V5_GEN_FORM

A2ALL
Adult to Adult Living Donor Liver Transplantation Cohort Study

Donor Study Entry Information

Samples/procedures at time of Donor Study Entry

*3 ACD tubes of whole blood (to be shipped to Rutgers Genetics Repository) *15 ml of whole blood, spun and serum aliquotted into ten 0.4ml samples (to be frozen and batch-shipped to McKesson BioSample Repository).
These samples should be labeled with the time point that matches the subject's study entry.

*Keris - QOL (and IC &Motivation if full Cohort subject)

ELIGIBILITY CRITERIA

Donor 18 years of age or older at time of evaluation?	○ Yes ○ No
Donor was evaluated for living liver donation surgery after Jan. 1, 1998 and before Jul. 31, 2007?	○ Yes ○ No

---

DEMOGRAPHIC INFORMATION

What is the month and year of birth for this donor subject?	[ ] *MM/YYYY*
Donor Gender	○ Male ○ Female

Donor Ethnicity	○ Hispanic/Latino ○ Non-Hispanic/Non-Latino
Donor Race	○ American Indian or Alaska Native ○ Asian ○ Black/African American ○ Native Hawaiian or Other Pacific Islander ○ White ○ More than One Race
Donor ABO blood type	○ A ○ B ○ O ○ AB

RECIPIENT MATCHING INFORMATION

Record the BioDBx Cohort Study Subject Number for the recipient this donor is associated with:	
If no RCP Cohort Study BioDBx ID, indicate reason.	○ Pending ○ Recipient refused consent for study participation ○ Recipient died prior to study enrollment
Month and year of birth of the recipient this donor is associated with: *MM/YYYY*	
Gender of the recipient this donor is associated with:	○ Male ○ Female

Ethnicity of the recipient this donor is associated with:	○ Hispanic/Latino ○ Non-Hispanic/Non-Latino
Race of the recipient this donor is associated with:	○ American Indian or Alaska Native ○ Asian ○ Black/African American ○ Native Hawaiian or Other Pacific Islander ○ White ○ More than One Race
Living Donor relationship to recipient	○ Biological, Blood-related Parent ○ Biological, Blood-related Child ○ Biological, Blood-related Identical Twin ○ Biological, Blood-related Full Sibling (not identical twin) ○ Biological, Blood-related Half Sibling ○ Biological, Blood-related Other Relative ○ Non-biological, Spouse ○ Non-biological, Other non-Blood-related Relative ○ Non-biological, Other Unrelated ○ Non-biological, Unrelated: Paired Exchange ○ Non-biological Unrelated: Anonymous Donation ○ Unknown

SUBJECT ENROLLMENT & PREVIOUS DONATION INFO

Enrollee category of subject:	○ Full Cohort ○ Former Retro Subject - Cohort Lite Enrollee ○ Non-Retro Subject - Cohort Lite Enrollee ○ Full Cohort Era - Consented to Retrospective & Prospective Chart Review & Abstraction Only ○ Former Retro Subject - Consented to Retrospective & Prospective Chart Review & Abstraction Only ○ Bridge Era - Consented to Retrospective & Prospective Chart Review & Abstraction Only ○ Bridge - Retrospective Chart Review and Abstraction Only ○ LADR Subject - waiting for donor's eval appointment	*(If "yes" to Retro study subject)* What is this donor's Retro BioDBx Subject Label?
Did the subject undergo living liver donation surgery prior to study entry?	○ Yes ○ No	Date of previous living donor surgery: *MM/DD/YYYY*
Is the patient a subject in another research study?	○ Yes ○ No ○ Unknown	If yes, what is the name of the study?

If you answered "No" to either question in the Eligibility Criteria section, the subject is NOT ELIGIBLE for enrollment in the A2ALL Cohort Study. ○

Start Time: 17:51:01Stop Time: 17:51:02Time To Generate: 0 seconds

save reset cancel print

V5_GEN_FORM

A2ALL
Adult to Adult Living Donor Liver Transplantation Cohort Study

Donor Evaluation

Samples/Labs/Procedures at Donor Evaluation

*3 ACD tubes of whole blood (to be shipped to Rutgers Genetics Repository)

*15 ml of whole blood, spun and serum aliquotted into ten 0.4ml samples (to be frozen and batch-shipped to McKesson BioSample Repository)

*Labs

*MRI/CT to assess liver volume

*Keris - full QOL, IC and Motivation

If this is a Retro subject who has some data recorded on the Donor Evaluation Form in Retro, you will still need to complete this form retrosepctively in Cohort beause there are many fields that are different from the Retro form.

What was the date of this donor's evaluation?	MM/DD/YYYY
Donor state of permanent residence at the time of evaluation:	

Donor highest education level at time of evaluation:	○ None ○ Grade School (0-8) ○ High school (9-12) ○ Attended college/Technical school ○ Associate/Bachelor degree ○ Post-college Graduate degree ○ Unknown
Donor height	○ Inches ○ Centimeters
Donor weight	○ Kilograms ○ Pounds
Primary source of payment (may be reflective of recipient's medical coverage):	○ Medicare ○ Medicaid ○ US State/Gov't Agency ○ Private Insurance ○ HMO/PPO ○ Self ○ Donation ○ Free Care ○ Dept. Veterans' Affairs ○ Pending ○ Foreign Gov't ○ Unknown ○ Other (specify)
Specify "other" source of primary payment:	
Serum ALT closest to date of donor evaluation IU/L	Not Done ☐

Serum AST closest to date of donor evaluation	IU/L	Not Done ☐
Serum Alkaline Phosphatase (ALK PHOS) closest to date of donor evaluation	IU/L	Not Done ☐
Serum Total Bilirubin closest to date of donor evaluation	mg/dl	Not Done ☐
Creatinine value closest to date of donor evaluation	mg/dl	Not Done ☐
Blood Urea Nitrogen value closest to date of donor evaluation	mg/dl	Not Done ☐
Albumin value closest to date of donor evaluation	g/dl	Not Done ☐

INR value closest to date of donor evaluation		Not Done ☐
Ferritin level closest to date of donor evaluation	ng/ml	Not Done ☐
White Blood Count value closest to date of donor evaluation	*x10^3/mm^3*	Not Done ☐
Hemoglobin (Hgb) closest to date of donor evaluation	mg/dl	Not Done ☐
Platelet count closest to date of donor evaluation	*x10^3/mm^3*	Not Done ☐
Homocysteine level closest to date of donor evaluation	mg/L	Not Done ☐

CMV IgG closest to date of donor evaluation	○ Positive ○ Negative ○ Indeterminate ○ Unknown ○ Not Done
HIV results closest to date of donor evaluation:	○ Positive ○ Negative ○ Unknown ○ Not Done ○ Cannot Disclose
HCV Antibody Test Result:	○ Positive ○ Negative ○ Unknown ○ Not Done
If HCV+, record the HCV RNA result:	○ Positive ○ Negative ○ Unknown ○ Not Done
Hep B surface antigen (HbsAg) result:	○ Positive ○ Negative ○ Unknown ○ Not Done
Hep. B core antibody screen (HBcAb) result:	○ Positive ○ Negative ○ Unknown ○ Not Done
If Hep B+, record Hepatitis D antibody screen result:	○ Positive ○ Negative ○ Unknown ○ Not Done
Previous upper abdominal surgery?	○ Yes ○ No ○ Unknown
If "Yes" to upper abdominal surgery, please check all that apply:	Cholecystectomy ☐
	Gastric Resection ☐

	Small Bowel Resection ☐	
	Ulcer Operation ☐	
	Other (specify):	
Date of evaluation liver MRI or CT: MM/DD/YYYY	Right Lobe Liver Volume: cc	Not Done ☐
	Left Lobe Liver Volume cc	

	None
Did the prospective donor have a history of any co-morbid conditions listed below? If yes, check all that apply.	☐
Diabetes mellitus	☐
Coronary artery disease	☐
Pulmonary disease	☐
Systemic hypertension	☐
Previous smoker	☐
Current smoker	☐
Depression	☐
Dyslipidemia	☐
Indicate what the patient states are typical pain drug use patterns:	
Patient reports no pain drug use.	☐
Plain Tylenol - Use	

NSAID (Motrin, Aleve, ibuprofen,etc) - Use	
Aspirin - Use	
Tylenol w/ Codeine - Use	
Darvocet - Use	
Vicodin - Use	
Percocet - Use	
Percodan - Use	
Dilaudid - Use	
Oxycontin - Use	
MS Contin - Use	
Methadone - Use	

Other (specify)		Use	

Was donor ruled out?

