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:
      (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

Version 3.0 1 June 20, 2016
Recipient Information

1. Blood type\textsuperscript{Tx1}:
   - \(\Box\) A
   - \(\Box\) B
   - \(\Box\) AB
   - \(\Box\) O

2. Primary Disease Diagnosis\textsuperscript{Tx1}:
   - \(\Box\) Acute liver failure: Acetaminophen
   - \(\Box\) Acute liver failure: Autoimmune Hepatitis
   - \(\Box\) Acute liver failure: Cytomegalovirus (CMV)
   - \(\Box\) Acute liver failure: Drug-induced Hepatitis (other than acetaminophen)
   - \(\Box\) Acute liver failure: Epstein–Barr virus (EBV)
   - \(\Box\) Acute liver failure: Fatty acid oxidation defect
   - \(\Box\) Acute liver failure: Hemophagocytic syndrome
   - \(\Box\) Acute liver failure: Hemangioendothelioma
   - \(\Box\) Acute liver failure: Hepatitis A
   - \(\Box\) Acute liver failure: Hepatitis B (+ delta)
   - \(\Box\) Acute liver failure: Hepatitis C
   - \(\Box\) Acute liver failure: Herpes Simplex
   - \(\Box\) Acute liver failure: Mitochondrial
   - \(\Box\) Acute liver failure: Neonatal iron storage disease
   - \(\Box\) Acute liver failure: Shock/ischemia
   - \(\Box\) Acute liver failure: Veno-occlusive disease
   - \(\Box\) Acute liver failure: Wilson's disease
   - \(\Box\) Acute liver failure: Indeterminate
   - \(\Box\) Acute liver failure: Other, specify: __________________
   - Alagille Syndrome
   - Alpha-1 Antitrypsin deficiency
   - Autoimmune Hepatitis
   - Bile Acid Synthesis defect
   - Biliary Atresia
   - Budd-Chiari syndrome
   - Carbamylphosphate synthetase deficiency
   - Citrullinemia
   - Congenital 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 \textsuperscript{Tx1} will only be collected for the first transplant.
Data elements marked with \textsuperscript{>Tx1} will only be collected for subsequent transplants.

Version 7.0 1 April 16, 2018
Primary Disease Diagnosis\textsuperscript{Tx1} (cont):
\begin{itemize}
  \item Ornithine transcarbamylase deficiency
  \item PFIC1 (FIC1 disease)
  \item PFIC2 (BSEP disease)
  \item PFIC3 (MDR3 disease)
  \item Primary Hyperoxaluria
  \item Primary Sclerosing Cholangitis
  \item Total parenteral nutrition (TPN) induced
  \item Tyrosinemia
  \item Other tumor, specify: _____________________
  \item Wilson's disease
  \item Other, specify: _____________________
\end{itemize}

3. Primary cause for graft failure\textsuperscript{Tx1}:
\begin{itemize}
  \item Primary graft dysfunction
  \item Hyperacute rejection
  \item Chronic rejection
  \item Post-operative hemorrhage
  \item Biliary tract complications
  \item De Novo Hepatitis
  \item Recurrent Primary Liver disease
  \item Hepatic Artery Thrombosis
  \item Portal Vein Thrombosis
  \item Other, specify: _____________________
\end{itemize}

4. Primary insurance type:
\begin{itemize}
  \item Australian National Federal funding
  \item Champus (military)
  \item HMO / Managed care
  \item Medicaid or equivalent and/or state funded children's services
  \item Provincial government (Canada)
  \item Traditional private insurance
  \item None: Self pay
  \item None: Donation
  \item None: No funding
  \item Other
\end{itemize}

5. Primary caregiver:
\begin{itemize}
  \item Mother
  \item Father
  \item Guardian
  \item Other, specify: _____________________
\end{itemize}

6. Primary caregiver’s marital status:
\begin{itemize}
  \item Single
  \item Married
  \item Divorced
  \item Widowed
  \item Domestic partnership
  \item Unknown
\end{itemize}
Studies of Pediatric Liver Transplantation

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.

