

Site: Participant ID:

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| --- | --- | --- | --- | --- | --- | --- |
| * Was the participant enrolled via waiver of consent? | | | No | Yes |  | |
| *Participants may only be enrolled via waiver of consent if waiver has been approved by the IRB, REB, or local ethics committee.* | | | | | | |
| * Date informed consent signed: | | | / / | | (mm/dd/yyyy) | |
| * Date HIPAA Data Authorization signed: | | | / / | | (mm/dd/yyyy) | N/A |
| *Select “N/A” if HIPAA does not apply (non-US centers)* | | | | | | |
| * Date informed assent signed: | | | / / | | (mm/dd/yyyy) | N/A |
| *Select “N/A” if informed assent does not apply due to the participant’s age.* | | | | | | |
| Date of transplant: | |  | / / | | (mm/dd/yyyy) | |
| * Did the participant have congenital heart disease, with the exception of patent foramen ovale (PFO)? | | | | | No Yes | |
| Inclusion Criteria | |  |  | |  | |
| No | Yes | 1. •Is the participant < 18 years of age at the time of first transplant? | | | | |
| No | Yes | 2. •Did the participant receive a liver-only, a combined liver-kidney, or a combined liver- pancreas transplant at a participating SPLIT Registry center: | | | | |
| If Yes, specify type:  Liver-only  Combined liver-kidney Combined liver-pancreas | | | | | | |
| Exclusion Criteria | |  |  | |  | |
| No | Yes | 1. •Has the participant previously received a solid organ transplant other than liver-only, kidney-only, combined liver-kidney, or combined liver-pancreas?  *A hepatocyte transplant is not considered a solid-organ transplant.* | | | | |

Version 7.0 1 August 18, 2017

Data elements marked with • will only be collected for the first transplant



Site: Participant ID:

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| --- | --- | --- | --- |
| 1. Date of birth: | / / | (mm/dd/yyyy) |  |
| 2. Gender: | Male Female |  |  |
| 3. Ethnicity: | Hispanic or Latino Not Hispanic or Latino Not Reported | | |
| *Hispanic is defined as Mexican, Puerto Rican, Cuban, Central or South American, or other Spanish culture or origin, regardless of race.* | | | |
| 4. Did the participant report race? | No Yes |  |  |
| *Select all origins that apply*: |  |  |  |
| a. **American Indian/Alaskan Native:**  (A person having origins in any of the original peoples of North and South America (including Central America), and who maintains tribal affiliations or community attachment) | | No | Yes |
| b. **Asian:**  (A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent, including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam) | | No | Yes |
| c. **Black or African American:**  (A person having origins in any of the black racial groups of Africa) | | No | Yes |
| d. **Native Hawaiian or Pacific Islander:**  (A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands) | | No | Yes |
| e. **White:**  (A person having origins in any of the original peoples of Europe, the Middle East, or North Africa) | | No | Yes |
| f. **Multi-racial, not otherwise specified:**  (Participant is reported as having multiple races but data regarding those specific races are unavailable) | | No | Yes |

Site: Participant ID: Transplant Number: Tx 1 Tx 2 Tx 3 Tx 4

Visit Number: sit 000

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| --- | --- |
| Recipient Information |  |
| 1. Blood typeTx1: | A B AB O |
| 2. Primary Disease Diagnosis Tx1: | Acute liver failure: Acetaminophen |
|  | Acute liver failure: Autoimmune Hepatitis Acute liver failure: Cytomegalovirus (CMV)  Acute liver failure: Drug-induced Hepatitis (other than acetaminophen)  Acute liver failure: Epstein–Barr virus (EBV) Acute liver failure: Fatty acid oxidation defect Acute liver failure: Hemophagocytic syndrome Acute liver failure: Hemangioendothelioma Acute liver failure: Hepatitis A  Acute liver failure: Hepatitis B (+ delta) Acute liver failure: Hepatitis C  Acute liver failure: Herpes Simplex Acute liver failure: Mitochondrial  Acute liver failure: Neonatal iron storage disease Acute liver failure: Shock/ischemia  Acute liver failure: Veno-occlusive disease Acute liver failure: Wilson’s disease  Acute liver failure: Indeterminate  Acute liver failure: Other, specify: |
|  | Alagille Syndrome |
|  | Alpha-1 Anti-trypsin deficiency |
|  | Autoimmune Hepatitis |
|  | Bile Acid Synthesis defect |
|  | Biliary Atresia |
|  | Budd-Chiari syndrome |
|  | Carbamylphosphate synthetase deficiency |
|  | Citrullinemia |
|  | Congential hepatic fibrosis |
|  | Crigler-Najjar |
|  | Cystic Fibrosis |
|  | Glycogen storage disease |
|  | Graft vs. Host Disease (GVHD) |
|  | Hepatitis B |
|  | Hepatitis C |
|  | Hepatoblastoma |
|  | Hepatocellular carcinoma |
|  | Other metabolic disease, specify: |
|  | Neonatal Hepatitis |
|  | Non-alcoholic steatohepatitis |

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| Primary Disease DiagnosisTx1 (cont): | Ornithine transcarbamylase deficiency |
|  | PFIC1 (FIC1 disease) PFIC2 (BSEP disease)  PFIC3 (MDR3 disease) |
|  | Primary Hyperoxaluria |
|  | Primary Sclerosing Cholangitis |
|  | Total parenteral nutrition (TPN) induced |
|  | Tyrosinemia |
|  | Other tumor, specify: |
|  | Wilson’s disease |
|  | Other, specify: |
| 3. Primary cause for graft failure>Tx1: | Primary graft dysfunction |
|  | Hyperacute rejection |
|  | Chronic rejection |
|  | Post-operative hemorrhage |
|  | Biliary tract complications |
|  | De Novo Hepatitis |
|  | Recurrent Primary Liver disease |
|  | Hepatic Artery Thrombosis |
|  | Portal Vein Thrombosis |
|  | Other, specify: |
| 4. Primary insurance type: | Australian National Federal funding Champus (military)  HMO / Managed care  Medicaid or equivalent and/or state funded children’s services |
|  | Provincial government (Canada) |
|  | Traditional private insurance |
|  | None: Self pay |
|  | None: Donation |
|  | None: No funding |
|  | Other |
| 5. Primary caregiver: | Mother |
|  | Father |
|  | Guardian |
|  | Other, specify: |
| 6. Primary caregiver’s marital status: | Single |
|  | Married |
|  | Divorced |
|  | Widowed  Domestic partnership Unknown |

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| 7. Primary caregiver’s highest level  of education: | Some high school or less | | |
|  | High school degree / GED | | |
|  | Vocational school or some college | | |
|  | College degree | | |
|  | Professional or graduate degree Unknown | | |
| Co-morbidities (Present within one month prior to transplant) | | | |
| 8. Diabetes: | No | | |
|  | Type I | | |
|  | Type II | | |
|  | Type other | | |
|  | Type unknown | | |
|  | Diabetes status unknown | | |
| 9. Dialysis: | No dialysis | | |
|  | Hemodialysis | | |
|  | Peritoneal dialysis | | |
|  | CAVH: Continuous arteriovenous hemofiltration | | |
|  | CV VH: Continous venous/venous hemofiltration | | |
|  | Dialysis status unknown | | |
|  | Dialysis unknown type performed | | |
| 10. Drug treated systemic hypertension: | No | Yes | Unknown |
| 11. Any previous malignancy: | No | Yes | Unknown |
| *For participants with a primary disease diagnosis of hepatoblastoma, previous malignancy of hepatoblastoma should only be indicated as “Yes” if the participant had surgical therapy to treat the hepatoblastoma prior to the current liver transplant and there was reoccurrence.* | | | |
| If yes, specify type: | Skin melanoma | | |
|  | Skin non-melanoma | | |
|  | Central nervous system (CNS) tumor | | |
|  | Genitourinary | | |
|  | Breast | | |
|  | Thyroid | | |
|  | Tongue/throat/larynx | | |
|  | Lung | | |
|  | Leukemia/lymphoma | | |
|  | Liver | | |
|  | Hepatoblastoma | | |
|  | Hepatocellular carcinoma | | |

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| 12. Does the participant have hepatopulmonary syndrome: | No | Yes | Unknown |
| If yes, specify: |  | | |
| Is the participant on home oxygen: | No | Yes | Unknown |

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| --- | --- | --- | --- |
| 13. Is the participant receiving supplemental feeding: | No | Yes | Unknown |
| If yes, specify: |  | | |
| Route of nutritional intake: | Tube | | |
|  | Parenteral (I.V.) | | |
|  | Tube and Parenteral (I.V.) | | |
|  | Unknown | | |
| 14. Does the participant have co-existing inflammatory bowel disease (IBD): | No | Yes | Unknown |
| *Co-existing IBD is defined as histologic evidence of chronic inflammation in the intestine consistent with*  *either ulcerative colitis or Crohn’s disease.* | | | |
| If yes, specify: |  | | |
| Type: | Crohn’s Disease | | |
|  | Ulcerative Colitis | | |
|  | Indeterminate | | |
| 15. Did the participant have congenital cardiac disease that required an operational procedure or therapeutic intervention? | No | Yes | Unknown |
| 16. Did the participant receive a previous liver, combined liver- kidney, or combined liver-pancreas transplant Tx1? | No | Yes | Unknown |
| If yes, specify number of previous liver, combined liver- kidney, or combined liver-pancreas transplants Tx1: |  | | |
| 17. Did the participant have previous abdominal surgery (excluding  liver, combined liver-kidney, or combined liver-pancreas transplant): | No | Yes | Unknown |
| If yes, specify: |  | | |
| Kasai portoenterostomy: | No | Yes | Unknown |
| Hepatic resection (lobe or segmental): | No | Yes | Unknown |
| Biliary diversion: | No | Yes | Unknown |
| Open liver biopsy: | No | Yes | Unknown |
| Cholecystectomy: | No | Yes | Unknown |
| Other biliary surgery/reconstruction: | No | Yes | Unknown |
| Operative Portosystemic shunt – not transjugular intrahepatic portosystemic shunt (TIPS): | No | Yes | Unknown |
| Splenectomy: | No | Yes | Unknown |

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| --- | --- | --- |
| Gastrostomy tube (G-tube)/ percutaneous endoscopic gastrostomy (PEG): | | No Yes Unknown |
| Transplant (excluding liver, combined liver-kidney, or  combined liver-pancreas transplant): | | No Yes Unknown |
| Other intra-abdominal procedures: | | No Yes Unknown |
| Participant Status at Transplant |  |  |
| 18. Date of listing: | / / | (mm/dd/yyyy) |

1. United Network for Organ Sharing (UNOS) Status 1a or 1b at transplant:

(Canadian Status 4 or 4f)

(Category 1, 2A TSANZ – Australian, New Zealand)

No  Yes

If Yes, specify:

Is the participant status 1 by exception:  No  Yes

If No, specify:

* 1. Indicate scoring system used to list with UNOS:  PELD  MELD
  2. Score type used to list with UNOS:  Calculated  Exception
     1. Pediatric End-Stage Liver Disease (PELD) exception score:
     2. Model for End-Stage Liver Disease (MELD) exception score:

*Record the height/weight measurements and chemistries/hematology results closest to the time of transplant. NOTE: entry of a value in the CU unit column will automatically calculate the corresponding SI unit column and vice versa for the Chemistry and Hematology panels.*

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| 20. Height at transplant: | Not Done |  |
| Date: | / / | (mm/dd/yyyy) |
| Value: |  | inches cm |
| 21. Weight at transplant: | Not Done |  |
| Date: | / / | (mm/dd/yyyy) |
| Value: |  | lbs kg |

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| 22. Sodium: | mEq/mL | or | mmol/L | | |
| 23. Total bilirubin: | mg/dL | or | µmol/L | | |
| 24. Albumin: | g/dL | or | g/L | | |
| 25. International normalized ratio (INR): |  | |  | | |
| 26. Serum creatinine: | mg/dL | or | µmol/L | | |
| 27. Did the participant have dialysis twice, or 24 hours of continuous  veno-venous hemodialysis (CVVHD), within a week prior to the serum creatinine test? | | | No | Yes | Unknown |

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| 28. Hospital status at transplant: | Intensive Care Unit (ICU) |
|  | Hospitalized, not in ICU |
|  | Not hospitalized |
| 29. Was the participant on life support at transplant: | No |
|  | Yes, ventilator |
|  | Yes, artificial liver |
|  | Yes, extracorporeal membrane oxygenation (ECMO) |
| 30. Was the participant intubated prior to being taken to the OR for transplant: | No Yes |

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| Donor Information |  |  | | |
| 31. Donor type: | Deceased–Brain Death  Deceased–Donation after Cardiac Death (DCD) Living | | | |
| 32. Donor age: |  | Months | Years |  |
| *If the participant is < 2 years of age, record age in months. If the participant is > 2 years of age, record the age in years.* | | | | |
| 33. Donor gender: | Male Female | | | |
| 34. Donor ethnicity: | Hispanic or Latino | | Not Hispanic or Latino | Not Reported |

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| 35. Donor race: | Unknown |  |  |
| *Select all origins that apply*. | | | |
|  | American Indian or Alaska Native: | | No Yes |
|  | Asian: |  | No Yes |
|  | Black or African American: | | No Yes |
|  | Native Hawaiian or Pacific Islander: | | No Yes |
|  | White: |  | No Yes |
|  | Multi-racial, not otherwise specified: | | No Yes |
| 36. Donor weight: |  | lbs kg |  |
| 37. Donor blood type: | A B AB O | |  |
| Transplant Procedure |  |  |  |
| 38. Surgical procedure: | Orthotopic Auxiliary |  |  |
| 39. Procedure type : | Whole liver |  |  |
| Partial liver, remainder not transplanted or living transplant | | | |
|  | Split liver |  |  |
|  | Unknown |  |  |
| 40. Partial type: | Right lobe without middle hepatic vein (segments 5,6,7,8) | |  |
| Right lobe with middle hepatic vein (segments 4,5,6,7,8) | | | |
| Left lobe (segments 2,3,4) | | | |
| Left lateral (segments 2,3) | | | |
|  | Unknown |  |  |
| 41. Split type: | Right lobe without middle hepatic vein in situ/ex situ (segments 5,6,7,8) | | |
| Right lobe with middle hepatic vein in situ /ex situ (segments 4,5,6,7,8) | | | |
| Left lobe in situ /ex situ (segment 2,3,4) | | | |
| Left lateral segment in situ /ex situ (segments 2,3) | | | |
|  | Unknown |  |  |
| 42. Biliary anastomosis: | Duct-to-duct  Roux-en-Y choledochojejunostomy Other | |  |
| 43. Biliary stent: | None Internal External | |  |

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| 44. Warm ischemia time: |  | minutes |
| *The number of minutes between the time of removal from cold storage and the time of reperfusion of warm*  *blood, whether venous or arterial.* | | |
| 45. Total cold ischemia time (if pumped, include pump time): | hours | minutes |
| *The number of hours and minutes between the time of preservation of the organ and the time of removal from cold storage.* | | |
| 46. Did the participant have a portal vein thrombosis in native liver: | No Yes |  |
| 47. Did the participant have a transjugular intrahepatic portocaval shunt (TIPS): | No Yes |  |

1. Was an incidental tumor found at time of transplant:  No  Yes

*For participants with a primary disease diagnosis of hepatoblastoma, incidental tumor found at time of transplant should not be indicated as “Yes” for the hepatoblastoma.*

* 1. If yes, tumor type (confirmed by pathology):  Hepatocellular adenoma  Hemangioma

 Hemangioendothelioma  Angiomyolipoma

 Bile duct cystadenocarcinoma  Cholangiocarcinoma

 Hepatocellular carcinoma  Hepatoblastoma

 Angiosarcoma

 Other primary liver tumor

|  |  |
| --- | --- |
| Immunosuppression |  |
| 1. Did the participant receive antibody therapy as induction:    1. If yes, specify type: | No Yes |
| ALG/ATG/ALS |
|  | OKT3/Monoclonal |
|  | IL-2mAb (Zenapax, Simulect, etc) |

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| 50. Initial Immunosuppression (within 7 days post-transplant): | | | | |
| Tacrolimus: | No | Yes |  | |
| Cyclosporine: | No | Yes |  | |
| Mycophenolate mofetil/ Mycophenolic acid (MMF/MPA): | No | Yes |  | |
| Azathioprine: | No | Yes |  | |
| Sirolimus: | No | Yes |  | |
| Corticosteroids: | No | Yes |  | |
| Everolimus: | No | Yes |  | |
| Participation in Other Research Networks | | | | |
| 51. Is the participant enrolled in any of the following research networks? | | | | |
| CHILDREN Tx1 | | | No | Yes, specify ID number: |
| PALF Tx1 | | | No | Yes, specify ID number: |

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Visit Number: Visit 001(Day 30) Visit 002 (Day 90)

1. Date of assessment: / / (mm/dd/yyyy)
2. Did the participant either die or require liver retransplantation prior to dischargeD30:

If yes, specify:

No  Yes

Type of event:  Death

 Retransplant

Date of event: / / (mm/dd/yyyy)

If no, specify date of primary / / (mm/dd/yyyy) hospital discharge:

*Report the date of primary hospital discharge even if it is after the Day 30 assessment date.*

1. Date of primary extubation post-op / / (mm/dd/yyyy)

D30:

*Report the date of primary extubation even if it is after the Day 30 assessment date.*

1. Re-intubated after primary extubation in the first 30 days post-transplant D30:  No  Yes  N/A

*Indicate N/A if date of primary extubation is after the Day 30 assessment date.*

1. Did the participant undergo a liver biopsy within the first 30 days D30:  No  Yes Did the participant undergo a liver biopsy since Day 30 D90:

If yes, specify:

Number of liver biopsies performed:

Liver Biopsy #1

Date of biopsy: / / (mm/dd/yyyy) Reason for biopsy:  Per protocol

 For cause

Was immunosuppressive therapy modified in response to the biopsy:

No  Yes

Was rejection confirmed:  No/indeterminate  Yes, Acute

 Yes, Chronic

*If insufficient tissue was obtained to make a diagnosis, report rejection as “No/indeterminate.”*

*For acute rejection. allograft dysfunction is defined to be present when either ALT or both alkaline phosphatase and GGT are elevated compared to baseline and biopsy findings including three main features, bile duct damage, endothelial inflammation and a mixed cellular infiltrate comprised of lymphocytes, eosinophils, plasma cells, and neutrophils.*

*Diagnosis of chronic rejection requires persistent elevation of direct bilirubin (1.5 x nl) and/or serum GGT level (2 times normal) >3 months even in the face of therapy for acute rejection together with liver histology that fulfills Banff criteria. The Banff criteria are degenerative changes of the majority of bile ducts/ loss of 50% of bile ducts with venulitis and/or fibrosis.*

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Liver Biopsy #2

Date of biopsy: / / (mm/dd/yyyy) Reason for biopsy:  Per protocol

 For cause

Was immunosuppressive therapy modified in response to the biopsy:

No  Yes

Was rejection confirmed:  No/indeterminate  Yes, Acute

 Yes, Chronic

Liver Biopsy #3

Date of biopsy: / / (mm/dd/yyyy) Reason for biopsy:  Per protocol

 For cause

Was immunosuppressive therapy modified in response to the biopsy:

No  Yes

Was rejection confirmed:  No/indeterminate  Yes, Acute

 Yes, Chronic

Liver Biopsy #4

Date of biopsy: / / (mm/dd/yyyy) Reason for biopsy:  Per protocol

 For cause

Was immunosuppressive therapy modified in response to the biopsy:

No  Yes

Was rejection confirmed:  No/indeterminate  Yes, Acute

 Yes, Chronic

1. Was the participant treated for antibody mediated rejection:  No  Yes
2. Was the participant relisted for a liver transplant:  No  Yes If yes, specify date relisted: / / (mm/dd/yyyy)

|  |  |
| --- | --- |
| 8. Did the participant have any vascular complications: | No Yes |
| If yes, specify: |  |
| *Diagnosis of vessel thrombosis requires imaging evidence of vessel occlusion (angiography, Doppler U/S, CT or MR angiography, or operative finding) in the vessel in question. No biochemical or clinical requirements for diagnosis.*  *Diagnosis of vessel stenosis requires imaging evidence of partial narrowing/occlusion of blood flow (angiography, CT or MR angiography, or operative finding) in question. No biochemical or clinical requirements for diagnosis.* | |

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Visit Number: Visit 001(Day 30) Visit 002 (Day 90)

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| *Observation should only be recorded as the treatment for a vascular complication if all other treatment*  *options (i.e. anticoagulation, reoperation, and interventional radiology) are “No”.* | | | |
| Portal vein thrombosis:  If yes, specify date of diagnosis:  / / | No Yes | Treatment: Anticoagulation Reoperation Interventional radiology Observation | No Yes  No Yes  No Yes  No Yes |
| Hepatic vein thrombosis:  If yes, specify date of diagnosis:  / / | No Yes | Treatment: Anticoagulation Reoperation Interventional radiology Observation | No Yes  No Yes  No Yes  No Yes |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Hepatic artery thrombosis:  If yes, specify date of diagnosis:  / / | No Yes | Treatment: Anticoagulation Reoperation Interventional radiology Observation | No No No No | Yes Yes Yes Yes |
| Portal vein stenosis:  If yes, specify date of diagnosis:  / / | No Yes | Treatment: Anticoagulation Reoperation Interventional radiology Observation | No No No No | Yes Yes Yes Yes |
| Outflow obstruction (hepatic vein stenosis, vena cava stenosis):  If yes, specify date of diagnosis:  / / | No Yes | Treatment: Anticoagulation Reoperation Interventional radiology Observation | No No No No | Yes Yes Yes Yes |
| Hepatic artery stenosis:  If yes, specify date of diagnosis:  / / | No Yes | Treatment: Anticoagulation Reoperation  Interventional radiology Observation | No No No No | Yes Yes Yes Yes |

|  |  |
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| 1. Did the participant have any biliary complications since the last visit?    1. If yes, did the participant have a biliary leak (from cut surface or biliary tree): | No Yes |
| No Yes |
| *Intrahepatic or extrahepatic fluid collection detected by imaging study* |  |

