

## Records

### Adult Pancreas 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<br><input type="radio"/> Non Transplant Center Specialty Physician<br><input type="radio"/> Primary Care Physician<br><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<br><input type="radio"/> DEAD<br><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"/>  |
| Physical Capacity:  | <input type="radio"/> No Limitations<br><input type="radio"/> Limited Mobility<br><input type="radio"/> Wheelchair bound or more limited  |

- Not Applicable (< 1 year old or hospitalized)
- Unknown

Working for income:

- YES
- NO
- UNK

If No, Not Working Due To:

If Yes:

- 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

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**

|           |   |                         |      |                          |
|-----------|---|-------------------------|------|--------------------------|
| Height:   | <input type="text"/> ft. <input type="text"/> in. | <input type="text"/> cm | %ile | St= <input type="text"/> |
| Weight: * | <input type="text"/> lbs.                         | <input type="text"/> kg | %ile | St= <input type="text"/> |
| BMI:      | kg/m <sup>2</sup>                                 |                         | %ile |                          |

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.

Method of blood sugar control:

- Insulin
- Oral medication
- Diet
- No Treatment

Date insulin/medication resumed:

Date of Failure:

Pancreas Graft Removed:

- YES
- NO
- UNK

Date Pancreas Removed:

Primary Cause of Graft Failure:

Other, Specify:

Contributory causes of graft failure:

Graft/Vascular Thrombosis:

- YES
- NO
- UNK

Infection:

- YES
- NO
- UNK

Bleeding:

- YES
- NO
- UNK

Anastomotic Leak:

YES  NO  UNK

Acute Rejection:

YES  NO  UNK

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

If Yes, Enteric Drainage Date:

Serum Amylase:

 u/L

St=

Pancreas Transplant Complications (Not leading to graft failure):

Pancreatitis: \*

YES  NO  UNK

Anastomotic Leak: \*

YES  NO  UNK

Abcess or Local Infection: \*

YES  NO  UNK

Other Complications:

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

Photopheresis

Plasmapheresis

Total Lymphoid Irradiation (TLI)

If Yes, check all that apply:

### Immunosuppressive Information

#### Previous Validated Maintenance Follow-Up Medications:

Yes, same as previous validated report

Were any medications given during the follow-up period for maintenance:  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 (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="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"/> |

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