   - 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

Version 7.0 3 April 16, 2018
12. Does the participant have hepatopulmonary syndrome:  
   - No  
   - Yes  
   - Unknown  
   If yes, specify:  
   - No  
   - Yes  
   - Unknown  
   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  
   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

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

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:
   (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
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

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Studies of Pediatric Liver Transplantation

Transplant

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

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

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

Version 7.0 April 16, 2018
### Transplant

**Site:**

**Participant ID:** ________________________________

**Transplant Number:** __ Tx 1 __ Tx 2 __ Tx 3 __ Tx 4

**Visit Number:** ___ Visit 000

**44. Warm ischemia time:**

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):**

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:**

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.

- [ ] No
- [ ] Yes

**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)
Studies of Pediatric Liver Transplantation

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

Version 7.0 9 April 16, 2018
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\textsuperscript{D30}:
   - No
   - Yes
   - N/A
   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)
   \textit{Report the date of primary hospital discharge even if it is after the Day 30 assessment date.}

3. Date of primary extubation post-op \textsuperscript{D30}: ___ / ___ / _____ (mm/dd/yyyy)
   \textit{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 \textsuperscript{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 \textsuperscript{D30}:
   - No
   - Yes
   Did the participant undergo a liver biopsy since Day 30 \textsuperscript{D90}:
     - No
     - Yes
     - N/A
     If yes, specify:
     Number of liver biopsies performed: _____
     Liver Biopsy #1
     Date of biopsy: ___ / ___ / _____ (mm/dd/yyyy)
     Reason for biopsy:
     - Per protocol
     - For cause
     - No
     Was immunosuppressive therapy modified in response to the biopsy:
     - No/indeterminate
     - Yes
       - Acute
       - Chronic
     Was rejection confirmed:

\textit{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.

Version 11.0 1 May 4, 2018

Data elements marked with \textsuperscript{D30} will only be collected at Day 30
Data elements marked with \textsuperscript{D90} will only be collected at Day 90
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)

Liver Biopsy #2
Date of biopsy: __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)
Reason for biopsy: ____________________________
Was immunosuppressive therapy modified in response to the biopsy:
Was rejection confirmed:

Liver Biopsy #3
Date of biopsy: __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)
Reason for biopsy: ____________________________
Was immunosuppressive therapy modified in response to the biopsy:
Was rejection confirmed:

Liver Biopsy #4
Date of biopsy: __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)
Reason for biopsy: ____________________________
Was immunosuppressive therapy modified in response to the biopsy:
Was rejection confirmed:

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

7. Was the participant relisted for a liver transplant:
   If yes, specify date relisted: __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)
   ☐ No ☐ Yes

8. Did the participant have any vascular complications:
   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.

   ☐ No ☐ Yes
### Portal vein thrombosis:

<table>
<thead>
<tr>
<th>Yes</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Anticoagulation</td>
</tr>
<tr>
<td></td>
<td>Reoperation</td>
</tr>
<tr>
<td></td>
<td>Interventional radiology</td>
</tr>
<tr>
<td></td>
<td>Observation</td>
</tr>
</tbody>
</table>

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

### Hepatic vein thrombosis:

<table>
<thead>
<tr>
<th>Yes</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
<td>Interventional radiology</td>
</tr>
<tr>
<td></td>
<td>Observation</td>
</tr>
</tbody>
</table>

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

### Hepatic artery thrombosis:

<table>
<thead>
<tr>
<th>Yes</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Anticoagulation</td>
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<td></td>
<td>Interventional radiology</td>
</tr>
<tr>
<td></td>
<td>Observation</td>
</tr>
</tbody>
</table>

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

### Portal vein stenosis:

<table>
<thead>
<tr>
<th>Yes</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Anticoagulation</td>
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<td></td>
<td>Interventional radiology</td>
</tr>
<tr>
<td></td>
<td>Observation</td>
</tr>
</tbody>
</table>

