Studies of Pediatric Liver Transplantation

Eligibility

Site: _____

Participant ID: _____

•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.

Studies of Pediatric Liver Transplantation

Demographics

Site: _____

Participant ID: _____

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:** ☐ No ☐ Yes
(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)

b. **Asian:** ☐ No ☐ Yes
(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)

c. **Black or African American:** ☐ No ☐ Yes
(A person having origins in any of the black racial groups of Africa)

d. **Native Hawaiian or Pacific Islander:** ☐ No ☐ Yes
(A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands)

e. **White:** ☐ No ☐ Yes
(A person having origins in any of the original peoples of Europe, the Middle East, or North Africa)

f. **Multi-racial, not otherwise specified:** ☐ No ☐ Yes
(Participant is reported as having multiple races but data regarding those specific races are unavailable)

Studies of Pediatric Liver Transplantation

Transplant

Site: _____
Participant ID: _____
Transplant Number: ___ Tx 1 ___ Tx 2 ___ Tx 3 ___ Tx 4
Visit Number: ___ Visit 000

Recipient Information

1. Blood type[Tx1]: ☐ 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

Data elements marked with Tx1 will only be collected for the first transplant
Data elements marked with >Tx1 will only be collected for subsequent transplants

Transplant

Site: _____
Participant ID: _____
Transplant Number: ___ Tx 1 ___ Tx 2 ___ Tx 3 ___ Tx 4
Visit Number: ___ Visit 000

Primary Disease Diagnosis[Tx1] (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

Data elements marked with Tx1 will only be collected for the first transplant
Data elements marked with >Tx1 will only be collected for subsequent transplants

Transplant

Site: _____
Participant ID: _____
Transplant Number: ___ Tx 1 ___ Tx 2 ___ Tx 3 ___ Tx 4
Visit Number: ___ Visit 000

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

Data elements marked with Tx1 will only be collected for the first transplant
Data elements marked with >Tx1 will only be collected for subsequent transplants

Transplant

Site: _____
Participant ID: _____
Transplant Number: ___ Tx 1 ___ Tx 2 ___ Tx 3 ___ Tx 4
Visit Number: ___ Visit 000

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

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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Data elements marked with >Tx1 will only be collected for subsequent transplants

Transplant

Site: _____
Participant ID: _____
Transplant Number: ___ Tx 1 ___ Tx 2 ___ Tx 3 ___ Tx 4
Visit Number: ___ Visit 000

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)

19. United Network for Organ Sharing (UNOS) Status 1a or 1b at transplant: ☐ No ☐ Yes
    (Canadian Status 4 or 4f)
    (Category 1, 2A TSANZ – Australian, New Zealand)

    If Yes, specify:
    Is the participant status 1 by exception: ☐ No ☐ Yes

    If No, specify:
    a. Indicate scoring system used to list with UNOS: ☐ PELD ☐ MELD
    b. Score type used to list with UNOS: ☐ Calculated ☐ Exception
        i. Pediatric End-Stage Liver Disease (PELD) exception score: _____
        ii. 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.

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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Data elements marked with >Tx1 will only be collected for subsequent transplants

Transplant

Site: _____
Participant ID: _____
Transplant Number: ___ Tx 1 ___ Tx 2 ___ Tx 3 ___ Tx 4
Visit Number: ___ Visit 000

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
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

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

Data elements marked with Tx1 will only be collected for the first transplant
Data elements marked with >Tx1 will only be collected for subsequent transplants

Transplant

Site: _____
Participant ID: _____
Transplant Number: ___ Tx 1 ___ Tx 2 ___ Tx 3 ___ Tx 4
Visit Number: ___ Visit 000

35. Donor race:
Select all origins that apply.

☐ Unknown

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

Data elements marked with Tx1 will only be collected for the first transplant
Data elements marked with >Tx1 will only be collected for subsequent transplants

Transplant

Site: _____
Participant ID: _____
Transplant Number: ___ Tx 1 ___ Tx 2 ___ Tx 3 ___ Tx 4
Visit Number: ___ Visit 000

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

48. 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.

a. 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

49. Did the participant receive antibody therapy as induction: ☐ No ☐ Yes

a. If yes, specify type:
- ☐ ALG/ATG/ALS
- ☐ OKT3/Monoclonal
- ☐ IL-2mAb (Zenapax, Simulect, etc)