- ○ Yes
- ○ No

If donor was ruled out

Date of decision to rule donor out:

If donor was ruled out

Primary reason why donor was ruled out:

- ○ Declined to Donate
- ○ Medical Contraindications - Obesity
- ○ Medical Contraindications - Heart Disease
- ○ Medical Contraindications - Hypertension
- ○ Medical Contraindications - Diabetes
- ○ Medical Contraindications - Positive Serology
- ○ Medical Contraindications - Other (specify)
- ○ Donor LIver Steatosis
- ○ Anatomical Contraindications
- ○ Psychosocial Contraindications
- ○ Recipient died
- ○ Recipient too sick/removed from transplant consideration
- ○ Recipient received deceased donor liver transplant
- ○ Recipient improved
- ○ Recipient declined/refused organ
- ○ Other (specify)

Specify "other" primary reason for ruling donor out		Specify "other" primary medical reason for ruling out donor:	

If donor was ruled out

Secondary reason why donor was ruled out:

- ○ Declined to Donate
- ○ Medical Contraindications - Obesity
- ○ Medical Contraindications - Heart Disease
- ○ Medical Contraindications - Hypertension
- ○ Medical Contraindications - Diabetes
- ○ Medical Contraindications - Positive Serology
- ○ Medical Contraindications - Other (specify)
- ○ Donor LIver Steatosis
- ○ Anatomical Contraindications
- ○ Psychosocial Contraindications
- ○ Recipient died
- ○ Recipient too sick/removed from transplant consideration
- ○ Recipient received deceased donor liver transplant
- ○ Recipient improved
- ○ Recipient declined/refused organ
- ○ Other (specify)

Specify "other" secondary reason for ruling donor out

Specify "other" secondary medical reason for ruling out donor:

Start Time: 15:44:19Stop Time: 15:44:20Time To Generate: 0 seconds

save reset cancel print

V5_GEN_FORM

A2ALL
Adult to Adult Living Donor Liver Transplantation Cohort Study

Recipient Study Entry Information

Samples/Labs/Procedures at RCP Study Entry

*3 ACD tubes of whole blood (to be shipped to Rutgers Genetics Repository)

*15ml of whole blood, spun and serum aliqotted into ten 0.4ml samples (to be frozen and batch-shipped to McKesson BioSample Respository).
These samples should be labeled with the subject's appropriate study entry timepoint.

*Keris QOL Assessment (SF-36)

ELIGIBILITY CRITERIA

Recipient subject 18 years of age or older at time of donor evaluation?	○ Yes ○ No
Recipient subject had a living donor evaluated/ scheduled for eval between Jan. 1, 1998 and 4 weeks from recipient's date of study consent?	○ Yes ○ No
Recipient subject was waitlisted for a liver transplant, and not for any additional organs?	○ Yes ○ No
Reason for transplant is NOT fulminant liver failure.	○ Yes ○ No
Date of first donor H&P (scheduled or actual) that qualified recipient subject for study entry:	*MM/DD/YYYY*

DEMOGRAPHIC INFORMATION

What is the month and year of birth for this subject?	_____ *MM/YYYY*
Recipient Gender	○ Male ○ Female
Recipient Ethnicity	○ Hispanic/ Latino ○ Non-Hispanic/ Non-Latino
Recipient Race	○ American Indian or Alaska Native ○ Asian ○ Black/African American ○ Native Hawaiian or Other Pacific Islander ○ White ○ More than One Race
Recipient ABO blood type	○ A ○ B ○ O ○ AB

SUBJECT ENROLLMENT & PREVIOUS TXP INFO

Enrollee category of subject:	○ Full Cohort ○ Former Retro Subject - Cohort Lite Enrollee ○ Non-Retro Subject - Cohort Lite Enrollee ○ Full Cohort Era - Consented to Retrospective & Prospective Chart Review & Abstraction Only ○ Former Retro Subject - Consented to Retrospective & Prospective Chart Review & Abstraction Only	*(If "yes" to Retro study subject)* What is this recipient subject's Retro BioDBx Subject Label?

○ Bridge Era - Consented to Retrospective & Prospective Chart Review & Abstraction Only

○ Bridge - Retrospective Chart Review and Abstraction Only

○ LADR Subject - waiting for donor's eval appointment

PXID Number:

Has the subject ever had a liver transplant?
○ Yes
○ No

If "yes" to previous liver transplant.

How many liver transplants has the subject had?
○ 1
○ 2
○ 3
○ ≥4

1st liver transplant type:
○ LDLT
○ DDLT - whole graft
○ DDLT - split graft
○ Domino transplant

1st liver transplant date:

MM/DD/YYYY

2nd liver transplant type:	○ LDLT ○ DDLT - whole graft ○ DDLT - split graft ○ Domino transplant	2nd liver transplant date: _____ *MM/DD/YYYY*
3rd liver transplant type:	○ LDLT ○ DDLT - whole graft ○ DDLT - split graft ○ Domino transplant	3rd liver transplant date: _____ *MM/DD/YYYY*
Is the subject currently a participant in another research study? ○ Yes ○ No ○ Unknown	If the subject is a participant in another study, what is the name of the study? _____	

If you answered "No" to any question in the Eligibility Criteria section, the subject is NOT ELIGIBLE for enrollment in the A2ALL Cohort Study. ○

Start Time: 17:49:22Stop Time: 17:49:23Time To Generate: 0 seconds

save reset cancel print

RCP Condition @ Time of DNR Evaluation

Samples/Labs/Procedures at Recipient Condition @ DNR Evaluation (for full Cohort Subjects)

*15ml of whole blood, spun, and serum aliquotted into ten 0.4ml samples (to be frozen and batch-shipped to McKesson BioSample Repository)

*Labs

*HLA Typing

*AFP

*Keris: QOL Assessment (SF-36)

Every question on this form refers to this recipient candidate's condition at the time of the evaluation of the first donor 18 years of age or older whose evaluation took place on or after January 1, 1998 (even if they didn't donate).

Date of first donor evaluation (actual or scheduled) that made this subject eligible for study entry:	*MM/DD/YYYY*
This subject was a subject in the Retro study and the subject's condition at the time of donor evaluation was recorded on the Retro form, RCP Condition @ Enrollment.	☐ **If you have checked this box, the only fields on the remainder of the form that you need to answer are: Functional Status (different answers from Retro), Diastolic and Systolic Blood Pressure, Serum Sodium, AFP and HLA (these questions were not included in the Retro study).**
Recipient state of permanent residence at time of donor evaluation:	
Recipient highest education level at time of donor evaluation:	○ None ○ Grade School (0-8) ○ High school (9-12) ○ Attended college/Technical school ○ Associate/Bachelor degree ○ Post-college Graduate degree ○ Unknown

Recipient medical condition at time of donor evaluation	○ Patient in ICU ○ Hospitalized, not in ICU ○ Not Hospitalized
Recipient on ventilator at time of donor evaluation?	○ Yes ○ No
Recipient functional status at time of donor evaluation	○ Normal, no complaints or evidence of disease ○ Able to perform normal activity; minor signs and symptoms of disease ○ Able to perform normal activity with effort; some signs and symptoms of disease ○ Cares for self, unable to perform normal activity or to do active work ○ Requires occasional assistance but is able to care for most of own needs ○ Requires considerable assistance and frequent medical care ○ Requires special care and assistance; disabled ○ Hospitalization indicated, although death not imminent; severely disabled ○ Hospitalization necessary; active supportive treatment required, very sick ○ Fatal processes progressing rapidly; moribund ○ Dead
Recipient employment status at time of donor evaluation	○ Working full time ○ Working part time by choice ○ Working part time due to disease ○ Working part time reason unknown ○ Not working by choice ○ Not working due to disease ○ Not working, unable to find employment ○ Not working, reason unknown ○ Retired ○ Employment status unknown

Primary payment source:	○ Medicare ○ Medicaid ○ US State/Gov't Agency ○ Private Insurance ○ HMO/PPO ○ Self ○ Donation ○ Free Care ○ Dept. Veterans' Affairs ○ Pending ○ Foreign Gov't ○ Unknown ○ Other (specify)
Specify "other" primary payment source:	
Recipient height	○ Inches ○ Centimeters
Recipient weight at time of donor evaluation	○ Kilograms ○ Pounds
Recipient systolic BP	mm/Hg
Recipient diastolic BP	mm/Hg
Recipient primary diagnosis at time of donor evaluation	
Specify "other" primary diagnosis	
Recipient secondary diagnosis at time of donor evaluation	
Specify "other" secondary diagnosis	

Recipient tertiary diagnosis at time of donor evaluation

Specify "other" tertiary diagnosis

Recipient hepatocellular carcinoma diagnosis at the time of time of donor evaluation

If "yes", fill out "HCC @ Enrollment".