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

### Outflow obstruction (hepatic vein stenosis, vena cava stenosis):

<table>
<thead>
<tr>
<th>Yes</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Anticoagulation</td>
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<td></td>
<td>Interventional radiology</td>
</tr>
<tr>
<td></td>
<td>Observation</td>
</tr>
</tbody>
</table>

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

### Hepatic artery stenosis:

<table>
<thead>
<tr>
<th>Yes</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Anticoagulation</td>
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<td></td>
<td>Interventional radiology</td>
</tr>
<tr>
<td></td>
<td>Observation</td>
</tr>
</tbody>
</table>

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

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):

   *Intrahepatic or extrahepatic fluid collection detected by imaging study*
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)

(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: □ No □ Yes □ N/A

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
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
Fever: □ No □ Yes
Dehydration: □ No □ Yes
Fluid-electrolyte imbalance: □ No □ Yes
### 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)

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<td>Other:</td>
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<tr>
<td>Specify: _______________________________</td>
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**Date of discharge from second readmission:** __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)

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11. Did the participant have reoperation in the first 30 days (excluding retransplant)?

- Yes
- No

**Number of reoperations in the first 30 days:**

---

*Record detailed information on up to first three reoperations.*

**First reoperation**

**Date of first reoperation:** __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)

- Intra-abdominal bleeding: | | |
- Biliary tract complication/bile leak: | | |
- Vascular complication: | | |
- Wound complication: | | |
- Bowel perforation: | | |

---

*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

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°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).*
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) |

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) |
| Pneumonia: | ☐ No ☐ Adenovirus ☐ Cytomegalovirus (CMV) |
| Meningitis: | ☐ No ☐ Adenovirus ☐ Cytomegalovirus (CMV) |
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/µL ________ 10^{12} cells/L
White blood cells (WBC): ________ 10^3 cells/µL ________ 10^9 cells/L
Hemoglobin: ________ g/dL ________ g/L
Hematocrit: ________ % ________ VF
Mean corpuscular volume (MCV): ________ um^3 ________ fl
Platelet count: ________ 10^9 cells/µL ________ 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
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)

Immunosuppression

16. Immunosuppression at Day 30\textsuperscript{D30}: Immunosuppression at Day 90\textsuperscript{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\textsuperscript{D30}: Has the participant received chemotherapy for a primary liver tumor since Day 30\textsuperscript{D90}:

19. Has the participant received chemotherapy for post-transplant lymphoproliferative disorder (PTLD) since transplant\textsuperscript{D30}: Has the participant received chemotherapy for Post-transplant lymphoproliferative disorder (PTLD) since Day 30\textsuperscript{D90}:

Data elements marked with \textsuperscript{D30} will only be collected at Day 30
Data elements marked with \textsuperscript{D90} will only be collected at Day 90
# 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

*Note: A hepatocyte transplant is not considered a solid-organ transplant.*

*If yes, specify type:*
- Liver
- Kidney
- Stomach
- Intestine
- Pancreas
- Heart
- 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)
### Studies of Pediatric Liver Transplantation

#### Long-term Follow-up

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<thead>
<tr>
<th>Site:</th>
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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

Version 10.0 2 April 16, 2018
| 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 inhibitor administration
  - 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
  - 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
  - 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

Version 10.0  3 April 16, 2018
# Long-term Follow-up

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</table>

**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

**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
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### 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 inhibitor administration
- [ ] 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
- [ ] 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)

☑ 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

Immunoglobulin:

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

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</tbody>
</table>

- 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 inhibitor administration
- 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
- 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

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<td></td>
<td>___ Visit 012 (Year 10) ___ (Other)</td>
</tr>
</tbody>
</table>

- 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 #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
# Long-term Follow-up

<table>
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<td></td>
<td>____ Visit 012 (Year 10) ____ (Other)</td>
</tr>
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</table>

- [ ] 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 inhibitor administration
  - [ ] 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

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</tr>
<tr>
<td></td>
<td>___ Visit 012 (Year 10) ___ (Other)</td>
</tr>
</tbody>
</table>