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*(ultrasound, CT, MRI) and direct continuity of the fluid collection to the biliary tract confirmed by scintography, cholangiography.*

If yes, specify date of diagnosis: / /

* 1. If yes, did the participant have a biloma:  No  Yes

*Extrahepatic fluid collection detected by imaging study (ultrasound, CT, MRI) which requires placement of an indwelling percutaneous drain for treatment.*

If yes, specify date of diagnosis: / /

* 1. If yes, did the participant have an non-anastomotic biliary stricture:  No  Yes

*Stricture which is not at the anastomotic site and typically multiple, longer in length and located in intrahepatic ducts and/or in the donor duct proximal to site of anastomosis.*

If yes, specify date of diagnosis: / /

* 1. If yes, did the participant have an anastomotic biliary stricture:  No  Yes

*Diagnosis requires cholangiographic (ERCP, MR, PTC) evidence of biliary duct stricture. No biochemical requirements for diagnosis.*

If yes, specify date of diagnosis: / /

1. Was the participant readmitted in the first 30 days D30:

*Select 'N/A' only in the event that the subject was never discharged during the initial 30 days post-transplant*

No  Yes  N/A

Was the participant readmitted since Day 30 D90:

*Select 'N/A' only in the event that the subject was never discharged since the Day 30 visit*

* 1. Number of times readmitted in the first 30 days D30:
  2. Number of times readmitted since Day 30 D90:

*If readmitted, record detailed information on up to first two readmissions.*

Date of first re-admission: / / (mm/dd/yyyy)

Discharge diagnosis D30

Fever:  No  Yes

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| Dehydration: |  | No | Yes |
| Fluid-electrolyte imbalance: |  | No | Yes |
| Gastrointestinal (GI) bleeding: |  | No | Yes |
| Bowel obstruction: |  | No | Yes |
| Seizures: |  | No | Yes |
| Wound dehiscence: |  | No | Yes |
| Allograft rejection: |  | No | Yes |
| Biliary complications: |  | No | Yes |
| Vascular complications: |  | No | Yes |
| Pneumonia: |  | No | Yes |
| Intra-abdominal infection: |  | No | Yes |
| Sepsis: |  | No | Yes |
| *Fever, hypotension, or oliguria, and all of the following: 1) blood not cultured or no microorganism isolated; 2) no apparent infection at another site; and 3) physician institutes appropriate antimicrobial therapy for sepsis.* | | | |
| Blood stream infection: |  | No | Yes |
| Urinary tract infection (UTI): |  | No | Yes |
| Wound infection: |  | No | Yes |
| Viral infection: |  | No | Yes |
| *Virus detected by PCR, culture or DFA, along with clinical symptoms that can be caused by the specific virus (i.e, fever, URI symptoms, diarrhea, lymphadenopathy). Asymptomatic Epstein-Barr Virus viremia should not be included.* | | | |
| Problems with outpatient medical regimen (medications not delivered, inability to purchase medications, medications not  taken): | | No | Yes |
| Renal failure (requiring dialysis): |  | No | Yes |
| Chemotherapy for cancer: |  | No | Yes |
| Infusions (Antibody): |  | No | Yes |
| Liver re-transplant: |  | No | Yes |
| Abnormal liver tests: |  | No | Yes |
| Other: |  | No | Yes |
| Specify: | | | |
| Date of discharge from first readmission : | / / | (mm/dd/yyyy) | |
| Date of second re-admission : | / / | (mm/dd/yyyy) | |
| Discharge diagnosis D30 |  |  | |
| Fever: |  | No | Yes |
| Dehydration: |  | No | Yes |
| Fluid-electrolyte imbalance: |  | No | Yes |

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|  |  |  |  |
| --- | --- | --- | --- |
| Gastrointestinal (GI) bleeding: |  | No | Yes |
| Bowel obstruction: |  | No | Yes |
| Seizures: |  | No | Yes |
| Wound dehiscence: |  | No | Yes |
| Allograft rejection: |  | No | Yes |
| Biliary complications: |  | No | Yes |
| Vascular complications: |  | No | Yes |
| Pneumonia: |  | No | Yes |
| Intra-abdominal infection: |  | No | Yes |
| Sepsis: |  | No | Yes |
| Blood stream infection: |  | No | Yes |
| Urinary tract infection (UTI): |  | No | Yes |
| Wound infection: |  | No | Yes |
| Viral infection: |  | No | Yes |
| Problems with outpatient medical regimen (medications not delivered, inability to purchase medications, medications not taken): | | No | Yes |
| Renal failure (requiring dialysis): |  | No | Yes |
| Chemotherapy for cancer: |  | No | Yes |
| Infusions (Antibody): |  | No | Yes |
| Liver re-transplant: |  | No | Yes |
| Abnormal liver tests: |  | No | Yes |
| Other: |  | No | Yes |
| Specify: | | | |
| Date of discharge from second readmission : | / / | (mm/dd/yyyy) | |

|  |  |  |
| --- | --- | --- |
| 11. Did the participant have reoperation in the first 30 days (excluding retransplant) D30: | | No Yes |
| Number of reoperations in the first 30 days D30: |  |  |
| *Record detailed information on up to first three reoperations.* | | |
| First reoperation |  |  |
| Date of first reoperation: | / / | (mm/dd/yyyy) |
| Reasons for reoperation: |  |  |
| Intra-abdominal bleeding: |  | No Yes |
| Biliary tract complication/bile leak: |  | No Yes |
| Vascular complication: |  | No Yes |
| Wound complication: |  | No Yes |
| Bowel perforation: |  | No Yes |

Site: Participant ID: Transplant Number: Tx 1 Tx 2 Tx 3 Tx 4

Visit Number: Visit 001(Day 30) Visit 002 (Day 90)

|  |  |
| --- | --- |
| Bowel obstruction: | No Yes |
| Fascia closure: | No Yes |
| Exploratory laparotomy: | No Yes |
| Other: | No Yes |
| Specify: |  |

|  |  |  |
| --- | --- | --- |
| Second reoperation |  |  |
| Date of second reoperation: | / / | (mm/dd/yyyy) |
| Reasons for reoperation: |  |  |
| Intra-abdominal bleeding: |  | No Yes |
| Biliary tract complication/bile leak: |  | No Yes |
| Vascular complication: |  | No Yes |
| Wound complication: |  | No Yes |
| Bowel perforation: |  | No Yes |
| Bowel obstruction: |  | No Yes |
| Fascia closure: |  | No Yes |
| Exploratory laparotomy: |  | No Yes |
| Other: |  | No Yes |
| Specify: | | |

|  |  |  |
| --- | --- | --- |
| Third reoperation |  |  |
| Date of third reoperation: | / / | (mm/dd/yyyy) |
| Reasons for reoperation: |  |  |
| Intra-abdominal bleeding: |  | No Yes |
| Biliary tract complication/bile leak: |  | No Yes |
| Vascular complication: |  | No Yes |
| Wound complication: |  | No Yes |
| Bowel perforation: |  | No Yes |
| Bowel obstruction: |  | No Yes |
| Fascia closure: |  | No Yes |
| Exploratory laparotomy: |  | No Yes |
| Other: |  | No Yes |
| Specify: | | |

Site: Participant ID: Transplant Number: Tx 1 Tx 2 Tx 3 Tx 4

Visit Number: Visit 001(Day 30) Visit 002 (Day 90)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 12. Did the participant have a cholangitis infection within the first 30 days D30: | | | No | Yes |
| Did the participant have a cholangitis infection since Day 30 D90: | | | No | Yes |
| *Diagnosis for cholangitis requires fever > 38°C in a child with no other obvious source of infection with at least 2 of the following:*   * *Laboratory changes indicating biliary obstruction* * *Elevation of direct bilirubin by 25% and at least >1.0 mg/dl above previous level baseline* * *Rise in 2 or more of AST, ALT, alkaline phosphatase or GGTP to 1.5X the upper limit of normal or >25% above baseline values if previously elevated* * *Right upper quadrant pain/tenderness* * *Imaging evidence of biliary tract obstruction* * *Clinical and biochemical improvement in response to treatment with antibiotics* * *Clinical and biochemical improvement in response to relief of biliary obstruction* | | | | |
| 13. Did the participant have a culture proven infection within the first 30 days  D30: | | | No | Yes |
| Did the participant have a culture proven infection since Day 30 D90: | | | No | Yes |
| Bacterial: | No | Yes |  | |
| If yes, specify: |  | |  | |
| Date of infection: | / / | | (mm/dd/yyyy) | |
| Infection type |  | |  | |
| Intra-abdominal (peritonitis, abscess): | No | Yes |  | |
| Surgical site infection (SSI): | No | Yes |  | |
| *An infection is considered to be an SSI when it occurs at the site of surgery within 30 days of an operation.* | | | | |
| Blood stream infection (BSI): | No | Yes |  | |
| *Microbiologically documented BSI required one of the following: 1) recognized pathogen in the blood and pathogen not related to an infection at another site; or 2) fever, chills, or hypotension; and any of the following: a) a common skin contaminant is isolated from at least two blood cultures drawn on separate occasions, and the organism is not related to infection at another site; b) a common skin contaminant is isolated from blood culture in a patient with an intravascular device, and the physician institutes appropriate antimicrobial therapy; c) a positive antigen test on blood and the organism is not related to infection at another site.* | | | | |
| Venous catheter infection: | No | Yes |  | |
| *Bloodstream infections (BSIs) for which other sources were excluded by examination of the patient record, and where a culture of the catheter tip demonstrated substantial colonies of an organism identical to those found in the bloodstream. BSIs are assessed according to definitions published by the National Healthcare Safety Network (NHSN) of the Centers for Disease Control and Prevention*  *(CDC).* | | | | |