- ○ Yes
- ○ No

Recipient hepatitis C diagnosis at the time of time of donor evaluation

If "yes", complete "HCV @ Enrollment".

- ○ Yes
- ○ No

Recipient encephalopathy prior to time of donor evaluation

- ○ Yes
- ○ No
- ○ Unknown

Recipient variceal bleeding prior to time of donor evaluation

- ○ Yes
- ○ No
- ○ Unknown

Recipient ascites prior to time of donor evaluation

- ○ Yes
- ○ No
- ○ Unknown

Recipient previous upper abdominal surgery prior to time of donor evaluation

- ○ Yes
- ○ No
- ○ Unknown

Check all that apply:

- Cholecystectomy ☐
- Gastric Resection ☐
- Small Bowel Resection ☐
- Ulcer Operation ☐
- Upper Abdominal Surgery, Other (specify)

Recipient spontaneous bacterial peritonitis prior to time of donor evaluation

- ○ Yes
- ○ No

Recipient history of TIPSS prior to time of donor evaluation	○ Yes ○ No
Recipient diabetes mellitus at time of donor evaluation	○ No ○ Yes, Insulin Dependent ○ Yes, Non-insulin Dependent ○ Yes, Type Unknown ○ Other
(if patient has diabetes) Diabetes Treatment	○ Insulin ○ Oral Agent ○ Both Insulin and Oral Agent ○ No medications
Recipient dialysis at time of donor evaluation	○ Yes ○ No
Recipient angina/coronary artery disease prior to time of donor evaluation	○ Yes ○ No ○ Unknown
Recipient drug treated systemic hypertension at time of donor evaluation	○ Yes ○ No

Recipient serum creatinine closest to time of donor evaluation	mg/dl	Not Done ☐
Recipient total serum albumin closest to time of donor evaluation	g/dl	Not Done ☐
Recipient total bilirubin closest to time of donor evaluation	mg/dl	Not Done ☐
Recipient PT closest to time of donor evaluation:		Not Done ☐
Recipient INR closest to time of donor evaluation:		Not Done ☐
Serum AST closest to time of donor evaluation	IU/L	Not Done ☐

Serum ALT closest to time of donor evaluation		IU/L	Not Done ☐
Serum Alkaline Phosphate (ALK) value closest to time of donor evaluation		IU/L	Not Done ☐
Record value of AFP closest to time of donor evaluation:		ng/ml	Not Done ☐
Record serum sodium value closest to time of donor evaluation:		MEq/L	Not Done ☐
Was HLA-ABDR antigen testing done?	○ Yes ○ No		*(If HLA-ABDR antigen testing was done)* Record first HLA-A antigen:
			Record second HLA-A antigen:
			Record first HLA-B antigen:
			Record second HLA-B antigen:
			Record first HLA-DR antigen:
			Record second HLA-DR antigen:

save reset cancel print

HCV Data @ Donor Evaluation

Samples/Labs/Procedures for Subjects with HCV at Enrollment

*HCV Labs

HCV RNA result closest to donor evaluation	○ Positive ○ Negative ○ Indeterminate ○ Not Done
Date of HCV RNA	MM/DD/YYYY
Was the patient receiving anti-viral treatment at the time of donor evaluation?	○ Yes ○ No
(If "yes" to HCV treatment) Was the patient receiving interferon at the time of donor evaluation?	○ Yes ○ No
(if "yes" to receiving interferon): What type of interferon was the patient receiving at to donor evaluation?	○ Standard interferon ○ PEG interferon ○ Consensus interferon ○ Unknown interferon
Record the date of initiation of interferon treatment (date should be prior to donor evaluation):	MM/DD/YYYY

(if "yes" to HCV treatment): Was the patient receiving ribavirin at the time of donor evaluation? ○ Yes ○ No	(if receiving ribavirin): Record the date of initiation of ribavirin treatment: [ ] MM/DD/YYYY
Did the patient undergo a course of HCV treatment prior to donor evaluation (do not count ongoing treatment that was occuring at the time of to donor evaluation)? ○ Yes ○ No ○ Unknown	What was the length of HCV treatment course prior to donor evaluation? ○ < 3 months ○ 3-6 months ○ > 6 months

(if "yes" to prior HCV treatment) Type of HCV treatment(s) prior to to donor evaluation:

Check all that apply

Standard interferon	☐
PEG interferon	☐
Consensus interferon	☐
Ribavirin	☐
Other	☐
Specify "other" prior HCV treatment	[ ]

save reset cancel print

A2ALL
Adult to Adult Living Donor Liver Transplantation Cohort Study

HCC Data at Enrollment

Samples/Procedures for Subjects with HCC at Enrollment

*Results from HCC imaging studies

HCC Location	○ Right Lobe Only ○ Left Lobe Only ○ Bilobar
What was the highest tumor score prior to enrollment?	*For tumor stage definitions, please see the study Manual of Operations.* ○ Stage I ○ Stage II ○ Stage III ○ Stage IVA ○ Stage IVB ○ Unknown
Date of the last abdominal CT scan or MRI that occurred prior to enrollment used to stage HCC	MM/DD/YYYY
Number of HCC Nodules in the liver	○ 0 (None) ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6+
Size of nodule 1 (cm)	
Size of nodule 2 (cm)	

Size of nodule 3 (cm)	
Size of nodule 4 (cm)	
Size of nodule 5 (cm)	
Size of nodule 6 (cm)	
Vascular Invasion	○ No ○ Yes, portal vein ○ Yes, other vascular structures
If yes to portal vein invasion **Location of tumor invasion on the portal vein (choose at least one)** Main Portal Vein	☐
Right Portal Vein	☐
Left Portal Vein	☐
Right-sided branches	☐
Left-sided branches	☐
Primary Tumor Classification	○ T0: Not Found ○ T1: one nodule < 1.9cm ○ T2: one nodule 2.0-5.0cm OR 2-3 nodules all < 3.0cm ○ T3: one nodule >5.0cm OR 2-3 nodules at least one > 3.0 cm ○ T4a: 4 or more nodules, any size ○ T4b: T2, T3 or T4a plus gross intrahepatic portal or hepatic vein involvement ○ TX: Not assessed

Evidence of HCC in regional lymph nodes	○ N0 : no regional (porta hepatitis) nodes involved ○ N1: regional (porta hepatitis) nodes involved ○ NX: not assessed.
Cancer spread beyond the liver	○ M0: no metastatic disease including extrahepatic portal or hepatic vein involvement ○ M1 metastatic disease including extrahepatic portal or hepatic vein involvement ○ MX not assessed
How many ablations did the patient receive prior to enrollment? (record 0 for none)	

For each ablation type, enter the number of ablations performed (0 for none)

Radiofrequency ablation	○ 0 (none)	○ 1	○ 2	○ 3	○ 4	○ 5	○ >5
Cryotherapy	○ 0 (none)	○ 1	○ 2	○ 3	○ 4	○ 5	○ >5
Alcohol Ablation	○ 0 (none)	○ 1	○ 2	○ 3	○ 4	○ 5	○ >5
Chemoembolization	○ 0 (none)	○ 1	○ 2	○ 3	○ 4	○ 5	○ >5
Chemoinfusion	○ 0 (none)	○ 1	○ 2	○ 3	○ 4	○ 5	○ >5
Surgical Resection	○ 0 (none)	○ 1	○ 2	○ 3	○ 4	○ 5	○ >5

If yes to resection, Type of Surgical Resection	○ Wedge ○ Segment ○ Lobe ○ Non-anatomic

Chemotherapy treatment prior to enrollment	○ Yes, Systemic ○ Yes, Local ○ Yes, Both ○ No ○ Unknown

Chemotherapeutic agent used (Check all that apply)	
Adriamycin	☐
Cisplatin	☐
5FU	☐
Unknown	☐
Other	☐
Specify other chemo agent	

Radiation treatment prior to enrollment	○ Yes ○ No ○ Unknown

save reset cancel print

RCP First Pre-TXP Quarterly Assessment

Samples/Labs to be Collected at Recipient Pre-TXP Quarterly Assessments

*15ml of whole blood, spun, and serum aliquotted into ten 0.4ml samples (to be frozen and batch-shipped to McKesson BioSample Repository)

*Labs

*AFP

Visit Missed ☐

What date was the patient seen for this assessment? _____ MM/DD/YYYY

What was the patient's listing status at the previous assessment?
- ○ Listed
- ○ Not Listed

Did this patient receive a MELD exception since the last assessment?
- ○ Yes
- ○ No

If "yes" to MELD exception

What type of MELD exception did the patient receive?
- ○ Small HCC
- ○ Large HCC
- ○ Hepatopulmonary Syndrome
- ○ Other (specify)