- **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
  - [ ] 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
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  Treatment:  
   Anticoagulation □ No □ Yes  Reoperation □ No □ Yes  Interventional radiology □ No □ Yes  Observation □ No □ Yes

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

   **Hepatic vein thrombosis:**
   
   □ No □ Yes  Treatment:  
   Anticoagulation □ No □ Yes  Reoperation □ No □ Yes  Interventional radiology □ No □ Yes  Observation □ No □ Yes

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

   **Hepatic artery thrombosis:**
   
   □ No □ Yes  Treatment:  
   Anticoagulation □ No □ Yes  Reoperation □ No □ Yes  Interventional radiology □ No □ Yes  Observation □ No □ Yes

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

   **Portal vein stenosis:**
   
   □ No □ Yes  Treatment:  
   Anticoagulation □ No □ Yes  Reoperation □ No □ Yes  Interventional radiology □ No □ Yes  Observation □ No □ Yes

   **If Yes, specify date of diagnosis:**
   __ __ / __ __ / __ __ __ __
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</tr>
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#### Outflow obstruction (hepatic vein stenosis, vena cava stenosis):
- [ ] No
- [ ] Yes

- Treatment:
  - [ ] Anticoagulation
  - [ ] Reoperation
  - [ ] Intervventional radiology
  - [ ] Observation

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

#### Hepatic artery stenosis:
- [ ] No
- [ ] Yes

- Treatment:
  - [ ] Anticoagulation
  - [ ] Reoperation
  - [ ] Intervventional radiology
  - [ ] Observation

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

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:
   - **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:
   - **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 a non-anastomotic biliary stricture since the last visit:
   - **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)
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 [ ]

       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
Studies of Pediatric Liver Transplantation

Long-term Follow-up

Site: __________________________________________________
Participant ID: __________________________________________
Transplant Number: ___ Tx 1 ___ Tx 2 ___ Tx 3 ___ Tx 4
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___ Visit 012 (Year 10) ___ (Other)

iii. 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:
   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:
   Date of diagnosis: ___ / ___ / ________
   (mm/dd/yyyy)

d. Hepatoblastoma:
   Date of diagnosis: ___ / ___ / ________
   (mm/dd/yyyy)

e. Other: ________________________________
   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
Studies of Pediatric Liver Transplantation

Long-term Follow-up

Site: __________________________________________________

Participant ID: __________________________________________

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

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___ 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):
   Date: ______/____/____ (mm/dd/yyyy)
   Value: ______ lbs kg

14. Blood pressure (+/90 days of assessment date):
   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

   Low-density lipoprotein (LDL) cholesterol: mg/dL
   Fasting >8hrs: No Yes

   High-density lipoprotein (HDL) cholesterol: mg/dL
   Fasting >8hrs: No Yes

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## Long-term Follow-up

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<td></td>
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</tr>
</tbody>
</table>

| Triglycerides:                  | ______ mg/dL Fasting >8hrs: □ No □ Yes □ Not recorded |
| Glucose:                        | ______ mg/dL Fasting >8hrs: □ No □ Yes □ Not recorded |
| Platelet count:                 | ______ 10³ cells/µL                                  |
| International normalized ratio (INR): | ______ |

16. **mGFR (+90 days of assessment date):**
   - Date: ______ / ______ / ______ / ______ / ______ / ______ / ______ / ______ / ______ (mm/dd/yyyy)
   - Method: □ Cr-EDTA □ I-ithalamate □ Tc-DPTA
   - Value: ______ mL/min

17. **Cystatin C (+90 days of assessment date):**
   - Date: ______ / ______ / ______ / ______ / ______ / ______ / ______ / ______ / ______ (mm/dd/yyyy)
   - Value: ______ mg/L