Site: Participant ID: Transplant Number: Tx 1 Tx 2 Tx 3 Tx 4

Visit Number: Visit 001(Day 30) Visit 002 (Day 90)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Urinary tract infection (UTI): | No | Yes |  |  | |
| *An infection that can occur in any part of the urinary system, i.e., bladder or kidneys relating to an infection. A bacterial count greater than 100,000 bacteria CFU/ml in the midstream sample suggests a bladder or kidney infection.* | | | | | |
| Sepsis: | No | Yes |  |  | |
| Pneumonia: | No | Yes |  |  | |
| Meningitis: | No | Yes |  |  | |
| Esophagitis: | No | Yes |  |  | |
| Gastritis: | No | Yes |  |  | |
| Enteritis: | No | Yes |  |  | |
| Colitis: | No | Yes |  |  | |
| Other: | No | Yes |  |  | |
| Fungal: | No | Yes |  |  | |
| If yes, specify: |  | | |  | |
| Date of infection: | / / | | | (mm/dd/yyyy) | |
| Infection type |  | | |  | |
| Intra-abdominal (peritonitis, abscess): | No | Candida | Aspergillus | | Other |
| Cholangitis: | No | Candida | Aspergillus | | Other |
| Surgical site infection (SSI): | No | Candida | Aspergillus | | Other |
| Blood stream infection (BSI): | No | Candida | Aspergillus | | Other |
| Venous catheter infection: | No | Candida | Aspergillus | | Other |
| Urinary tract infection (UTI): | No | Candida | Aspergillus | | Other |
| Sepsis: | No | Candida | Aspergillus | | Other |
| Pneumonia: | No | Candida | Aspergillus | | Other |
| Meningitis: | No | Candida | Aspergillus | | Other |
| Esophagitis: | No | Yes |  |  | |
| Gastritis: | No | Yes |  |  | |
| Enteritis: | No | Yes |  |  | |
| Colitis: | No | Yes |  |  | |
| Other: | No | Candida | Aspergillus | | Other |
| Viral: | No | Yes |  |  | |
| If yes, specify: |  | | |  | |
| Date of infection: | / / | | | (mm/dd/yyyy) | |
| Infection type |  | | |  | |
| Sepsis: | No Adenovirus Cytomegalovirus (CMV) Epstein-Barr virus (EBV) Other | | | | |
| Pneumonia: | No Adenovirus Cytomegalovirus (CMV) Epstein-Barr virus (EBV) Other | | | | |
| Meningitis: | No Adenovirus Cytomegalovirus (CMV)  Epstein-Barr virus (EBV) Other | | | | |

Site: Participant ID: Transplant Number: Tx 1 Tx 2 Tx 3 Tx 4

Visit Number: Visit 001(Day 30) Visit 002 (Day 90)

|  |  |  |
| --- | --- | --- |
| Esophagitis: | No | Yes |
| Gastritis: | No | Yes |
| Enteritis: | No | Yes |
| Colitis: | No | Yes |
| Other: | No Adenovirus Cytomegalovirus (CMV) Epstein-Barr virus (EBV) Other | |
| *Record the results of the labs drawn closest to the assessment date (within +/- 7 days). If certain labs were not drawn or lab results were not measured within 7 days of the assessment date, indicate that labs were not done by checking the "Not Done" box.* D30  *Record the results of the labs drawn closest to the assessment date (within +/- 14 days). If certain labs were not drawn or lab results were not measured within 14 days of the assessment date, indicate that labs were not done by checking the "Not Done" box.* D90  *NOTE: Entry of a value in the CU unit column will automatically calculate the corresponding SI unit column and vice versa for the Chemistry and Hematology panels in AdvantageEDC.* | | |

|  |  |  |  |
| --- | --- | --- | --- |
| 14. Chemistries at Day 30 (+7 days) D30 |  |  |  |
| Chemistries at Day 90 (+14 days) D90 |  |  |  |
| Date the majority of labs drawn: | / / | | (mm/dd/yyyy) |
| Total bilirubin: |  | mg/dL | µmol/L |
| Direct bilirubin: |  | mg/dL | µmol/L |
| Conjugated bilirubin: |  | mg/dL | µmol/L |
| AST/SGOT: |  | U/L |  |
| ALT/SGPT: |  | U/L |  |
| Albumin: |  | g/dL | g/L |
| Alkaline phosphatase: |  | U/L |  |
| Serum creatinine: |  | mg/dL | µmol/L |
| GGT: |  | U/L |  |
| International normalized ratio (INR): |  |  |  |
| 15. Complete blood count (CBC) at Day 30 (+7 days) D30 | | | |
| Complete blood count (CBC) at Day 90 (+14 days) D90 | | | |
| Date the majority of labs drawn: | / / | | (mm/dd/yyyy) |
| Red blood cells (RBC): |  | 106 cells/uL | 1012 cells/L |
| White blood cells (WBC): |  | 103 cells/uL | 109 cells/L |
| Hemoglobin: |  | g/dL | g/L |
| Hematocrit: |  | % | VF |
| Mean corpuscular volume (MCV): |  | um3 | fL |
| Platelet count: |  | 103 cells/uL | 109 cells/L |

Site: Participant ID: Transplant Number: Tx 1 Tx 2 Tx 3 Tx 4

Visit Number: Visit 001(Day 30) Visit 002 (Day 90)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Immunosuppression |  | |  |  |  | |
| 16. Immunosuppression at Day 30 D30: | | | | | | |
| Immunosuppression at Day 90 D90: | | | | | | |
| Tacrolimus: | No | Yes | Frequency: | QD (24 hours)  TID (8 hours)  QOD (48 hours) | | BID (12 hours)  QID (6 hours) Other |
| Cyclosporine: | No | Yes | Frequency: | QD (24 hours)  TID (8 hours)  QOD (48 hours) | | BID (12 hours)  QID (6 hours) Other |
| Mycophenolate mofetil/ Mycophenolic acid (MMF/MPA): | No | Yes |  |  |  | |
| Azathioprine: | No | Yes |  |  |  | |
| Sirolimus: | No | Yes |  |  |  | |
| Corticosteroids: | No | Yes |  |  |  | |
| Everolimus: | No | Yes |  |  |  | |
| Concomitant Medications |  | |  |  |  | |
| 17. Is the participant taking anti-hypertensives: | | | |  | No | Yes |
| 18. Has the participant received chemotherapy for a primary liver tumor since transplant D30:  Has the participant received chemotherapy for a primary liver tumor since Day 30 D90: | | | | | No | Yes |
| 19. Has the participant received chemotherapy for post-transplant lymphoproliferative disorder (PTLD) since transplant D30:  Has the participant received chemotherapy for Post-transplant lymphoproliferative disorder (PTLD) since Day 30 D90: | | | | | No | Yes |

Site: Participant ID:

Transplant Number:

Tx 1 Tx 2 Tx 3 Tx 4

Visit Number: Visit 003 (Year 1) Visit 004 (Year 2) Visit 005 (Year 3)

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Visit 009 (Year 7) Visit 010 (Year 8) Visit 011 (Year 9)

Visit 012 (Year 10) (Other)

|  |  |  |
| --- | --- | --- |
| 1. Date of assessment: | / / | (mm/dd/yyyy) |
| 2. Did the participant receive a solid organ transplant since the last visit: | | No Yes |
| *A hepatocyte transplant is not considered a solid-organ transplant.* | | |
| If yes, specify type: |  |  |
| Liver |  | No Yes |
| Kidney |  | No Yes |
| Stomach |  | No Yes |
| Intestine |  | No Yes |
| Pancreas |  | No Yes |
| Heart |  | No Yes |
| Lung |  | No Yes |
| 3. Did the participant receive a bone marrow transplant since the last visit: | | No Yes |
| *If the participant received a bone marrow transplant, complete the Exit form.* | | |
| 4. Did the participant have recurrence of primary disease since the last visit (excluding cancers – see question 11): | | No Yes |
| 5. Did the participant undergo a liver biopsy since the last visit: | | No Yes |
| If yes, specify: |  |  |
| Number of liver biopsies performed: | |  |
| *If more than four biopsies were performed, data for additional biopsies may be recorded on pages 15-*  *19 of the CRF*. | | |
| Liver Biopsy #1 |  |  |
| Date of biopsy: | / / | (mm/dd/yyyy) |
| Reason for biopsy: |  | Per protocol For cause |
| Record ALT/SGPT and GGT results closest prior to biopsy: | | |
| ALT: U/L ALT result date: / / | | (mm/dd/yyyy) |
| GGT: U/L GGT result date: / / | | (mm/dd/yyyy) |

Site: Participant ID:

Transplant Number:

Tx 1 Tx 2 Tx 3 Tx 4

Visit Number: Visit 003 (Year 1) Visit 004 (Year 2) Visit 005 (Year 3)

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Visit 009 (Year 7) Visit 010 (Year 8) Visit 011 (Year 9)

Visit 012 (Year 10) (Other)

|  |  |  |
| --- | --- | --- |
| Was rejection confirmed: | No/indeterminate |  |
|  | Yes, acute |  |
|  | Yes, chronic |  |
| *If insufficient tissue was obtained to make a diagnosis, report rejection as “No/indeterminate.” For acute rejection, allograft dysfunction is defined to be present when either ALT or both alkaline phosphatase and GGT are elevated compared to baseline and biopsy findings including three main features, bile duct damage, endothelial inflammation and a mixed cellular infiltrate comprised of lymphocytes, eosinophils, plasma cells, and neutrophils.*  *Diagnosis of chronic rejection requires persistent elevation of direct bilirubin (1.5 x nl) and/or serum GGT level (2 times normal) >3 months even in the face of therapy for acute rejection together with liver histology that fulfills Banff criteria. The Banff criteria are degenerative changes of the majority of bile ducts/ loss of 50% of bile ducts with venulitis and/or fibrosis.* | | |
| Was immunosuppressive  therapy modified in response to the biopsy: |  | No Yes |
| *Thymoglobulin IV treatment should be reported as antibody treatment.* | | |
| If yes, specify modifications: | Calcineurin inhibitor (CNI): | Increased CNI dose amount and/or frequency  Started on CNI medication Decreased CNI dose  amount and/or frequency Stopped all CNI  medications  Changed to a different CNI medication  No change to CNI administration  N/A – not taking medication |
|  | Mammalian target of rapamycin (mTOR) inhibitor: | Increased mTOR inhibitor dose amount and/or frequency  Started on mTOR inhibitor Decreased mTOR inhibitor  dose amount and/or frequency Stopped all mTOR inhibitors |

Site: Participant ID:

Transplant Number:

Tx 1 Tx 2 Tx 3 Tx 4

Visit Number: Visit 003 (Year 1) Visit 004 (Year 2) Visit 005 (Year 3)

Visit 006 (Year 4) Visit 007 (Year 5) Visit 008 (Year 6)

Visit 009 (Year 7) Visit 010 (Year 8) Visit 011 (Year 9)

Visit 012 (Year 10) (Other)

|  |  |
| --- | --- |
|  | Changed to another mTOR No change to mTOR  inhibitor administration  N/A – not taking medication |
| Antimetabolite: | Increased antimetabolite dose amount and/or frequency  Started on antimetabolites Decreased antimetabolite  dose amount and/or frequency Stopped all antimetabolites Changed to another  antimetabolite No change to  antimetabolite administration N/A – not taking medication |
| Corticosteroids: | Increased corticosteroids dose amount and/or frequency  Started on corticosteroids Decreased corticosteroid  dose amount and/or frequency Stopped all corticosteroids Changed to another  corticosteroid  No change to corticosteroid administration  N/A – not taking medication |
| Antibody treatment: | Increased Ab treatment dose amount and/or frequency  Started on Ab treatment Decreased Ab treatment  dose amount and/or frequency Stopped all Ab treatment Changed to another Ab  treatment  No change to Ab treatment N/A – not taking medication |