Specify "other" MELD exception _____

What is the recipient's current status?
- ○ Alive
- ○ Dead
- ○ Unknown

(If dead)

What was the patient's date of death? _____ MM/DD/YYYY

Select the primary cause of death from the list: _____

Select the secondary cause of death from the list: _____

Select the tertiary cause of death from the list: _____

(if status is unknown)

What was the last known date of contact with the patient? _____ MM/DD/YYYY

Has the patient been hospitalized since the last assessment? *(If "Yes", fill out a Hospitalization Form for each hospitalization that occurred during this interval)*	○ Yes ○ No ○ Unknown
(If "Yes", to hospitalizations) *Each hospitalization requires a separate Hospitalization Form.* How many hospitalizations have occurred since the last assessment? *Leave blank for "None"*	

Recipient medical condition at this assessment	○ Patient in ICU ○ Hospitalized, not in ICU ○ Not Hospitalized
Recipient on ventilator at this assessment?	○ Yes ○ No
Recipient functional status at this assessment	○ Normal, no complaints or evidence of disease ○ Able to perform normal activity; minor signs and symptoms of disease ○ Able to perform normal activity with effort; some signs and symptoms of disease ○ Cares for self, unable to perform normal activity or to do active work ○ Requires occasional assistance but is able to care for most of own needs ○ Requires considerable assistance and frequent medical care ○ Requires special care and assistance; disabled ○ Hospitalization indicated, although death not imminent; severely disabled ○ Hospitalization necessary; active supportive treatment required, very sick ○ Fatal processes progressing rapidly; moribund ○ Dead
Recipient employment status at this assessment:	○ Working full time ○ Working part time by choice ○ Working part time due to disease ○ Working part time reason unknown ○ Not working by choice ○ Not working due to disease ○ Not working, unable to find employment ○ Not working, reason unknown ○ Retired ○ Employment status unknown

Primary source of payment:	○ Medicare ○ Medicaid ○ US State/Gov't Agency ○ Private Insurance ○ HMO/PPO ○ Self ○ Donation ○ Free Care ○ Dept. Veterans' Affairs ○ Pending ○ Foreign Gov't ○ Unknown ○ Other (specify)
Specify "other" primary source of payment:	
Recipient weight at this assessment	○ Kilograms ○ Pounds
Recipient systolic blood pressure at this assessment:	*mm/Hg*
Recipient diastolic blood pressure at this assessment:	*mm/Hg*
At the last assessment, the recipient's primary diagnosis was &RECIP_PRIMDX_ENROLL If the primary diagnosis has changed, choose the new primary diagnosis from the list.	
Specify "other" new primary diagnosis	
At the last assessment, the recipient's secondary diagnosis was &RECIP_SECDX_ENROLL If the secondary diagnosis has changed, choose the new secondary diagnosis from the list.	
Specify "other" new secondary diagnosis	
At the last assessment, the recipient's tertiary diagnosis was &RECIP_TERTDX_ENROLL If the tertiary diagnosis has changed, choose the new tertiary diagnosis from the list.	

Specify "other" new tertiary diagnosis	
Has the patient had encephalopathy between the last assessment and this one?	○ Yes ○ No
Has the patient had variceal bleeding between the last assessment and this one?	○ Yes ○ No
Has the patient had ascites between the last assessment and this one?	○ Yes ○ No

Has the patient had upper abdominal surgery between the last assessment and this one?	○ Yes ○ No ○ Unknown	*If "Yes" to upper abdominal surgery.* **Check all that apply.**	
		Cholecystectomy	☐
		Gastric Resection	☐
		Ulcer Operation	☐
		Small Bowel Resection	☐
		Other	☐

Has the patient had spontaneous bacterial peritonitis between the last assessment and this one?	○ Yes ○ No
Has the patient had a history of TIPSS between the last assessment and this one?	○ Yes ○ No
Recipient diabetes mellitus at this assessment?	○ No ○ Yes, Insulin Dependent ○ Yes, Non-insulin Dependent ○ Yes, Type Unknown ○ Other
(if patient has diabetes) Diabetes Treatment	○ Insulin ○ Oral Agent ○ Both Insulin and Oral Agent ○ No medications
Recipient dialysis at this assessment?	○ No ○ Hemodialysis/CVVHD ○ Peritoneal Dialysis ○ Dialysis-Unknown type ○ Unknown
Has the patient developed coronary artery disease between the last assessment and this one?	○ Yes ○ No
Recipient drug-treated systemic hypertension present at this assessment?	○ Yes ○ No

Record the serum creatinine value at this assessment:	*mg/dl*
	☐ Not Done
Record the total serum bilirubin value at this assessment:	*mg/dl*
	☐ Not Done
Record the total serum albumin value at this assessment:	*g/dl*
	☐ Not Done
Record the INR value at this assessment:	
	☐ Not Done
Record the PT value at this assessment:	
	☐ Not Done
Record the serum aspartate transaminase (AST) value at this assessment:	*IU/L*
	☐ Not Done
Record the serum alanine aminotransferase (ALT) value at this assessment:	*IU/L*
	☐ Not Done
Record the serum alkaline phosphatase (ALK) value at this assessment:	*U/L*
	☐ Not Done
Record serum sodium at this assessment:	MEq/L

	☐ Not Done
Record the AFP value at this assessment:	*ng/ml*
	☐ Not Done

Was the patient brought to the operating room with the intention of receiving a liver transplant during this interval?	○ Yes ○ No ○ Unknown
Did the patient receive a liver transplant during this interval?	○ Yes ○ No ○ Unknown

if "yes" to liver transplant

What was the date of transplant?

MM/DD/YYYY

if "yes" to liver transplant

What type of donor provided the liver for transplantation?	○ Living Donor ○ Deceased Donor
Has the patient's listing status changed since the previous assessment?	○ Yes ○ No

if "yes" to Change in Listing Status

How has the patient's listing status changed since the previous assessment?	○ Listed ○ Removed from list

if listed since last assessment

What was the date of listing? MM/DD/YYYY

if removed from list since last assessment

What was the date of removal from the waiting list? MM/DD/YYYY

if removed from list since last assessment

Why was the patient removed from the wait list at your transplant center?

Hepatocellular carcinoma diagnosis since previous assessment? *If new diagnosis or previously reported, fill out "HCC Pre-TXP Quarterly Assessment".*	○ Yes ○ No ○ Unknown
Hepatitis C diagnosis since previous assessment? *If new diagnosis or previously reported, fill out "HCV Pre-TXP Quarterly Assessment".*	○ Yes ○ No ○ Unknown
Is the subject currently a partipant in another research study?	○ Yes, new to this assessment interval. ○ Yes, previously reported. ○ No ○ Unknown

If the subject is a participant in another research study, what is the name of that study?	

save reset cancel print

HCV First Pre-TXP Quarterly Assessment

Samples/Procedures for Subjects with HCV at Pre-TXP Quarterly Assessments

*HCV Labs

What date did this assessment occur?

MM/DD/YYYY

Record most recent RNA result since enrollment/last assessment:

- ○ Positive
- ○ Negative
- ○ Indeterminate
- ○ Not Done

Record the date of the RNA test:

MM/DD/YYYY

Was ongoing treatment for HCV being given at last assessment?

- ○ Yes
- ○ No

Was the patient receiving any anti-viral treatment during the 3 months covered by this assessment?

- ○ Yes
- ○ No

(if "Yes" to HCV treatment)
What type of HCV treatment(s) did the patient receive during the interval between the last assessment and this one?
Check all that apply.