18. **eGFR (+90 days of assessment date):**
   - 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
# 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)
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<tr>
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<th>Current Use</th>
<th>Frequency</th>
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<tbody>
<tr>
<td>Cyclosporine:</td>
<td></td>
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<tr>
<td>No</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Frequency:</td>
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<tr>
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<tr>
<td>TID (8 hours)</td>
<td>QID (6 hours)</td>
<td></td>
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<tr>
<td>QOD (48 hours)</td>
<td>Other</td>
<td></td>
</tr>
<tr>
<td>Mycophenolate mofetil/</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mycophenolic acid (MMF/MPA):</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Azathioprine:</td>
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<td>Yes</td>
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<tr>
<td>Sirolimus:</td>
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<td>Yes</td>
</tr>
<tr>
<td>Corticosteroids:</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Everolimus:</td>
<td>No</td>
<td>Yes</td>
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20. Is the participant currently taking concomitant medications of the types listed below?

- 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


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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

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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):
[ ] 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
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)

☐ 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
☐ 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
☐ 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

Version 10.0 20 April 16, 2018
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
<table>
<thead>
<tr>
<th>Mammalian target of rapamycin (mTOR) inhibitor:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Increased mTOR inhibitor dose amount and/or frequency</td>
<td></td>
</tr>
<tr>
<td>Started on mTOR inhibitor</td>
<td></td>
</tr>
<tr>
<td>Decreased mTOR inhibitor dose amount and/or frequency</td>
<td></td>
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<tr>
<td>Stopped all mTOR inhibitors</td>
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</tr>
<tr>
<td>Changed to another mTOR inhibitor administration</td>
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<tr>
<td>No change to mTOR inhibitor administration</td>
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</tr>
<tr>
<td>N/A – not taking medication</td>
<td></td>
</tr>
<tr>
<td>Antimetabolite:</td>
<td></td>
</tr>
<tr>
<td>Increased antimetabolite dose amount and/or frequency</td>
<td></td>
</tr>
<tr>
<td>Started on antimetabolites</td>
<td></td>
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<tr>
<td>Decreased antimetabolite dose amount and/or frequency</td>
<td></td>
</tr>
<tr>
<td>Stopped all antimetabolites</td>
<td></td>
</tr>
<tr>
<td>Changed to another antimetabolite</td>
<td></td>
</tr>
<tr>
<td>No change to antimetabolite administration</td>
<td></td>
</tr>
<tr>
<td>N/A – not taking medication</td>
<td></td>
</tr>
<tr>
<td>Increased corticosteroids dose amount and/or frequency</td>
<td></td>
</tr>
<tr>
<td>Started on corticosteroids</td>
<td></td>
</tr>
<tr>
<td>Decreased corticosteroid dose amount and/or frequency</td>
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</tr>
<tr>
<td>Stopped all corticosteroids</td>
<td></td>
</tr>
<tr>
<td>Changed to another corticosteroid</td>
<td></td>
</tr>
<tr>
<td>No change to corticosteroid administration</td>
<td></td>
</tr>
<tr>
<td>N/A – not taking medication</td>
<td></td>
</tr>
<tr>
<td>Antibody treatment:</td>
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</tr>
<tr>
<td>Increased Ab treatment dose amount and/or frequency</td>
<td></td>
</tr>
<tr>
<td>Started on Ab treatment</td>
<td></td>
</tr>
<tr>
<td>Decreased Ab treatment dose amount and/or frequency</td>
<td></td>
</tr>
</tbody>
</table>
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)

Immuno globulin:

□ 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 biopsy:
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 inhibitor administration
- [ ] 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
☐ 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

<table>
<thead>
<tr>
<th>Site:</th>
<th>__________________________________________________________</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participant ID:</td>
<td>__________________________________________________________</td>
</tr>
<tr>
<td>Transplant Number:</td>
<td>____ Tx 1 ___ Tx 2 ___ Tx 3 ___ Tx 4</td>
</tr>
<tr>
<td>Visit Number:</td>
<td>___ Visit 003 (Year 1) ___ Visit 004 (Year 2) ___ Visit 005 (Year 3)</td>
</tr>
<tr>
<td></td>
<td>___ Visit 006 (Year 4) ___ Visit 007 (Year 5) ___ Visit 008 (Year 6)</td>
</tr>
<tr>
<td></td>
<td>___ Visit 009 (Year 7) ___ Visit 010 (Year 8) ___ Visit 011 (Year 9)</td>
</tr>
<tr>
<td></td>
<td>___ Visit 012 (Year 10) ___ (Other)</td>
</tr>
</tbody>
</table>