Site: Participant ID:

Transplant Number:

Tx 1 Tx 2 Tx 3 Tx 4

Visit Number: Visit 003 (Year 1) Visit 004 (Year 2) Visit 005 (Year 3)

Visit 006 (Year 4) Visit 007 (Year 5) Visit 008 (Year 6)

Visit 009 (Year 7) Visit 010 (Year 8) Visit 011 (Year 9)

Visit 012 (Year 10) (Other)

Liver Biopsy #2

Immunoglobulin:

 Increased immunoglobulin amount and/or frequency

 Started on immunoglobulin  Decreased immunoglobulin amount and/or frequency

 Stopped all immunoglobulin  No change to immunoglobulin

 N/A – not taking medication

Date of biopsy: / / (mm/dd/yyyy) Reason for biopsy:  Per protocol

 For cause

Record ALT/ SGPT and GGT results closest prior to biopsy:

ALT: U/L ALT result date: / / (mm/dd/yyyy) GGT: U/L GGT result date: / / (mm/dd/yyyy)

Was rejection confirmed:  No/indeterminate

 Yes, acute  Yes, chronic

Was immunosuppressive therapy modified in response to the biopsy:

If yes, specify modifications: Calcineurin inhibitor

(CNI):

 No  Yes

 Increased CNI dose amount and/or frequency

 Started on CNI medication  Decreased CNI dose amount and/or frequency

 Stopped all CNI medications

 Changed to a different CNI medication

 No change to CNI administration

 N/A – not taking medication

Site: Participant ID:

Transplant Number:

Tx 1 Tx 2 Tx 3 Tx 4

Visit Number: Visit 003 (Year 1) Visit 004 (Year 2) Visit 005 (Year 3)

Visit 006 (Year 4) Visit 007 (Year 5) Visit 008 (Year 6)

Visit 009 (Year 7) Visit 010 (Year 8) Visit 011 (Year 9)

Visit 012 (Year 10) (Other)

|  |  |
| --- | --- |
| Mammalian target of rapamycin (mTOR) inhibitor: | Increased mTOR inhibitor dose amount and/or frequency  Started on mTOR inhibitor Decreased mTOR inhibitor  dose amount and/or frequency Stopped all mTOR inhibitors Changed to another mTOR No change to mTOR  inhibitor administration  N/A – not taking medication |
| Antimetabolite: | Increased antimetabolite dose amount and/or frequency  Started on antimetabolites Decreased antimetabolite  dose amount and/or frequency Stopped all antimetabolites Changed to another  antimetabolite No change to  antimetabolite administration N/A – not taking medication |
| Corticosteroids: | Increased corticosteroids dose amount and/or frequency  Started on corticosteroids Decreased corticosteroid  dose amount and/or frequency Stopped all corticosteroids Changed to another  corticosteroid  No change to corticosteroid administration  N/A – not taking medication |
| Antibody treatment: | Increased Ab treatment dose amount and/or frequency  Started on Ab treatment Decreased Ab treatment  dose amount and/or frequency |

Site: Participant ID:

Transplant Number:

Tx 1 Tx 2 Tx 3 Tx 4

Visit Number: Visit 003 (Year 1) Visit 004 (Year 2) Visit 005 (Year 3)

Visit 006 (Year 4) Visit 007 (Year 5) Visit 008 (Year 6)

Visit 009 (Year 7) Visit 010 (Year 8) Visit 011 (Year 9)

Visit 012 (Year 10) (Other)

|  |  |  |
| --- | --- | --- |
|  |  | Stopped all Ab treatment Changed to another Ab  treatment  No change to Ab treatment N/A – not taking medication |
|  | Immunoglobulin: | Increased immunoglobulin amount and/or frequency  Started on immunoglobulin Decreased immunoglobulin  amount and/or frequency Stopped all immunoglobulin No change to  immunoglobulin  N/A – not taking medication |
| Liver Biopsy #3 |  |  |
| Date of biopsy: | / / | (mm/dd/yyyy) |
| Reason for biopsy:: |  | Per protocol For cause |
| Record ALT/ SGPT and GGT results closest prior to biopsy: | | |
| ALT: U/L ALT result date: / / | | (mm/dd/yyyy) |
| GGT: U/L GGT result date / / | | (mm/dd/yyyy) |
| Was rejection confirmed: | No/indeterminate |  |
|  | Yes, acute |  |
|  | Yes, chronic |  |
| Was immunosuppressive therapy modified in response to the biopsy: | | No Yes |
| If yes, specify modifications: | Calcineurin inhibitor (CNI): | Increased CNI dose amount and/or frequency  Started on CNI medication |

Site: Participant ID:

Transplant Number:

Tx 1 Tx 2 Tx 3 Tx 4

Visit Number: Visit 003 (Year 1) Visit 004 (Year 2) Visit 005 (Year 3)

Visit 006 (Year 4) Visit 007 (Year 5) Visit 008 (Year 6)

Visit 009 (Year 7) Visit 010 (Year 8) Visit 011 (Year 9)

Visit 012 (Year 10) (Other)

|  |  |
| --- | --- |
|  | Decreased CNI dose amount and/or frequency  Stopped all CNI medications  Changed to a different CNI medication  No change to CNI administration  N/A – not taking medication |
| Mammalian target of rapamycin (mTOR) inhibitor: | Increased mTOR inhibitor dose amount and/or frequency  Started on mTOR inhibitor Decreased mTOR inhibitor  dose amount and/or frequency Stopped all mTOR inhibitors Changed to another mTOR No change to mTOR  inhibitor administration  N/A – not taking medication |
| Antimetabolite: | Increased antimetabolite dose amount and/or frequency  Started on antimetabolites Decreased antimetabolite  dose amount and/or frequency Stopped all antimetabolites Changed to another  antimetabolite No change to  antimetabolite administration N/A – not taking medication |
| Corticosteroids: | Increased corticosteroids dose amount and/or frequency  Started on corticosteroids Decreased corticosteroid  dose amount and/or frequency Stopped all corticosteroids |

Site: Participant ID:

Transplant Number:

Tx 1 Tx 2 Tx 3 Tx 4

Visit Number: Visit 003 (Year 1) Visit 004 (Year 2) Visit 005 (Year 3)

Visit 006 (Year 4) Visit 007 (Year 5) Visit 008 (Year 6)

Visit 009 (Year 7) Visit 010 (Year 8) Visit 011 (Year 9)

Visit 012 (Year 10) (Other)

|  |  |  |
| --- | --- | --- |
|  |  | Changed to another corticosteroid  No change to corticosteroid administration  N/A – not taking medication |
|  | Antibody treatment: | Increased Ab treatment dose amount and/or frequency  Started on Ab treatment Decreased Ab treatment  dose amount and/or frequency Stopped all Ab treatment Changed to another Ab  treatment  No change to Ab treatment N/A – not taking medication |
|  | Immunoglobulin: | Increased immunoglobulin amount and/or frequency  Started on immunoglobulin Decreased immunoglobulin  amount and/or frequency Stopped all immunoglobulin No change to  immunoglobulin  N/A – not taking medication |
| Liver Biopsy #4 |  |  |
| Date of biopsy: | / / | (mm/dd/yyyy) |
| Reason for biopsy: |  | Per protocol For cause |
| Record ALT/ SGPT and GGT results closest prior to biopsy: | | |
| ALT: U/L ALT result date: / / | | (mm/dd/yyyy) |
| GGT: U/L GGT result date: / / | | (mm/dd/yyyy) |
| Was rejection confirmed: | No/indeterminate |  |

Site: Participant ID:

Transplant Number:

Tx 1 Tx 2 Tx 3 Tx 4

Visit Number: Visit 003 (Year 1) Visit 004 (Year 2) Visit 005 (Year 3)

Visit 006 (Year 4) Visit 007 (Year 5) Visit 008 (Year 6)

Visit 009 (Year 7) Visit 010 (Year 8) Visit 011 (Year 9)

Visit 012 (Year 10) (Other)

|  |  |  |
| --- | --- | --- |
|  | Yes, acute |  |
|  | Yes, chronic |  |
| Was immunosuppressive therapy modified in response to the biopsy: | | No Yes |
| If yes, specify modifications: | Calcineurin inhibitor (CNI): | Increased CNI dose amount and/or frequency  Started on CNI medication Decreased CNI dose  amount and/or frequency Stopped all CNI  medications  Changed to a different CNI medication  No change to CNI administration  N/A – not taking medication |
|  | Mammalian target of rapamycin (mTOR) inhibitor: | Increased mTOR inhibitor dose amount and/or frequency  Started on mTOR inhibitor Decreased mTOR inhibitor  dose amount and/or frequency Stopped all mTOR inhibitors Changed to another mTOR No change to mTOR  inhibitor administration  N/A – not taking medication |
|  | Antimetabolite: | Increased antimetabolite dose amount and/or frequency  Started on antimetabolites Decreased antimetabolite  dose amount and/or frequency Stopped all antimetabolites Changed to another  antimetabolite |

Site: Participant ID:

Transplant Number:

Tx 1 Tx 2 Tx 3 Tx 4

Visit Number: Visit 003 (Year 1) Visit 004 (Year 2) Visit 005 (Year 3)

Visit 006 (Year 4) Visit 007 (Year 5) Visit 008 (Year 6)

Visit 009 (Year 7) Visit 010 (Year 8) Visit 011 (Year 9)

Visit 012 (Year 10) (Other)

|  |  |
| --- | --- |
|  | No change to antimetabolite administration  N/A – not taking medication |
| Corticosteroids: | Increased corticosteroids dose amount and/or frequency  Started on corticosteroids Decreased corticosteroid  dose amount and/or frequency Stopped all corticosteroids Changed to another  corticosteroid  No change to corticosteroid administration  N/A – not taking medication |
| Antibody treatment: | Increased Ab treatment dose amount and/or frequency  Started on Ab treatment Decreased Ab treatment  dose amount and/or frequency Stopped all Ab treatment Changed to another Ab  treatment  No change to Ab treatment N/A – not taking medication |
| Immunoglobulin: | Increased immunoglobulin amount and/or frequency  Started on immunoglobulin Decreased immunoglobulin  amount and/or frequency Stopped all immunoglobulin No change to  immunoglobulin  N/A – not taking medication |

Site: Participant ID:

Transplant Number:

Tx 1 Tx 2 Tx 3 Tx 4

Visit Number: Visit 003 (Year 1) Visit 004 (Year 2) Visit 005 (Year 3)

Visit 006 (Year 4) Visit 007 (Year 5) Visit 008 (Year 6)

Visit 009 (Year 7) Visit 010 (Year 8) Visit 011 (Year 9)