- ☐ Standard Interferon
- ☐ PEG Interferon
- ☐ Consensus Interferon

Ribavirin	☐
Other treatment	☐
Specify "other treatment"	
Record the date of initiation of HCV treatment:	MM/DD/YYYY
Was ongoing treatment with interferon being given at the last assessment?	○ Yes ○ No
If subject was receiving interferon at the last assessment, record the date of completion of interferon treatment:	MM/DD/YYYY
Not Applicable, interferon treatment continuing.	☐
Was ongoing treatment with ribavirin being given at the last assessment?	○ Yes ○ No
If patient was receiving ribavirin at the last assessment, record the date of completion of ribavirin treatment:	MM/DD/YYYY
Not Applicable, ribavirin treatment continuing.	☐

save reset cancel print

HCC First Pre-TXP Quarterly Assessment

Samples/Labs/Procedures for Subject with HCC at Pre-TXP Quarterly Assessments

*Imaging studies

Date of assessment:	MM/DD/YYYY
HCC Location	○ Right Lobe Only ○ Left Lobe Only ○ Bilobar
Date of the last abdominal CT scan or MRI that occurred since the last assessment to stage HCC:	MM/DD/YYYY
Number of HCC nodules in the liver?	○ 0 (None) ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6+
Size of nodule 1	cm
Size of nodule 2	cm
Size of nodule 3	cm
Size of nodule 4	cm
Size of nodule 5	cm

Size of nodule 6	cm
Vascular Invasion	○ No ○ Yes, portal vein ○ Yes, other vascular structures
(if "yes" to portal vein invasion), **Location of tumor invasion on the portal vein. (Choose at least one).**	
Main Portal Vein	☐
Right Portal Vein	☐
Left Portal Vein	☐
Right-Sided Branches	☐
Left-Sided Branches	☐
Primary Tumor Classification	○ T0: Not Found ○ T1: one nodule < 1.9cm ○ T2: one nodule 2.0-5.0cm OR 2-3 nodules all < 3.0cm ○ T3: one nodule >5.0cm OR 2-3 nodules at least one > 3.0 cm ○ T4a: 4 or more nodules, any size ○ T4b: T2, T3 or T4a plus gross intrahepatic portal or hepatic vein involvement ○ TX: Not assessed
Evidence of HCC in regional lymph nodes	○ N0 : no regional (porta hepatitis) nodes involved ○ N1: regional (porta hepatitis) nodes involved ○ NX: not assessed.

Cancer spread beyond the liver	○ M0: no metastatic disease including extrahepatic portal or hepatic vein involvement ○ M1 metastatic disease including extrahepatic portal or hepatic vein involvement ○ MX not assessed

How many ablations did the patient receive since the last assessment? [ ]

Enter "0" for none

For each ablation type, enter the number of ablations performed ("0" for none):

Radiofrequency ablation	○ 0 (none)	○ 1	○ 2	○ 3	○ 4	○ 5	○ >5
Cryotherapy	○ 0 (none)	○ 1	○ 2	○ 3	○ 4	○ 5	○ >5
Alcohol ablation	○ 0 (none)	○ 1	○ 2	○ 3	○ 4	○ 5	○ >5
Chemoembolization	○ 0 (none)	○ 1	○ 2	○ 3	○ 4	○ 5	○ >5
Chemoinfusion	○ 0 (none)	○ 1	○ 2	○ 3	○ 4	○ 5	○ >5
Surgical resection	○ 0 (none)	○ 1	○ 2	○ 3	○ 4	○ 5	○ >5

(if "yes" to surgical resection)

Type of surgical resection	○ Wedge ○ Segment ○ Lobe ○ Non-anatomic

Has the patient received chemotherapy treatment since the last assessment?	○ Yes, Systemic ○ Yes, Local ○ Yes, Both ○ No ○ Unknown
Chemotherapeutic agent used (check all that apply):	
Adriamycin	☐
Cisplatin	☐
5FU	☐
Unknown chemotherapeutic agent	☐
Other (specify):	
Did the patient receive radiation therapy since the last assessment?	○ Yes ○ No
Result of bone scan done at this assessment	○ Extra-hepatic metastases found ○ No metastatic spread found ○ Not done
Result of the chest CT done at this assessment	○ Extra-hepatic metastases found ○ No metastatic spread found ○ Not done
Result of the MRI/CT scan done at this assessment.	○ Extra-hepatic metastases found ○ No metastatic spread found ○ Not done

save reset cancel print

A2ALL
Adult to Adult Living Donor Liver Transplantation Cohort Study

Donor Intraoperative Data

Samples to Be Collected at Donation Surgery

Immediately Pre-op

**15ml of whole blood, spun and serum aliquotted into ten 0.4ml containers and frozen

**Blood for HLA testing

**Whole Blood for Genetics Repository

Prior to Removal of Right Lobe

**2 liver Bx samples of right lobe in 2ml container preserved in RNALater

**1 liver Bx sample of right lobe in 2ml container preserved in formalin

**15ml of whole blood, spun and serum aliquotted into ten 0.4ml containers and frozen

30-60 Minutes After Cross-Clamp

**15 of whole blood, spun and serum aliquotted into ten 0.4ml containers and frozen

All of the above samples to be batch-shipped to McKesson BioSample Repository

*

Reminder:
Remember that the donation surgery counts as a hospitalization and should have a Hospitalization Form associated with it.

Date of donation surgery:	MM/DD/YYYY

PXID Number:		
Record the ALT value closest to the time of donation: *iu/L*		Not Done ☐
Record the AST value closest to the time of donation: *iu/L*		Not Done ☐
Record the ALK value closest to the time of donation: *iu/L*		Not Done ☐
Record the total bilirubin value closest to the time of donation: *mg/dl*		Not Done ☐
Record the serum creatinine value closest to the time of donation: *mg/dl*		Not Done ☐
Record the albumin value closest to the time of donation: *g/dl*		Not Done ☐
Record the blood urea nitrogen (BUN) value closest to the time of donation: *mg/dl*		Not Done ☐
Record the INR value at time of donation:		Not Done ☐

Record the white blood cell count (WBC) closest to the time of donation: *x10³mm³*	Not Done ☐
Record the ferritin value closest to the time of donation: *ng/ml*	Not Done ☐
Record the hemoglobin (Hgb) value at time of donation: *g/dl*	Not Done ☐
Record the platelet value closest to the time of donation: *x10³mm³*	Not Done ☐
Record the homocysteine value closest to the time of donation: *umd/L*	Not Done ☐
Was HLA-ABDR antigen testing done? ○ Yes ○ No	*(If HLA-ABDR antigen testing was done)* Record first HLA-A antigen:
	Record second HLA-A antigen:
	Record first HLA-B antigen:
	Record second HLA-B antigen:
	Record first HLA-DR antigen:

	Record second HLA-DR antigen:
Was the donation procedure aborted before completion? ○ Yes ○ No	*(If "yes" to procedure abortion)* Why was the procedure aborted? Check all that apply. Quality of donor liver ☐
	Insufficient liver mass ☐
	Technical difficulties in the donor ☐
	Donor instability ☐
	Unexpected medical findings in recipient ☐
	Recipient instability ☐
	Recipient death on table ☐
	Other ☐
	Specify "other" reason for procedure abortion:
Was the resected graft transplanted into the recipient? ○ Yes ○ No	*(If "no" to graft transplantation)* Why wasn't the resected graft transplanted into the recipient? Check all that apply. Quality of donor liver ☐
	Insufficient liver mass ☐
	Recipient instability ☐
	Unexpected medical findings in recipient ☐

	Recipient death on table ☐
	Other ☐
	Specify "other" reason why the resected graft was not transplanted into the recipient:
Was a pre-operative or intraoperative biopsy of the donor liver performed? ○ Yes ○ No	*(If "yes" to preop/ intraop liver Bx)* What was the percentage of macrovesicular and microvesicular fat noted on the biopsy report? Percentage of **macrovesicular** fat: %
	Percentage of **microvesicular** fat: %
	Other findings (specify)
	No other findings noted. ☐
General anesthesia start date: *MM/DD/YYYY*	General anesthesia end date: *MM/DD/YYYY*
General anesthesia start time: *HHMM*	General anesthesia end time: *HHMM*
Date of first skin incision: *MM/DD/YYYY*	Date of skin closure: *MM/DD/YYYY*
Time of first skin incision: *HHMM*	Time of skin closure: *HHMM*

Total number of hepatic veins from the right lobe >5mm preserved for anastomosis:	○1 ○2 ○3 ○4 ○5
Site of the first hepatic vein preserved for anastomosis:	Specify "other" site of first hepatic vein preserved for anastomosis:
Site of the second hepatic vein preserved for anastomosis:	Specify "other" site of second hepatic vein preserved for anastomosis:
Site of the third hepatic vein preserved for anastomosis:	Specify "other" site of third hepatic vein preserved for anastomosis:
Site of the fourth hepatic vein preserved for anastomosis:	Specify "other" site of fourth hepatic vein preserved for anastomosis:
Site of the fifth hepatic vein preserved for anastomosis:	Specify "other" site of fifth hepatic vein preserved for anastomosis:
How many portal vein(s) to right lobe?	
How many hepatic arteries to right lobe?	
How many bile ducts from right lobe?	

What was the weight of the right lobe of the donor liver after resection?

gm

What was the percentage of residual volume in the remnant liver?

%

What were the results of the post-resection cholangiogram?

- ○ Normal
- ○ Stricture
- ○ Leak
- ○ Not Done

What solution was used to preserve the graft?

- ○ UW - Viaspan
- ○ HTK - Custodiol
- ○ Crytalloid
- ○ Eurocollins
- ○ Other

Was auto-transfusion used?