Data elements marked with Tx1 will only be collected for the first transplant
Data elements marked with >Tx1 will only be collected for subsequent transplants

Transplant

Site: _____
Participant ID: _____
Transplant Number: ___ Tx 1 ___ Tx 2 ___ Tx 3 ___ Tx 4
Visit Number: ___ Visit 000

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:	_____

Data elements marked with Tx1 will only be collected for the first transplant
Data elements marked with >Tx1 will only be collected for subsequent transplants

Studies of Pediatric Liver Transplantation

Early Follow-up

Site: _____

Participant ID: _____

Transplant Number: ___ Tx 1 ___ Tx 2 ___ Tx 3 ___ Tx 4

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 discharge[D30]: ☐ No ☐ Yes

   If yes, specify:

   Type of event: ☐ Death ☐ Retransplant

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

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

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

3. Date of primary extubation post-op[D30]: __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)

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

4. 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.

5. 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.

Data elements marked with D30 will only be collected at Day 30
Data elements marked with D90 will only be collected at Day 90

Early Follow-up

Site: _____
Participant ID: _____
Transplant Number: ___ Tx 1 ___ Tx 2 ___ Tx 3 ___ Tx 4
Visit Number: ___ Visit 001(Day 30) ___ Visit 002 (Day 90)

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

6. Was the participant treated for antibody mediated rejection: ☐ No ☐ Yes

7. 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.

Data elements marked with D30 will only be collected at Day 30
Data elements marked with D90 will only be collected at Day 90

Early Follow-up

Site: _____
Participant ID: _____
Transplant Number: ___ Tx 1 ___ Tx 2 ___ Tx 3 ___ Tx 4
Visit Number: ___ Visit 001(Day 30) ___ Visit 002 (Day 90)

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: ☐ No ☐ Yes
If yes, specify date of diagnosis:
__ __ / __ __ / __ __ __ __

Treatment:
Anticoagulation ☐ No ☐ Yes
Reoperation ☐ No ☐ Yes
Interventional radiology ☐ No ☐ Yes
Observation ☐ No ☐ Yes

Hepatic vein thrombosis: ☐ No ☐ Yes
If yes, specify date of diagnosis:
__ __ / __ __ / __ __ __ __

Treatment:
Anticoagulation ☐ No ☐ Yes
Reoperation ☐ No ☐ Yes
Interventional radiology ☐ No ☐ Yes
Observation ☐ No ☐ Yes

Hepatic artery thrombosis: ☐ No ☐ Yes
If yes, specify date of diagnosis:
__ __ / __ __ / __ __ __ __

Treatment:
Anticoagulation ☐ No ☐ Yes
Reoperation ☐ No ☐ Yes
Interventional radiology ☐ No ☐ Yes
Observation ☐ No ☐ Yes

Portal vein stenosis: ☐ No ☐ Yes
If yes, specify date of diagnosis:
__ __ / __ __ / __ __ __ __

Treatment:
Anticoagulation ☐ No ☐ Yes
Reoperation ☐ No ☐ Yes
Interventional radiology ☐ No ☐ Yes
Observation ☐ No ☐ Yes

Outflow obstruction (hepatic vein stenosis, vena cava stenosis): ☐ No ☐ Yes
If yes, specify date of diagnosis:
__ __ / __ __ / __ __ __ __

Treatment:
Anticoagulation ☐ No ☐ Yes
Reoperation ☐ No ☐ Yes
Interventional radiology ☐ No ☐ Yes
Observation ☐ No ☐ Yes

Hepatic artery stenosis: ☐ No ☐ Yes
If yes, specify date of diagnosis:
__ __ / __ __ / __ __ __ __

Treatment:
Anticoagulation ☐ No ☐ Yes
Reoperation ☐ No ☐ Yes
Interventional radiology ☐ No ☐ Yes
Observation ☐ No ☐ Yes

9. Did the participant have any biliary complications since the last visit? ☐ No ☐ Yes

   a. If yes, did the participant have a biliary leak (from cut surface or biliary tree): ☐ No ☐ Yes

Intrahepatic or extrahepatic fluid collection detected by imaging study

Data elements marked with D30 will only be collected at Day 30
Data elements marked with D90 will only be collected at Day 90

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

If yes, specify date of diagnosis: __ __ / __ __ / __ __ __ __

b. 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: __ __ / __ __ / __ __ __ __

c. 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: __ __ / __ __ / __ __ __ __

d. 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: __ __ / __ __ / __ __ __ __