Visit 012 (Year 10) (Other)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 6. Was the participant treated for antibody mediated rejection since the last visit: | | | No | Yes |  |
| 7. Did the participant have any vascular complications since the last visit: | | | No | Yes |  |
| If yes, specify: |  |  |  | | |
| *Diagnosis of vessel thrombosis requires imaging evidence of vessel occlusion (angiography, Doppler U/S, CT or MR angiography, or operative finding) in the vessel in question. No biochemical or clinical requirements for diagnosis.*  *Diagnosis of vessel stenosis requires imaging evidence of partial narrowing/occlusion of blood flow (angiography, CT or MR angiography, or operative finding) in question. No biochemical or clinical requirements for diagnosis.*  *Observation should only be recorded as the treatment for a vascular complication if all other treatment options (i.e. anticoagulation, reoperation, and interventional radiology are “No”.* | | | | | |
| Portal vein thrombosis:  If Yes, specify date of diagnosis:  / / | No Yes | Treatment: Anticoagulation Reoperation Interventional radiology Observation |  | No No No No | Yes Yes Yes Yes |
| Hepatic vein thrombosis:  If Yes, specify date of diagnosis:  / / | No Yes | Treatment: Anticoagulation Reoperation Interventional radiology  Observation |  | No No No  No | Yes Yes Yes  Yes |

|  |  |  |  |
| --- | --- | --- | --- |
| Hepatic artery thrombosis:  If Yes, specify date of diagnosis:  / / | No Yes | Treatment: Anticoagulation Reoperation Interventional radiology Observation | No Yes  No Yes  No Yes  No Yes |
| Portal vein stenosis:  If Yes, specify date of diagnosis:  / / | No Yes | Treatment: Anticoagulation Reoperation Interventional radiology  Observation | No Yes  No Yes  No Yes  No Yes |

Site: Participant ID:

Transplant Number:

Tx 1 Tx 2 Tx 3 Tx 4

Visit Number: Visit 003 (Year 1) Visit 004 (Year 2) Visit 005 (Year 3)

Visit 006 (Year 4) Visit 007 (Year 5) Visit 008 (Year 6)

Visit 009 (Year 7) Visit 010 (Year 8) Visit 011 (Year 9)

Visit 012 (Year 10) (Other)

1. Did the p

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Outflow obstruction (hepatic vein  stenosis, vena cava stenosis): | No  Yes | Treatment:  Anticoagulation | No | Yes |
| If Yes, specify date of diagnosis: |  | Reoperation Interventional radiology | No No | Yes Yes |
| / / |  | Observation | No | Yes |
| Hepatic artery stenosis:  If Yes, specify date of diagnosis | No Yes | Treatment:  Anticoagulation Reoperation | No  No No | Yes  Yes Yes |
| (mm/dd/yyyy): Interventional radiology No Yes  / / Observation  articipant have any biliary complications since the last visit: No Yes | | | | |

* 1. Did the participant have a biliary leak (from cut surface or biliary tree) since the last visit:

No  Yes

*Intrahepatic or extrahepatic fluid collection detected by imaging study (ultrasound, CT, MRI) and direct continuity of the fluid collection to the biliary tract confirmed by scintography, cholangiography.*

If yes, specify date of diagnosis: / / (mm/dd/yyyy)

* 1. Did the participant have a biloma since the last visit:  No  Yes *Extrahepatic fluid collection detected by imaging study (ultrasound, CT, MRI) which requires placement of an indwelling percutaneous drain for treatment.*

If yes, specify date of diagnosis: / / (mm/dd/yyyy)

* 1. Did the participant have an non-anastomotic biliary stricture since the last visit:

No  Yes

*Stricture which is not at the anastomotic site and typically multiple, longer in length and located in intrahepatic ducts and/or in the donor duct proximal to site of anastomosis.*

If yes, specify date of diagnosis: / / (mm/dd/yyyy)

Site: Participant ID:

Transplant Number:

Tx 1 Tx 2 Tx 3 Tx 4

Visit Number: Visit 003 (Year 1) Visit 004 (Year 2) Visit 005 (Year 3)

Visit 006 (Year 4) Visit 007 (Year 5) Visit 008 (Year 6)

Visit 009 (Year 7) Visit 010 (Year 8) Visit 011 (Year 9)

Visit 012 (Year 10) (Other)

|  |  |  |  |
| --- | --- | --- | --- |
| d. Did the participant have an anastomotic biliary stricture since | No | Yes |  |
| *Diagnosis requires cholangiographic (ERCP, MR, PTC) evidence of biliary duct stricture. No biochemical requirements for diagnosis.* | | | |
| If yes, specify date of diagnosis: / / | (mm/dd/yyyy) | | |
| 9. Did the participant have a esophageal variceal bleeding requiring endoscopic or surgical intervention since the last visit: |  | No | Yes |
| *Gastrointestinal hemorrhage: Hematemesis, hematochezia or melena, causing a drop in hematocrit of >5% with either documentation of actively bleeding esophageal varices by esophagoscopy OR identification of esophageal varices and no other identifiable cause of hemorrhage.* | | | |
| If yes, specify date of diagnosis: / / | (mm/dd/yyyy) | | |
| 10. Did the participant receive an operative shunt since the last visit: |  | No | Yes |
| If yes, specify date of event: / / | (mm/dd/yyyy) | | |

|  |  |  |
| --- | --- | --- |
| 1. Was the participant diagnosed with cancer since the last visit:    1. Post-transplant lymphoproliferative disorder (PTLD): | | No Yes |
| No Yes |
| If yes, specify: |  |  |
| i. Type of PTLD: |  | Non-central nervous system (CNS) (biopsy proven)  CNS (either biopsy proven or not) |
| ii. Date of diagnosis: | / / | (mm/dd/yyyy) |
| iii. Was the participant PCR positive for Epstein-Barr Virus (EBV) at the time of the diagnosis of PTLD: | | No  Yes, blood only Yes, tissue only  Yes, both blood and tissue |

Site: Participant ID:

Transplant Number:

Tx 1 Tx 2 Tx 3 Tx 4

Visit Number: Visit 003 (Year 1) Visit 004 (Year 2) Visit 005 (Year 3)

Visit 006 (Year 4) Visit 007 (Year 5) Visit 008 (Year 6)

Visit 009 (Year 7) Visit 010 (Year 8) Visit 011 (Year 9)

Visit 012 (Year 10) (Other)

|  |  |  |  |
| --- | --- | --- | --- |
| iiii. Treatment for PTLD: | Decrease immunosuppression: |  | No Yes |
|  | Resection: |  | No Yes |
|  | Anti-virals: |  | No Yes |
|  | Anti-B cell antibody: |  | No Yes |
|  | Chemotherapy: |  | No Yes |

1. Skin Cancer:  No  Yes

If yes, specify:

* 1. Melanoma:  No  Yes

Date of diagnosis: / / (mm/dd/yyyy)

* 1. Basal Cell Carcinoma:  No  Yes

Date of diagnosis: / / (mm/dd/yyyy)

* 1. Squamous Cell Carcinoma:  No  Yes Date of diagnosis: / / (mm/dd/yyyy)
  2. Other:  No  Yes

Date of diagnosis: / / (mm/dd/yyyy)

1. Hepatocellular carcinoma:  No  Yes, de novo  Yes, recurrent disease

Date of diagnosis: / / (mm/dd/yyyy)

1. Hepatoblastoma:  No  Yes, de novo

 Yes, recurrent disease Date of diagnosis: / / (mm/dd/yyyy)

1. Other:  No  Yes, de novo  Yes, recurrent disease

Date of diagnosis: / / (mm/dd/yyyy)

*Record results of the height, weight, and blood pressure measurements closest to the time of the assessment date. If height, weight, or blood pressure was not measured within +/-90 days of the assessment date, indicate that the assessment was not done.*

12. Height (+90 days of assessment date):  Not Done

Site: Participant ID:

Transplant Number:

Tx 1 Tx 2 Tx 3 Tx 4

Visit Number: Visit 003 (Year 1) Visit 004 (Year 2) Visit 005 (Year 3)

Visit 006 (Year 4) Visit 007 (Year 5) Visit 008 (Year 6)

Visit 009 (Year 7) Visit 010 (Year 8) Visit 011 (Year 9)

Visit 012 (Year 10) (Other)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Date: | / / | | (mm/dd/yyyy) | |
| Value: |  | inches cm | |  |
| 13. Weight (+90 days of assessment date): | Not Done |  |  |  |
| Date: | / / | | (mm/dd/yyyy) | |
| Value: |  | lbs kg |  |  |
| 14. Blood pressure (+90 days of assessment date): | Not Done |  |  |  |
|  | / / | | (mm/dd/yyyy) | |
|  | Systolic |  | Diastolic |  |
|  |  | mmHg |  | mmHg |
|  | Method: | Manual Dinamap Unknown | | |
| Chemistries and Hematology  *Record results of the lab results closest to the time of the anniversary date of the transplant. If lab results were not collected within +/-90 days of the assessment date, indicate that the assessment was not done.* | | | | |
| 15. Date the majority of labs drawn (+90 days of assessment date): | / / | | (mm/dd/yyyy) | |
| Total bilirubin: |  | mg/dL |  |  |
| Direct bilirubin: |  | mg/dL |  |  |
| Conjugated bilirubin: |  | mg/dL |  |  |
| AST/SGOT: |  | U/L |  |  |
| ALT/SGPT: |  | U/L |  |  |
| Albumin: |  | g/dL |  |  |
| Alkaline phosphatase: |  | U/L |  |  |
| GGT: |  | U/L |  |  |
| Serum creatinine: |  | mg/dL |  |  |
| Total cholesterol: |  | mg/dL | Fasting >8hrs: No Yes  Not recorded | |
| Low-density lipoprotein (LDL) cholesterol: |  | mg/dL | Fasting >8hrs: No Yes  Not recorded | |
| High-density lipoprotein (HDL) cholesterol: |  | mg/dL | Fasting >8hrs: No Yes | |

Site: Participant ID:

Transplant Number:

Tx 1 Tx 2 Tx 3 Tx 4

Visit Number: Visit 003 (Year 1) Visit 004 (Year 2) Visit 005 (Year 3)

Visit 006 (Year 4) Visit 007 (Year 5) Visit 008 (Year 6)

Visit 009 (Year 7) Visit 010 (Year 8) Visit 011 (Year 9)

Visit 012 (Year 10) (Other)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  | Not recorded |
| Triglycerides: |  |  | mg/dL | Fasting >8hrs: No Yes  Not recorded |
| Glucose: |  |  | mg/dL | Fasting >8hrs: No Yes  Not recorded |
| Platelet count: |  |  | 103 cells/uL |  |
| HbA1c: |  |  |  |  |
| International normalized ratio (INR): | |  |  |  |
| 16. mGFR (+90 days of assessment date): | | Not Done |  |  |
| Date: |  | / / | | (mm/dd/yyyy) |
| Method: |  | Cr-EDTA |  |  |
| I-Iothalamate | | | | |
|  |  | Tc-DPTA |  |  |
| Value: |  |  | mL/min |  |
| 17. Cystatin C (+90 days of assessment date): | | Not Done |  |  |
| Date: |  | / / | | (mm/dd/yyyy) |
| Value: |  |  | mg/L |  |
| 18. eGFR (+90 days of assessment date): | | Not Done |  |  |
| Date: |  | / / | | (mm/dd/yyyy) |
| Value: |  |  | mL/min/1.73m2 | |
| Formula used: |  | Schwartz |  |  |
| Cockroft-Gault | | | | |
|  |  | MDRD |  |  |
|  |  | CKD-EPI |  |  |
| Mayo Quadratic | | | | |
| Immunosuppression |  |  |  |  |
| 19. Is the participant currently on immunosuppression: | | | No Yes |  |
| Tacrolimus: | No Yes | Frequency: | QD (24 hours) BID (12 hours)  TID (8 hours) QID (6 hours) QOD (48 hours) Other | |