- ○ Yes
- ○ No

If "yes" to auto-transfusion

Total amount transfused:

cc

Number of units of transfused packed RBC's during donation surgery:

Enter "0" for "none"

Did the subject experience episode(s) of hypotension (systolic BP < 100 mmHg) during the surgery?

- ○ Yes
- ○ No

(If "yes" to hypotensive episode)

Total duration of the hypotensive episode (s). If more than one episode occured, add them together.

minutes

Did the subject experience a systolic BP < 80 mmHg for five or more continuous minutes?

- ○ Yes
- ○ No

Did an intraoperative injury occur? ○ Yes ○ No	What structure(s) were injured (check all that apply)?
	Bile Duct ☐
	Hepatic Artery ☐
	Portal Vein ☐
	Other ☐
	Specify "other" structure injured:
Did other complications occur during the surgery? ○ Yes ○ No	*(if "yes" to other complications)* What other complication(s) occurred?
Were there other surgical procedures performed at the time of donor surgery? ○ Yes ○ No	*(if "yes" to other surgical procedures)* What other surgery(s) was performed?

save reset cancel print

A2ALL
Adult to Adult Living Donor Liver Transplantation Cohort Study

RCP Condition at Transplant

Samples/Labs to be Collected at Recipient Pre-TXP Quarterly Assessments

*See Intraop Form for summary of samples to be collected at Transplant

*Labs

*AFP

What date was the patient seen for this assessment? MM/DD/YYYY

What was the patient's listing status at the previous assessment?
- ○ Listed
- ○ Not Listed

Did this patient receive a MELD exception since the last assessment?
- ○ Yes
- ○ No

If "yes" to MELD exception

What type of MELD exception did the patient receive?
- ○ Small HCC
- ○ Large HCC
- ○ Hepatopulmonary Syndrome
- ○ Other (specify)

Specify "other" MELD exception

What is the recipient's current status?
- ○ Alive
- ○ Dead
- ○ Unknown

(If dead)

What was the patient's date of death? MM/DD/YYYY

Select the primary cause of death from the list:

Select the secondary cause of death from the list:

Select the tertiary cause of death from the list:

(if status is unknown)

What was the last known date of contact with the patient? MM/DD/YYYY

Has the patient been hospitalized since the last assessment? *(If "Yes", fill out a Hospitalization Form for each hospitalization that occurred during this interval)*	○ Yes ○ No ○ Unknown
(If "Yes", to hospitalizations) *Each hospitalization requires a separate Hospitalization Form.* How many hospitalizations have occurred since the last assessment? *Leave blank for "None"*	

Recipient medical condition at this assessment	○ Patient in ICU ○ Hospitalized, not in ICU ○ Not Hospitalized
Recipient on ventilator at this assessment?	○ Yes ○ No
Recipient functional status at this assessment	○ Normal, no complaints or evidence of disease ○ Able to perform normal activity; minor signs and symptoms of disease ○ Able to perform normal activity with effort; some signs and symptoms of disease ○ Cares for self, unable to perform normal activity or to do active work ○ Requires occasional assistance but is able to care for most of own needs ○ Requires considerable assistance and frequent medical care ○ Requires special care and assistance; disabled ○ Hospitalization indicated, although death not imminent; severely disabled ○ Hospitalization necessary; active supportive treatment required, very sick ○ Fatal processes progressing rapidly; moribund ○ Dead
Recipient employment status at this assessment:	○ Working full time ○ Working part time by choice ○ Working part time due to disease ○ Working part time reason unknown ○ Not working by choice ○ Not working due to disease ○ Not working, unable to find employment ○ Not working, reason unknown ○ Retired ○ Employment status unknown

Primary source of payment:	○ Medicare ○ Medicaid ○ US State/Gov't Agency ○ Private Insurance ○ HMO/PPO ○ Self ○ Donation ○ Free Care ○ Dept. Veterans' Affairs ○ Pending ○ Foreign Gov't ○ Unknown ○ Other (specify)
Specify "other" primary source of payment:	
Recipient weight at this assessment	○ Kilograms ○ Pounds
Recipient systolic blood pressure at this assessment:	*mm/Hg*
Recipient diastolic blood pressure at this assessment:	*mm/Hg*
At the last assessment, the recipient's primary diagnosis was &RECIP_PRIMDX_ENROLL If the primary diagnosis has changed, choose the new primary diagnosis from the list.	
Specify "other" new primary diagnosis	
At the last assessment, the recipient's secondary diagnosis was &RECIP_SECDX_ENROLL If the secondary diagnosis has changed, choose the new secondary diagnosis from the list.	
Specify "other" new secondary diagnosis	
At the last assessment, the recipient's tertiary diagnosis was &RECIP_TERTDX_ENROLL If the tertiary diagnosis has changed, choose the new tertiary diagnosis from the list.	

Specify "other" new tertiary diagnosis	
Has the patient had encephalopathy between the last assessment and this one?	○ Yes ○ No
Has the patient had variceal bleeding between the last assessment and this one?	○ Yes ○ No
Has the patient had ascites between the last assessment and this one?	○ Yes ○ No

Has the patient had upper abdominal surgery between the last assessment and this one?	○ Yes ○ No ○ Unknown	*If "Yes" to upper abdominal surgery.* **Check all that apply.**	
		Cholecystectomy	☐
		Gastric Resection	☐
		Ulcer Operation	☐
		Small Bowel Resection	☐
		Other	☐

Has the patient had spontaneous bacterial peritonitis between the last assessment and this one?	○ Yes ○ No
Has the patient had a history of TIPSS between the last assessment and this one?	○ Yes ○ No
Recipient diabetes mellitus at this assessment?	○ No ○ Yes, Insulin Dependent ○ Yes, Non-insulin Dependent ○ Yes, Type Unknown ○ Other
(if patient has diabetes) Diabetes Treatment	○ Insulin ○ Oral Agent ○ Both Insulin and Oral Agent ○ No medications
Recipient dialysis at this assessment?	○ No ○ Hemodialysis/CVVHD ○ Peritoneal Dialysis ○ Dialysis-Unknown type ○ Unknown
Has the patient developed coronary artery disease between the last assessment and this one?	○ Yes ○ No
Recipient drug-treated systemic hypertension present at this assessment?	○ Yes ○ No

Record the serum creatinine value at this assessment:	*mg/dl*
	☐ Not Done
Record the total serum bilirubin value at this assessment:	*mg/dl*
	☐ Not Done
Record the total serum albumin value at this assessment:	*g/dl*
	☐ Not Done
Record the INR value at this assessment:	
	☐ Not Done
Record the PT value at this assessment:	
	☐ Not Done
Record the serum aspartate transaminase (AST) value at this assessment:	*IU/L*
	☐ Not Done
Record the serum alanine aminotransferase (ALT) value at this assessment:	*IU/L*
	☐ Not Done
Record the serum alkaline phosphatase (ALK) value at this assessment:	*U/L*
	☐ Not Done
Record serum sodium at this assessment:	MEq/L

	☐ Not Done
Record the AFP value at this assessment:	*ng/ml*
	☐ Not Done

Was the patient brought to the operating room with the intention of receiving a liver transplant during this interval?	○ Yes ○ No ○ Unknown
Did the patient receive a liver transplant during this interval?	○ Yes ○ No ○ Unknown

if "yes" to liver transplant

What was the date of transplant?

MM/DD/YYYY

if "yes" to liver transplant

What type of donor provided the liver for transplantation?	○ Living Donor ○ Deceased Donor
Has the patient's listing status changed since the previous assessment?	○ Yes ○ No

if "yes" to Change in Listing Status

How has the patient's listing status changed since the previous assessment?

○ Listed

○ Removed from list

if listed since last assessment

What was the date of listing? MM/DD/YYYY

if removed from list since last assessment

What was the date of removal from the waiting list? MM/DD/YYYY

if removed from list since last assessment

Why was the patient removed from the wait list at your transplant center?

Hepatocellular carcinoma diagnosis since previous assessment? *If "yes", fill out "HCC Pre-TXP Quarterly Assessment".*	○ Yes ○ No ○ Unknown
Hepatitis C diagnosis since previous assessment? *If "yes", fill out "HCV Pre-TXP Quarterly Assessment".*	○ Yes ○ No ○ Unknown
Is the subject currently a partipant in another research study?	○ Yes, new to this assessment interval. ○ Yes, previously reported. ○ No ○ Unknown
If the subject is a participant in another research study, what is the name of that study?	

save reset cancel print

LDLT Recipient Intraoperative Data

Samples to Be Collected at TXP Surgery

Immediately Pre-op

**15ml of whole blood, spun and serum aliquotted into ten 0.4ml containers and frozen

On the Back Table

**2 liver Bx of graft in 2ml container preserved in RNALater

**1 liver Bx of graft in 2ml container preserved in formalin

**15ml of whole blood, spun and serum aliquotted into ten 0.4ml containers and frozen (anhepatic blood sample)

At 30-60 Minutes Post-Reperfusion

**2 liver Bx of graft in 2ml container preserved in RNALater

**1 liver Bx of graft in 2ml0 container preserved in formalin

**15ml of whole blood, spun and serum aliquotted into ten 0.4ml containers and frozen

All of the above samples to be batch-shipped to McKesson BioSample Repository.