10. Was the participant readmitted in the first 30 days D30: ☐ No ☐ Yes ☐ N/A
Select 'N/A' only in the event that the subject was never discharged during the initial 30 days post-transplant

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

a. Number of times readmitted in the first 30 days D30: ____
b. 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

Data elements marked with D30 will only be collected at Day 30
Data elements marked with D90 will only be collected at Day 90

Early Follow-up

Site: _____
Participant ID: _____
Transplant Number: ___ Tx 1 ___ Tx 2 ___ Tx 3 ___ Tx 4
Visit Number: ___ Visit 001(Day 30) ___ Visit 002 (Day 90)

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

Data elements marked with D30 will only be collected at Day 30
Data elements marked with D90 will only be collected at Day 90

Early Follow-up

Site: _____
Participant ID: _____
Transplant Number: ___ Tx 1 ___ Tx 2 ___ Tx 3 ___ Tx 4
Visit Number: ___ Visit 001(Day 30) ___ Visit 002 (Day 90)

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

Data elements marked with D30 will only be collected at Day 30
Data elements marked with D90 will only be collected at Day 90

Early Follow-up

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: _____

Data elements marked with D30 will only be collected at Day 30
Data elements marked with D90 will only be collected at Day 90

Early Follow-up

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℃ 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).

Data elements marked with D30 will only be collected at Day 30
Data elements marked with D90 will only be collected at Day 90

Early Follow-up

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

Data elements marked with D30 will only be collected at Day 30
Data elements marked with D90 will only be collected at Day 90

Early Follow-up

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):	_____	10^6 cells/uL	_____	10^{12} cells/L
White blood cells (WBC):	_____	10^3 cells/uL	_____	10^9 cells/L
Hemoglobin:	_____	g/dL	_____	g/L
Hematocrit:	_____	%	_____	VF
Mean corpuscular volume (MCV):	_____	um^3	_____	fL
Platelet count:	_____	10^3 cells/uL	_____	10^9 cells/L

Data elements marked with D30 will only be collected at Day 30
Data elements marked with D90 will only be collected at Day 90

Early Follow-up

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) ☐ BID (12 hours) ☐ TID (8 hours) ☐ QID (6 hours) ☐ QOD (48 hours) ☐ Other
Cyclosporine:	☐ No ☐ Yes	Frequency: ☐ QD (24 hours) ☐ BID (12 hours) ☐ TID (8 hours) ☐ QID (6 hours) ☐ QOD (48 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: ☐ No ☐ Yes
    Has the participant received chemotherapy for a primary liver tumor since Day 30 D90:
19. Has the participant received chemotherapy for post-transplant lymphoproliferative disorder (PTLD) since transplant D30: ☐ No ☐ Yes
    Has the participant received chemotherapy for Post-transplant lymphoproliferative disorder (PTLD) since Day 30 D90:

Data elements marked with D30 will only be collected at Day 30
Data elements marked with D90 will only be collected at Day 90

Studies of Pediatric Liver Transplantation

Long-term Follow-up

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. 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)

Long-term Follow-up

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)

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

Long-term Follow-up

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)

Antimetabolite:	☐ Changed to another mTOR ☐ No change to mTOR inhibitor administration ☐ N/A – not taking medication
Corticosteroids:	☐ 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
Antibody treatment:	☐ 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
	☐ 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

Long-term Follow-up

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)

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 #2

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
☐ 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

Long-term Follow-up

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

Studies of Pediatric Liver Transplantation

Long-term Follow-up

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)

Immunoglobulin:
☐ 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 #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

Long-term Follow-up

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

Long-term Follow-up

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:
☐ 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

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

Long-term Follow-up

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)

Corticosteroids:	☐ No change to antimetabolite administration ☐ N/A – not taking medication ☐ 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

Long-term Follow-up

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: ☐ No ☐ Yes
If Yes, specify date of diagnosis: __ __ / __ __ / __ __ __ __

Treatment:
Anticoagulation ☐ No ☐ Yes
Reoperation ☐ No ☐ Yes
Interventional radiology ☐ No ☐ Yes
Observation ☐ No ☐ Yes

Hepatic vein thrombosis: ☐ No ☐ Yes
If Yes, specify date of diagnosis: __ __ / __ __ / __ __ __ __

Treatment:
Anticoagulation ☐ No ☐ Yes
Reoperation ☐ No ☐ Yes
Interventional radiology ☐ No ☐ Yes
Observation ☐ No ☐ Yes