## Yes, acute

## Yes, chronic

- [ ] 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 inhibitor administration
- [ ] 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)

- [ ] 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
- [ ] 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
# Previous Transplant

<table>
<thead>
<tr>
<th>Site:</th>
<th>Participant ID:</th>
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<tbody>
<tr>
<td></td>
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</tbody>
</table>

<table>
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<th>Sequence Number:</th>
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<th>02</th>
<th>03</th>
<th>04</th>
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</table>

<table>
<thead>
<tr>
<th>Date of transplant:</th>
<th>__ __ / __ __ / __ __ __ __ (mm/dd/yyyy)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Type of transplant:</th>
<th>Liver-only</th>
<th>Combined liver-kidney</th>
<th>Combined liver-pancreas</th>
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</thead>
</table>

<table>
<thead>
<tr>
<th>Primary cause for graft failure:</th>
<th>Primary graft dysfunction</th>
<th>Hyperacute rejection</th>
<th>Chronic rejection</th>
<th>Post-operative hemorrhage</th>
<th>Biliary tract complications</th>
<th>De Novo Hepatitis</th>
<th>Recurrent Primary Liver disease</th>
<th>Hepatic Artery Thrombosis</th>
<th>Portal Vein Thrombosis</th>
<th>Other, specify:</th>
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</thead>
</table>

<table>
<thead>
<tr>
<th>Donor type:</th>
<th>Deceased–Brain Death</th>
<th>Deceased– Donation after Cardiac Death (DCD)</th>
<th>Living</th>
<th>Unknown</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Procedure type:</th>
<th>Whole liver</th>
<th>Partial liver, remainder not transplanted or living transplant</th>
<th>Split liver</th>
<th>Unknown</th>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Partial type:</th>
<th>Right lobe without middle hepatic vein (segments 5,6,7,8)</th>
<th>Right lobe with middle hepatic vein (segments 4,5,6,7,8)</th>
<th>Left lobe (segments 2,3,4)</th>
<th>Left lateral (segments 2,3)</th>
<th>Unknown</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Split type:</th>
<th>Right lobe without middle hepatic vein in situ/ex situ (segments 5,6,7,8)</th>
<th>Right lobe with middle hepatic vein in situ /ex situ (segments 4,5,6,7,8)</th>
<th>Left lobe in situ /ex situ (segment 2,3,4)</th>
<th>Left lateral segment in situ /ex situ (segments 2,3)</th>
<th>Unknown</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Comments:</th>
<th>______________________________________________________________________</th>
</tr>
</thead>
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**Version 2.0**

1 June 20, 2016
Reconsent

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:**

<table>
<thead>
<tr>
<th>No</th>
<th>Yes</th>
<th>Cause of Death</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Primary graft non-function</td>
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<tr>
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<td></td>
<td>Chronic rejection</td>
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<td>Recurrent disease</td>
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<td>Hepatic artery thrombosis</td>
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<td>Portal vein thrombosis</td>
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<td>Liver failure</td>
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<td></td>
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<td>Graft-versus-host disease (GVHD)</td>
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<td>Renal failure</td>
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<td>Sepsis, not specified</td>
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<td>Malignancy/cancer - primary</td>
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<td>Malignancy/cancer – de novo</td>
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<td>Primary respiratory failure</td>
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<td>Intrinsic heart disease</td>
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<td>Bowel perforation</td>
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<td>Accident</td>
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<td>Other, specify:______________________</td>
</tr>
</tbody>
</table>

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Version 2.0 1 June 20, 2016
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.