*

Reminder:
Remember that the transplant surgery counts as a hospitalization and should have a Hospitalization Form associated with it.

Date of transplant surgery:

MM/DD/YYYY

Was the transplant procedure aborted before completion?

- ○ Yes
- ○ No

(If "yes" to procedure aborted)
Reason for Transplant Procedure Termination Prior to Completion (check all that apply)

- Quality of donor liver ☐
- Insufficient liver mass ☐
- Technical difficulties in donor ☐
- Donor instability ☐
- Unexpected medical findings in recipient ☐
- Recipient instability ☐
- Recipient death on table ☐
- Other ☐

Specify "other" reason for termination of transplant procedure prior to completion:

Graft type:

- ○ Right Lobe Living Donor
- ○ Left Lobe Living Donor
- ○ Living Donor Other

Cold ischemia time: minutes

(from time of donor cross clamp to the time the liver was taken out of ice)

Are portal and arterial reperfusion performed separately or simultaneously?

- ○ Separately
- ○ Simultaneously
- ○ Unknown

(if previous answer is separately, record warm ischemia time as out of ice to portal reperfusion time)

Warm ischemia time: _____ minutes

Time from portal reperfusion to arterialization: _____ minutes

(if portal and arterial perfusion are performed simultaneously or unknown, record warm ischemia time as out of ice to portal and arterial reperfusion time)

Warm ischemia time _____ minutes

General anesthesia start date: _____ *MM/DD/YYYY*

General anesthesia stop date: _____ *MM/DD/YYYY*

General anesthesia start time: _____ *HHMM*

General anesthesia stop time: _____ *HHMM*

Date of first skin incision: _____ *MM/DD/YYYY*

Date that skin closure was completed: _____ *MM/DD/YYYY*

Time of first skin incision _____ *HHMM*

Time that skin closure was completed: _____ *HHMM*

Number of hepatic venous anastomoses performed:

- ○ 1
- ○ 2
- ○ 3
- ○ 4

Describe the first living donor to recipient hepatic venous anastomosis: _____

Describe the second living donor to recipient hepatic venous anastomosis:

Describe the third living donor to recipient hepatic venous anastomosis:

Describe the fourth living donor to recipient hepatic venous anastomosis:

Did back-table hepatic venous reconstruction occur?
- ○ Yes
- ○ No

(if "yes" to back-table hepatic venous reconstruction)

Describe the type of back-table hepatic venous reconstruction:
- ○ Venoplasty
- ○ Anastomosis of hepatic veins
- ○ Graft venous anastomosis
- ○ Other

Specify "other" back-table hepatic venous reconstruction type:

(if "Graft venous anastomosis" chosen)

Type of graft venous anastomosis
- ○ Donor saphenous vein
- ○ Third-party vein
- ○ Synthetic vein
- ○ Other

Specify "other" graft venous anastomosis type:

Number of portal venous anastomoses performed:
○ 1 ○ 2 ○ 3 ○ 4 ○ 5

Describe the first portal venous anastomosis:

Describe the second portal venous anastomosis:

Describe the third portal venous anastomosis:

Describe the fourth portal venous anastomosis:

Describe the fifth portal venous anastomosis:

Did back-table portal venous reconstruction occcur?
- ○ Yes
- ○ No

(if "yes" to portal venous back-table reconstruction)

Type of back-table portal venous reconstruction:
- ○ Venoplasty
- ○ Anastomosis of portal veins
- ○ Graft venous anastomosis
- ○ Other

Specify "other" type of back-table portal venous reconstruction:

(if "graft venous anastomosis" was chosen)

Type of venous graft anastomosis:
- ○ Donor saphenous vein
- ○ Third-party vein
- ○ Synthetic vein
- ○ Other

Specify "other" graft anastomosis:

Number of arterial anastomoses: ○ 1 ○ 2 ○ 3

Describe the first arterial anastomosis:

Describe the second arterial anastomosis:

Describe the third arterial anastomosis:

Was a graft/conduit utilized to complete arterial anastomosis? ○ Yes ○ No

(If "yes" to graft utilization)

Specify what type of graft/conduit was used to complete arterial anastomosis:

Number of biliary anastomoses were performed: ○ 1 ○ 2 ○ 3 ○ 4 ○ 5

Describe the first biliary anastomosis:

Describe the second biliary anastomosis:

Describe the third biliary anastomosis:

Describe the fourth biliary anastomosis:

Describe the fifth biliary anastomosis:

Was there back-table biliary reconstruction: ○ Yes ○ No

(If "yes" to back-table biliary reconstruction)

Describe back-table biliary reconstruction: ○ Ductoplasty ○ Anastomosis of more than one duct into one orifice ○ Other

Specify "other" back-table biliary reconstruction:

Were other non-transplant procedures performed during the operation? ○ Yes ○ No

(if "yes" to other surgical procedures)

What other non-transplant procedures performed during the operation?

How much ascites was suctioned out during the surgery? cc

Enter "0" for none

Was auto-transfusion used? ○ Yes ○ No

If "yes" to auto-transfusion

Total amount transfused: cc

How many units of packed red blood cells were given during the surgery? units

Enter "0" for none

save reset cancel print

DDLT Recipient Intraoperative Data

Samples to Be Collected at TXP Surgery

Immediately Pre-op

**15ml of whole blood, spun and serum aliquotted into ten 0.4ml containers and frozen

On the Back Table

**2 liver Bx of graft in 2ml container preserved in RNALater

**1 liver Bx of graft in 2ml container preserved in formalin

**15ml of whole blood, spun and serum aliquotted into ten 0.4ml containers and frozen (anhepatic blood sample)

At 30-60 Minutes Post-Reperfusion

**2 liver Bx of graft in 2ml container preserved in RNALater

**1 liver Bx of graft in 2ml container preserved in formalin

**15ml of whole blood, spun and serum aliquotted into ten 0.4ml containers and frozen

All of the above samples to be batch-shipped to McKesson BioSample Repository.

*

Reminder:
Remember that the transplant surgery counts as a hospitalization and should have a Hospitalization Form associated with it.

Date of transplant surgery:	MM/DD/YYYY
Deceased Donor HCV Antibody Test Result:	○ Positive ○ Negative ○ Unknown ○ Not Done
Deceased Donor Hep B Core Antibody Screen Result (HBcAb):	○ Positive ○ Negative ○ Unknown ○ Not Done
Was the transplant procedure aborted before completion?	○ Yes ○ No

(If "yes" to procedure aborted)
Reason for Transplant Procedure Termination Prior to Completion (check all that apply)

Quality of donor liver	☐
Insufficient liver mass	☐
Technical difficulties in donor	☐
Unexpected medical findings in recipient	☐
Recipient instability	☐
Recipient death on table	☐
Other	☐
Specify "other" reason for termination of transplant procedure prior to completion:	

Graft type:
- ○ Cadaveric Whole
- ○ Cadaveric Split
- ○ Cadaveric Other

Was cadaveric graft done as a piggy back?
- ○ Yes
- ○ No

Cold ischemia time: _____ minutes

(from time of donor cross clamp to the time the liver was taken out of ice)

Are portal and arterial reperfusion performed separately or simultaneously?
- ○ Separately
- ○ Simultaneously
- ○ Unknown

(if previous answer is separately, record warm ischemia time as out of ice to portal reperfusion time)

Warm ischemia time: _____ minutes

Time from portal reperfusion to arterialization: _____ minutes

(if portal and arterial perfusion are performed simultaneously, or unknown, record warm ischemia time as out of ice to portal and arterial reperfusion time)