Site: Participant ID:

Transplant Number:

Tx 1 Tx 2 Tx 3 Tx 4

Visit Number: Visit 003 (Year 1) Visit 004 (Year 2) Visit 005 (Year 3)

Visit 006 (Year 4) Visit 007 (Year 5) Visit 008 (Year 6)

Visit 009 (Year 7) Visit 010 (Year 8) Visit 011 (Year 9)

Visit 012 (Year 10) (Other)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Cyclosporine: | No | Yes | Frequency: | QD (24 hours)  TID (8 hours)  QOD (48 hours) | BID (12 hours)  QID (6 hours) Other |
| Mycophenolate mofetil/ Mycophenolic acid (MMF/MPA): | No | Yes |  |  | |
| Azathioprine: | No | Yes |  |  | |
| Sirolimus: | No | Yes |  |  | |
| Corticosteroids: | No | Yes |  |  | |
| Everolimus: | No | Yes |  |  | |

|  |  |  |
| --- | --- | --- |
| 20. Is the participant currently taking concomitant medications of the types listed below: | | No Yes |
| Anti-hypertensives: | No Yes |  |
| Statins: | No Yes |  |
| Oral Hypoglycemics: | No Yes |  |
| Insulin: | No Yes |  |
| Anti-microbials: | No Yes |  |
| Anti-virals: | No Yes |  |
| Anti-depressants: | No Yes |  |

Site: Participant ID:

Transplant Number:

Tx 1 Tx 2 Tx 3 Tx 4

Visit Number: Visit 003 (Year 1) Visit 004 (Year 2) Visit 005 (Year 3)

Visit 006 (Year 4) Visit 007 (Year 5) Visit 008 (Year 6)

Visit 009 (Year 7) Visit 010 (Year 8) Visit 011 (Year 9)

Visit 012 (Year 10) (Other)

|  |  |  |
| --- | --- | --- |
| 21. Total days participant was hospitalized (inpatient) since the last visit  (at any institution including the day of admission and discharge): |  | Days |

Site: Participant ID:

Transplant Number:

Tx 1 Tx 2 Tx 3 Tx 4

Visit Number: Visit 003 (Year 1) Visit 004 (Year 2) Visit 005 (Year 3)

Visit 006 (Year 4) Visit 007 (Year 5) Visit 008 (Year 6)

Visit 009 (Year 7) Visit 010 (Year 8) Visit 011 (Year 9)

Visit 012 (Year 10) (Other)

*If more than four biopsies were performed, data for 5th-8th biopsies may be recorded below*.

Liver Biopsy #5

Date of biopsy: / / (mm/dd/yyyy) Reason for biopsy:  Per protocol

 For cause

Record ALT/SGPT and GGT results closest prior to biopsy:

ALT: U/L ALT result date: / / (mm/dd/yyyy) GGT: U/L GGT result date: / / (mm/dd/yyyy)

Was rejection confirmed:  No/indeterminate

 Yes, acute  Yes, chronic

Was immunosuppressive therapy modified in response to the biopsy:

If yes, specify modifications: Calcineurin inhibitor

(CNI):

Mammalian target of rapamycin (mTOR) inhibitor:

 No  Yes

 Increased CNI dose amount and/or frequency

 Started on CNI medication  Decreased CNI dose amount and/or frequency

 Stopped all CNI medications

 Changed to a different CNI medication

 No change to CNI administration

 N/A – not taking medication  Increased mTOR inhibitor dose amount and/or frequency  Started on mTOR inhibitor  Decreased mTOR inhibitor dose amount and/or frequency Stopped all mTOR inhibitors  Changed to another mTOR

Site: Participant ID:

Transplant Number:

Tx 1 Tx 2 Tx 3 Tx 4

Visit Number: Visit 003 (Year 1) Visit 004 (Year 2) Visit 005 (Year 3)

Visit 006 (Year 4) Visit 007 (Year 5) Visit 008 (Year 6)

Visit 009 (Year 7) Visit 010 (Year 8) Visit 011 (Year 9)

Visit 012 (Year 10) (Other)

|  |  |
| --- | --- |
|  | No change to mTOR inhibitor administration  N/A – not taking medication |
| Antimetabolite: | Increased antimetabolite dose amount and/or frequency  Started on antimetabolites Decreased antimetabolite  dose amount and/or frequency Stopped all antimetabolites Changed to another  antimetabolite No change to  antimetabolite administration N/A – not taking medication |
| Corticosteroids: | Increased corticosteroids dose amount and/or frequency  Started on corticosteroids Decreased corticosteroid  dose amount and/or frequency Stopped all corticosteroids Changed to another  corticosteroid  No change to corticosteroid administration  N/A – not taking medication |
| Antibody treatment: | Increased Ab treatment dose amount and/or frequency  Started on Ab treatment Decreased Ab treatment  dose amount and/or frequency Stopped all Ab treatment Changed to another Ab  treatment  No change to Ab treatment N/A – not taking medication |
| Immunoglobulin: | Increased immunoglobulin amount and/or frequency |

Site: Participant ID:

Transplant Number:

Tx 1 Tx 2 Tx 3 Tx 4

Visit Number: Visit 003 (Year 1) Visit 004 (Year 2) Visit 005 (Year 3)

Visit 006 (Year 4) Visit 007 (Year 5) Visit 008 (Year 6)

Visit 009 (Year 7) Visit 010 (Year 8) Visit 011 (Year 9)

Visit 012 (Year 10) (Other)

 Started on immunoglobulin  Decreased immunoglobulin amount and/or frequency

 Stopped all immunoglobulin  No change to immunoglobulin

 N/A – not taking medication

Liver Biopsy #6

Date of biopsy: / / (mm/dd/yyyy) Reason for biopsy:  Per protocol

 For cause

Record ALT/ SGPT and GGT results closest prior to biopsy:

ALT: U/L ALT result date: / / (mm/dd/yyyy) GGT: U/L GGT result date: / / (mm/dd/yyyy)

Was rejection confirmed:  No/indeterminate

 Yes, acute  Yes, chronic

Was immunosuppressive therapy modified in response to the biopsy:

If yes, specify modifications: Calcineurin inhibitor

(CNI):

 No  Yes

 Increased CNI dose amount and/or frequency

 Started on CNI medication  Decreased CNI dose amount and/or frequency

 Stopped all CNI medications

 Changed to a different CNI medication

 No change to CNI administration

 N/A – not taking medication

Site: Participant ID:

Transplant Number:

Tx 1 Tx 2 Tx 3 Tx 4

Visit Number: Visit 003 (Year 1) Visit 004 (Year 2) Visit 005 (Year 3)

Visit 006 (Year 4) Visit 007 (Year 5) Visit 008 (Year 6)

Visit 009 (Year 7) Visit 010 (Year 8) Visit 011 (Year 9)

Visit 012 (Year 10) (Other)

|  |  |
| --- | --- |
| Mammalian target of rapamycin (mTOR) inhibitor: | Increased mTOR inhibitor dose amount and/or frequency  Started on mTOR inhibitor Decreased mTOR inhibitor  dose amount and/or frequency Stopped all mTOR inhibitors Changed to another mTOR No change to mTOR  inhibitor administration  N/A – not taking medication |
| Antimetabolite: | Increased antimetabolite dose amount and/or frequency  Started on antimetabolites Decreased antimetabolite  dose amount and/or frequency Stopped all antimetabolites Changed to another  antimetabolite No change to  antimetabolite administration N/A – not taking medication |
| Corticosteroids: | Increased corticosteroids dose amount and/or frequency  Started on corticosteroids Decreased corticosteroid  dose amount and/or frequency Stopped all corticosteroids Changed to another  corticosteroid  No change to corticosteroid administration  N/A – not taking medication |
| Antibody treatment: | Increased Ab treatment dose amount and/or frequency  Started on Ab treatment Decreased Ab treatment  dose amount and/or frequency |

Site: Participant ID:

Transplant Number:

Tx 1 Tx 2 Tx 3 Tx 4

Visit Number: Visit 003 (Year 1) Visit 004 (Year 2) Visit 005 (Year 3)

Visit 006 (Year 4) Visit 007 (Year 5) Visit 008 (Year 6)

Visit 009 (Year 7) Visit 010 (Year 8) Visit 011 (Year 9)

Visit 012 (Year 10) (Other)

|  |  |
| --- | --- |
|  | Stopped all Ab treatment Changed to another Ab  treatment  No change to Ab treatment N/A – not taking medication |
| Immunoglobulin: | Increased immunoglobulin amount and/or frequency  Started on immunoglobulin Decreased immunoglobulin  amount and/or frequency Stopped all immunoglobulin No change to  immunoglobulin  N/A – not taking medication |

Liver Biopsy #7

Date of biopsy: / / (mm/dd/yyyy) Reason for biopsy::  Per protocol

 For cause

Record ALT/ SGPT and GGT results closest prior to biopsy:

ALT: U/L ALT result date: / / (mm/dd/yyyy) GGT: U/L GGT result date: / / (mm/dd/yyyy)

Was rejection confirmed:  No/indeterminate

 Yes, acute  Yes, chronic

Was immunosuppressive therapy modified in response to the biopsy:

No  Yes

If yes, specify modifications:

Calcineurin inhibitor (CNI):

 Increased CNI dose amount and/or frequency

 Started on CNI medication

Site: Participant ID:

Transplant Number:

Tx 1 Tx 2 Tx 3 Tx 4

Visit Number: Visit 003 (Year 1) Visit 004 (Year 2) Visit 005 (Year 3)

Visit 006 (Year 4) Visit 007 (Year 5) Visit 008 (Year 6)

Visit 009 (Year 7) Visit 010 (Year 8) Visit 011 (Year 9)

Visit 012 (Year 10) (Other)

|  |  |
| --- | --- |
|  | Decreased CNI dose amount and/or frequency  Stopped all CNI medications  Changed to a different CNI medication  No change to CNI administration  N/A – not taking medication |
| Mammalian target of rapamycin (mTOR) inhibitor: | Increased mTOR inhibitor dose amount and/or frequency  Started on mTOR inhibitor Decreased mTOR inhibitor  dose amount and/or frequency Stopped all mTOR inhibitors Changed to another mTOR No change to mTOR  inhibitor administration  N/A – not taking medication |
| Antimetabolite: | Increased antimetabolite dose amount and/or frequency  Started on antimetabolites Decreased antimetabolite  dose amount and/or frequency Stopped all antimetabolites Changed to another  antimetabolite No change to  antimetabolite administration N/A – not taking medication |
| Corticosteroids: | Increased corticosteroids dose amount and/or frequency  Started on corticosteroids Decreased corticosteroid  dose amount and/or frequency Stopped all corticosteroids |