Hepatic artery thrombosis: ☐ No ☐ Yes
If Yes, specify date of diagnosis: __ __ / __ __ / __ __ __ __

Treatment:
Anticoagulation ☐ No ☐ Yes
Reoperation ☐ No ☐ Yes
Interventional radiology ☐ No ☐ Yes
Observation ☐ No ☐ Yes

Portal vein stenosis: ☐ No ☐ Yes
If Yes, specify date of diagnosis: __ __ / __ __ / __ __ __ __

Treatment:
Anticoagulation ☐ No ☐ Yes
Reoperation ☐ No ☐ Yes
Interventional radiology ☐ No ☐ Yes
Observation ☐ No ☐ Yes

Long-term Follow-up

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)

Outflow obstruction (hepatic vein stenosis, vena cava stenosis): ☐No ☐Yes

If Yes, specify date of diagnosis:
__ __ / __ __ / __ __ __ __

Treatment:
Anticoagulation ☐ No ☐ Yes
Reoperation ☐ No ☐ Yes
Interventional radiology ☐ No ☐ Yes
Observation ☐ No ☐ Yes

Hepatic artery stenosis: ☐No ☐Yes

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

Treatment: ☐ No ☐ Yes
Anticoagulation ☐ No ☐ Yes
Reoperation ☐ No ☐ Yes
Interventional radiology ☐ No ☐ Yes
Observation

8. Did the participant have any biliary complications since the last visit: ☐ No ☐ Yes

   a. 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)

   b. 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)

   c. 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 the last visit: ☐ 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)

11. Was the participant diagnosed with cancer since the last visit: ☐ No ☐ Yes

a. Post-transplant lymphoproliferative disorder (PTLD): ☐ 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

Long-term Follow-up

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

b. Skin Cancer: ☐ No ☐ Yes
If yes, specify:
i. Melanoma: ☐ No ☐ Yes
Date of diagnosis: __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)

ii. Basal Cell Carcinoma: ☐ No ☐ Yes
Date of diagnosis: __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)

iii. Squamous Cell Carcinoma: ☐ No ☐ Yes
Date of diagnosis: __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)

iv. Other: ☐ No ☐ Yes
Date of diagnosis: __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)

c. Hepatocellular carcinoma: ☐ No ☐ Yes, de novo ☐ Yes, recurrent disease
Date of diagnosis: __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)

d. Hepatoblastoma: ☐ No ☐ Yes, de novo ☐ Yes, recurrent disease
Date of diagnosis: __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)

e. 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

Long-term Follow-up

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 _____ mmHg Diastolic _____ 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

Long-term Follow-up

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: _____ 10^3 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/1.73m^2
    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

Long-term Follow-up

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) ☐ BID (12 hours) ☐ TID (8 hours) ☐ QID (6 hours) ☐ QOD (48 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

Studies of Pediatric Liver Transplantation

Long-term Follow-up

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

Long-term Follow-up

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: ☐ 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

Long-term Follow-up

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)

Antimetabolite:	☐ No change to mTOR inhibitor administration ☐ N/A – not taking medication ☐ 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
Corticosteroids:	☐ N/A – not taking medication ☐ 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
Antibody treatment:	☐ 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
Immunoglobulin:	☐ N/A – not taking medication ☐ Increased immunoglobulin amount and/or frequency

Long-term Follow-up

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: ☐ 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

Long-term Follow-up

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

Long-term Follow-up

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)

Immunoglobulin:
☐ 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 #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

Long-term Follow-up

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:	☐ 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 ☐ No change to mTOR inhibitor administration
Antimetabolite:	☐ N/A – not taking medication ☐ 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
Corticosteroids:	☐ N/A – not taking medication ☐ Increased corticosteroids dose amount and/or frequency ☐ Started on corticosteroids ☐ Decreased corticosteroid dose amount and/or frequency ☐ Stopped all corticosteroids

Long-term Follow-up

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:
- ☐ 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

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 #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

Long-term Follow-up

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

Long-term Follow-up

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)

Corticosteroids:	☐ No change to antimetabolite administration ☐ N/A – not taking medication ☐ 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: _____

Studies of Pediatric Liver Transplantation

Death

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:_____

Studies of Pediatric Liver Transplantation

Death

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

Studies of Pediatric Liver Transplantation

Exit

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.*