vascular Thrombosis  YES  NO  UNK

Pancreas Infection  YES  NO  UNK

Pancreas Bleeding  YES  NO  UNK

Anastomotic Leak  YES  NO  UNK

Pancreas Rejection: Acute  YES  NO  UNK

Pancreas Chronic Rejection  YES  NO  UNK

Biopsy Proven Isletitis  YES  NO  UNK

Pancreatitis  YES  NO  UNK

Patient Noncompliance  YES  NO  UNK

Other, Specify:

Conv. From Bladder to Enteric Drain Performed:  YES  NO  UNK

Enteric Drain Date:

Serum Amylase:  u/L St=

Pancreas Transplant Complications (Not leading to graft failure):

Pancreatitis  YES  NO  UNK

Anastomotic Leak  YES  NO  UNK

Abscess or Local Infection  YES  NO  UNK

Other, Specify:

Yes, at least one episode treated with anti-rejection agent

Did patient have any kidney acute rejection episodes during the follow-up period:  Yes, none treated with additional anti-rejection agent

No

Unknown

Biopsy not done

Was biopsy done to confirm acute rejection:  Yes, rejection confirmed

- Yes, rejection not confirmed
- Unknown

- Did patient have any pancreas 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

**Viral Detection:**

- CMV IgG:
- Positive
  - Negative
  - Not Done
  - UNK/Cannot Disclose
- CMV IgM:
- Positive
  - Negative
  - Not Done
  - UNK/Cannot Disclose

Is growth hormone therapy used during this followup period:\*

YES  NO  UNK

Coronary Artery Disease Since Last Follow Up:\*

YES  NO  UNK

Post Transplant 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

**Bone Disease:**

Fracture in the past year (or since last follow-up):\*

YES  NO  UNK

Specify Location and number of fractures:\*

Spine-compression fracture: # of fractures:

Extremity: # of fractures:

Other: # of fractures:

AVN (avascular necrosis):\*

YES  NO  UNK

## Treatment

Biological or Anti-viral therapy:

YES  NO  Unknown/Cannot disclose

Acyclovir (Zovirax)

Cytogam (CMV)

Gamimune

Gammagard

Ganciclovir (Cytovene)

If Yes, check all that apply:

Valgancyclovir (Valcyte)

HBIG (Hepatitis B Immune Globulin)

Flu Vaccine (Influenza Virus)

Lamivudine (Epivir) (for treatment of Hepatitis B)

Valacyclovir (Valtrex)

Other, Specify

Specify: \*

Specify:

Treatment for BK (polyoma) virus:

YES  NO

Yes, Immunosuppression reduction

Yes, Cidofovir

If Yes, check all that apply:

Yes, IVIG

Yes, Type Unknown

Yes, Other, Specify

Specify: \*

Other therapies:

YES  NO

Photopheresis

If Yes, check all that apply:

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

UNOS View Only	
Comments:	<input type="text"/>