Site: Participant ID:

Transplant Number:

Tx 1 Tx 2 Tx 3 Tx 4

Visit Number: Visit 003 (Year 1) Visit 004 (Year 2) Visit 005 (Year 3)

Visit 006 (Year 4) Visit 007 (Year 5) Visit 008 (Year 6)

Visit 009 (Year 7) Visit 010 (Year 8) Visit 011 (Year 9)

Visit 012 (Year 10) (Other)

Antibody treatment:

Immunoglobulin:

 Changed to another corticosteroid

 No change to corticosteroid administration

 N/A – not taking medication  Increased Ab treatment dose amount and/or frequency  Started on Ab treatment

 Decreased Ab treatment dose amount and/or frequency  Stopped all Ab treatment  Changed to another Ab treatment

 No change to Ab treatment  N/A – not taking medication  Increased immunoglobulin amount and/or frequency

 Started on immunoglobulin  Decreased immunoglobulin amount and/or frequency

 Stopped all immunoglobulin  No change to immunoglobulin

 N/A – not taking medication

Liver Biopsy #8

Date of biopsy: / / (mm/dd/yyyy) Reason for biopsy:  Per protocol

 For cause

Record ALT/ SGPT and GGT results closest prior to biopsy:

ALT: U/L ALT result date: / / (mm/dd/yyyy) GGT: U/L GGT result date: / / (mm/dd/yyyy)

Was rejection confirmed:  No/indeterminate

Site: Participant ID:

Transplant Number:

Tx 1 Tx 2 Tx 3 Tx 4

Visit Number: Visit 003 (Year 1) Visit 004 (Year 2) Visit 005 (Year 3)

Visit 006 (Year 4) Visit 007 (Year 5) Visit 008 (Year 6)

Visit 009 (Year 7) Visit 010 (Year 8) Visit 011 (Year 9)

Visit 012 (Year 10) (Other)

|  |  |  |
| --- | --- | --- |
|  | Yes, acute |  |
|  | Yes, chronic |  |
| Was immunosuppressive therapy modified in response to the biopsy: | | No Yes |
| If yes, specify modifications: | Calcineurin inhibitor (CNI): | Increased CNI dose amount and/or frequency  Started on CNI medication Decreased CNI dose  amount and/or frequency Stopped all CNI  medications  Changed to a different CNI medication  No change to CNI administration  N/A – not taking medication |
|  | Mammalian target of rapamycin (mTOR) inhibitor: | Increased mTOR inhibitor dose amount and/or frequency  Started on mTOR inhibitor Decreased mTOR inhibitor  dose amount and/or frequency Stopped all mTOR inhibitors Changed to another mTOR No change to mTOR  inhibitor administration  N/A – not taking medication |
|  | Antimetabolite: | Increased antimetabolite dose amount and/or frequency  Started on antimetabolites Decreased antimetabolite  dose amount and/or frequency Stopped all antimetabolites Changed to another  antimetabolite |

Site: Participant ID:

Transplant Number:

Tx 1 Tx 2 Tx 3 Tx 4

Visit Number: Visit 003 (Year 1) Visit 004 (Year 2) Visit 005 (Year 3)

Visit 006 (Year 4) Visit 007 (Year 5) Visit 008 (Year 6)

Visit 009 (Year 7) Visit 010 (Year 8) Visit 011 (Year 9)

Visit 012 (Year 10) (Other)

|  |  |
| --- | --- |
|  | No change to antimetabolite administration  N/A – not taking medication |
| Corticosteroids: | Increased corticosteroids dose amount and/or frequency  Started on corticosteroids Decreased corticosteroid  dose amount and/or frequency Stopped all corticosteroids Changed to another  corticosteroid  No change to corticosteroid administration  N/A – not taking medication |
| Antibody treatment: | Increased Ab treatment dose amount and/or frequency  Started on Ab treatment Decreased Ab treatment  dose amount and/or frequency Stopped all Ab treatment Changed to another Ab  treatment  No change to Ab treatment N/A – not taking medication |
| Immunoglobulin: | Increased immunoglobulin amount and/or frequency  Started on immunoglobulin Decreased immunoglobulin  amount and/or frequency Stopped all immunoglobulin No change to  immunoglobulin  N/A – not taking medication |

**Studies of Pediatric Liver Transplantation**

# Previous Transplant

Site: Participant ID: Sequence Number: 01 02 03 04

|  |  |
| --- | --- |
| Date of transplant: | / / (mm/dd/yyyy) |
| Type of transplant: | Liver-only  Combined liver-kidney Combined liver-pancreas |
| Primary cause for graft failure: | Primary graft dysfunction |
|  | Hyperacute rejection |
|  | Chronic rejection |
|  | Post-operative hemorrhage |
|  | Biliary tract complications |
|  | De Novo Hepatitis |
|  | Recurrent Primary Liver disease |
|  | Hepatic Artery Thrombosis |
|  | Portal Vein Thrombosis |
|  | Other, specify: |
| Donor type: | Deceased–Brain Death |
|  | Deceased– Donation after Cardiac Death (DCD) |
|  | Living |
|  | Unknown |
| Procedure type: | Whole liver |
|  | Partial liver, remainder not transplanted or living transplant |
|  | Split liver |
|  | Unknown |
| Partial type: | Right lobe without middle hepatic vein (segments 5,6,7,8) |
|  | Right lobe with middle hepatic vein (segments 4,5,6,7,8) |
|  | Left lobe (segments 2,3,4) |
|  | Left lateral (segments 2,3) |
|  | Unknown |
| Split type: | Right lobe without middle hepatic vein in situ/ex situ (segments 5,6,7,8) |
|  | Right lobe with middle hepatic vein in situ /ex situ (segments 4,5,6,7,8) |
|  | Left lobe in situ /ex situ (segment 2,3,4) |
|  | Left lateral segment in situ /ex situ (segments 2,3) |
|  | Unknown |

Comments:

**Studies of Pediatric Liver Transplantation**

# Reconsent

Site: Participant ID:

To be completed if a participant is transferred from one SPLIT center to another and is reconsented at the center to which the participant was transferred, or is reconsented as a legal adult while enrolled in the SPLIT registry.

|  |  |  |
| --- | --- | --- |
| Date informed consent signed: | / / | (mm/dd/yyyy) |
| Date HIPAA Data Authorization signed: | / / | (mm/dd/yyyy) N/A |
| *Select “N/A” if HIPAA does not apply (non-US) centers.* | | |
| Date assent signed: | / / | (mm/dd/yyyy) N/A |
| *Select “N/A” if informed assent does not apply due to the participant’s age.* | | |
| Reason for reconsent: | Transfer from another SPLIT center  Participant reached age for consent per local policies Other, specify: | |

Version 2.0 1 June 20, 2016

Site: Participant ID:

|  |  |  |  |
| --- | --- | --- | --- |
| 1. Date of death: | / / | | (mm/dd/yyyy) |
| 2. Causes of death: | No Yes | Primary graft non-function | |
|  | No Yes | Chronic rejection | |
|  | No Yes | Recurrent disease | |
|  | No Yes | Hepatic artery thrombosis | |
|  | No Yes | Portal vein thrombosis | |
|  | No Yes | Liver failure | |
|  | No Yes | Graft-versus-host disease (GVHD) | |
|  | No Yes | Renal failure | |
|  | No Yes | Multi-organ failure | |
|  | No Yes | Human immunodeficiency virus (HIV) infection | |
|  | No Yes | Cytomegalovirus (CMV) infection | |
|  | No Yes | Epstein-Barr virus (EBV) infection | |
|  | No Yes | Lymphoproliferative disease | |
|  | No Yes | Hepatitis B infection | |
|  | No Yes | Hepatitis C virus (HCV) infection | |
|  | No Yes | Bacterial infection | |
|  | No Yes | Fungal infection | |
|  | No Yes | Sepsis, not specified | |
|  | No Yes | Malignancy/cancer - primary | |
|  | No Yes | Malignancy/cancer - recurrent | |
|  | No Yes | Malignancy/cancer – de novo | |
|  | No Yes | Other cancer/malignancy | |
|  | No Yes | Primary respiratory failure | |
|  | No Yes | Intrinsic hear disease | |
|  | No Yes | Intra-abdominal hemorrhage | |
|  | No Yes | Bowel perforation | |
|  | No Yes | Ischemic/necrotic bowel | |
|  | No Yes | Pancreatitis | |
|  | No Yes | Cerebral edema | |
|  | No Yes | Intracranial hemorrhage | |
|  | No Yes | Cerebral infarction | |
|  | No Yes | Other central nervous system (CNS) | |
|  | No Yes | Suicide |  |
|  | No Yes | Accident |  |
|  | No Yes | Other, |  |
|  |  | specify: | |

Site: Participant ID:

|  |  |  |
| --- | --- | --- |
| 3. Did the participant die while waiting for a transplant: | | No Yes |
| If yes, specify: |  |  |
| a. Primary cause for graft failure: | Primary graft dysfunction | |
|  | Hyperacute rejection |  |
|  | Chronic rejection |  |
| Post-operative hemorrhage | | |
| Biliary tract complications | | |
|  | De Novo Hepatitis |  |
| Recurrent Primary Liver disease | | |
| Hepatic Artery Thrombosis | | |
| Portal Vein Thrombosis | | |
| Other, specify: | | |
| b. Date of relisting: | / / | (mm/dd/yyyy) |
| 4. Was the participant on dialysis/hemofiltration just prior to death: | | No Yes |
| 5. Was the participant in the intensive care unit (ICU) at time of death: | | No Yes |
| If yes, intubated: |  | No Yes |
| 6. Was this an intraoperative death: |  | No Yes |

Site: Participant ID:

|  |  |  |
| --- | --- | --- |
| 1. Date participant exited the study: | / / | (mm/dd/yyyy) |
| 2. Reason for exit: | Participant moved to a non-participating center  Participant transferred to a participating SPLIT center, has not re-consented | |
|  | Participant transferred to an adult program Participant reached legal age for consent, has not re-  consented | |
|  | Participant no longer followed by liver transplant program, transplant physician, or hepatologist | |
|  | Participant received a bone marrow transplant | |
|  | Participant lost to follow-up\* | |
|  | Participant decision |  |
|  | Guardian decision |  |
|  | Investigator decision |  |
|  | Steering Committee decision to stop the study | |

*\* If a participant is exited as lost to follow-up but eventually returns to be followed by the transplant center, the Exit form should be deleted from the system and missing form exception requests should be submitted for the missed visits.*