Warm ischemia time _____ minutes

General anesthesia start date: _____ *MM/DD/YYYY*

General anesthesia stop date: _____ *MM/DD/YYYY*

General anesthesia start time: _____ *(HHMM)*

General anesthesia stop time: _____ *HHMM*

Date of first skin incision: *MM/DD/YYYY*	Date that skin closure was completed: *MM/DD/YYYY*
Time of first skin incision *HHMM*	Time that skin closure was completed *MMHH*
Did back-table portal venous reconstruction occcur? ○ Yes ○ No	*(if "yes" to portal venous back-table reconstruction)* Type of back-table portal venous reconstruction: ○ Venoplasty ○ Anastomosis of portal veins ○ Graft venous anastomosis ○ Other
	Specify "other" type of back-table portal venous reconstruction:
	(if "graft venous anastomosis" was chosen) Type of venous graft anastomosis: ○ Donor saphenous vein ○ Third-party vein ○ Synthetic vein ○ Other
	Specify "other" graft anastomosis:
Was a graft/conduit utilized to complete arterial anastomosis? ○ Yes ○ No	*(If "yes" to graft utilization)* Specify what type of graft/conduit was used to complete arterial anastomosis:

Number of arteries connected: ○1 ○2 ○3 ○4 ○5 ○6

Describe the first arterial connection:

Describe the second arterial connection:

Describe the third arterial connection:

Describe the fourth arterial connection:

Describe the fifth arterial connection:

Describe the sixth arterial connection:

Number of biliary anastomoses were performed: ○1 ○2 ○3 ○4 ○5

Describe the first biliary anastomosis:

Describe the second biliary anastomosis:

Describe the third biliary anastomosis:

Describe the fourth biliary anastomosis:

Describe the fifth biliary anastomosis:

Were other non-transplant procedures performed during the operation? ○ Yes ○ No

(if "yes" to other surgical procedures)

What other non-transplant procedures performed during the operation?

How much ascites was suctioned out during the surgery? cc

Enter "0" for none

Was auto-transfusion used? ○ Yes ○ No	*If "yes" to auto-transfusion* Total amount transfused: _____ cc
How many units of packed red blood cells were given during the surgery? *Enter "0" for none*	_____ units

save reset cancel print

A2ALL
Adult to Adult Living Donor Liver Transplantation Cohort Study

HCV @ TXP

Samples/Procedures for Subjects with HCV at Pre-TXP Quarterly Assessments

*HCV Labs

What date did this assessment occur? _____ MM/DD/YYYY

Record the date of the Quantitative RNA test that occurred closest to and **prior to** transplant: _____ MM/DD/YYYY

Quantitative RNA Result: _____

Units for HCV Quantification:
- ○ Copies/ml
- ○ Equiv/ml
- ○ IU/ml
- ○ Unknown

Lower Limit of Detection: _____

Was ongoing treatment for HCV being given at last assessment?
- ○ Yes
- ○ No

Was the patient receiving any anti-viral treatment during the 3 months covered by this assessment?
- ○ Yes
- ○ No

(if "Yes" to HCV treatment)
What type of HCV treatment(s) did the patient receive during the interval between the last assessment and this one?
Check all that apply.

Standard Interferon	☐
PEG Interferon	☐
Consensus Interferon	☐
Ribavirin	☐
Other treatment	☐

Specify "other treatment"

Record the date of initiation of HCV treatment: MM/DD/YYYY

Was ongoing treatment with interferon being given at the last assessment? ○ Yes ○ No

If subject was receiving interferon at the last assessment, record the date of completion of interferon treatment: MM/DD/YYYY

Not Applicable, interferon treatment continuing. ☐

Was ongoing treatment with ribavirin being given at the last assessment?

- ○ Yes
- ○ No

If patient was receiving ribavirin at the last assessment, record the date of completion of ribavirin treatment:

MM/DD/YYYY

Not Applicable, ribavirin treatment continuing. ☐

save reset cancel print

A2ALL
Adult to Adult Living Donor Liver Transplantation Cohort Study

HCC @ TXP

Samples/Labs/Procedures for Subject with HCC at Pre-TXP Quarterly Assessments

*Imaging studies

Date of assessment:	MM/DD/YYYY
HCC Location	○ Right Lobe Only ○ Left Lobe Only ○ Bilobar
Date of the last abdominal CT scan or MRI that occurred since the last assessment to stage HCC:	MM/DD/YYYY
Number of HCC nodules in the liver?	○ 0 (None) ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6+
Size of nodule 1	cm
Size of nodule 2	cm
Size of nodule 3	cm
Size of nodule 4	cm
Size of nodule 5	cm

Size of nodule 6	cm
Vascular Invasion	○ No ○ Yes, portal vein ○ Yes, other vascular structures
(if "yes" to portal vein invasion), **Location of tumor invasion on the portal vein. (Choose at least one).**	
Main Portal Vein	☐
Right Portal Vein	☐
Left Portal Vein	☐
Right-Sided Branches	☐
Left-Sided Branches	☐
Primary Tumor Classification	○ T0: Not Found ○ T1: one nodule < 1.9cm ○ T2: one nodule 2.0-5.0cm OR 2-3 nodules all < 3.0cm ○ T3: one nodule >5.0cm OR 2-3 nodules at least one > 3.0 cm ○ T4a: 4 or more nodules, any size ○ T4b: T2, T3 or T4a plus gross intrahepatic portal or hepatic vein involvement ○ TX: Not assessed
Evidence of HCC in regional lymph nodes	○ N0 : no regional (porta hepatitis) nodes involved ○ N1: regional (porta hepatitis) nodes involved ○ NX: not assessed.

Cancer spread beyond the liver	○ M0: no metastatic disease including extrahepatic portal or hepatic vein involvement ○ M1 metastatic disease including extrahepatic portal or hepatic vein involvement ○ MX not assessed

How many ablations did the patient receive since the last assessment?	[ ] *Enter "0" for none*

For each ablation type, ener the number of ablations performed ("0" for none):

Radiofrequency ablation	○ 0 (none)	○ 1	○ 2	○ 3	○ 4	○ 5	○ >5
Cryotherapy	○ 0 (none)	○ 1	○ 2	○ 3	○ 4	○ 5	○ >5
Alcohol ablation	○ 0 (none)	○ 1	○ 2	○ 3	○ 4	○ 5	○ >5
Chemoembolization	○ 0 (none)	○ 1	○ 2	○ 3	○ 4	○ 5	○ >5
Chemoinfusion	○ 0 (none)	○ 1	○ 2	○ 3	○ 4	○ 5	○ >5
Surgical resection	○ 0 (none)	○ 1	○ 2	○ 3	○ 4	○ 5	○ >5

(if "yes" to surgical resection)

Type of surgical resection	○ Wedge ○ Segment ○ Lobe ○ Non-anatomic

Has the patient received chemotherapy treatment since the last assessment?	○ Yes, Systemic ○ Yes, Local ○ Yes, Both ○ No ○ Unknown
Chemotherapeutic agent used (check all that apply):	
Adriamycin	☐
Cisplatin	☐
5FU	☐
Unknown chemotherapeutic agent	☐
Other (specify):	
Did the patient receive radiation therapy since the last assessment?	○ Yes ○ No
Result of bone scan done at this assessment	○ Extra-hepatic metastases found ○ No metastatic spread found ○ Not done
Result of the chest CT done at this assessment	○ Extra-hepatic metastases found ○ No metastatic spread found ○ Not done
Result of the MRI/CT scan done at this assessment.	○ Extra-hepatic metastases found ○ No metastatic spread found ○ Not done

save reset cancel print

A2ALL
Adult to Adult Living Donor Liver Transplantation Cohort Study

HCC Explant Assessment

Was the HCC an incidental finding?	○ Yes ○ No
HCC location	○ Right Lobe Only ○ Left Lobe Only ○ Bilobar
Number of HCC nodules in the liver	○ 0 (None) ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6+
Describe nodule 1. Size of nodule 1 (cm)	
Was there tumor invasion into vascular structures?	○ No ○ Micro Invasion = micrometer tumor invasion into the portal or hepatic vein ○ Macro Invasion = millimeter tumor invasion into the portal or hepatic vein ○ Unknown/not assessed
Tumor Grade	○ G1 = well-differentiated ○ G2 = moderately differentiated ○ G3 = poorly differentiated ○ Unknown/not assessed

What level of mitosis was observed on microscopic analysis?	○ < 10 HPF ○ > = 10 HPF ○ Unknown
Proportion of Tumor Necrosis	○ 0% ○ 1%-25% ○ 26%-50% ○ 51%-75% ○ 76%-100% ○ Unknown

Describe nodule 2.

Size of nodule 2 (cm)	
Was there tumor invasion into vascular structures?	○ No ○ Micro Invasion = micrometer tumor invasion into the portal or hepatic vein ○ Macro Invasion = millimeter tumor invasion into the portal or hepatic vein ○ Unknown/not assessed
Tumor Grade	○ G1 = well-differentiated ○ G2 = moderately differentiated ○ G3 = poorly differentiated ○ Unknown/not assessed
What level of mitosis was observed on microscopic analysis?	○ < 10 HPF ○ > = 10 HPF ○ Unknown

Proportion of Tumor Necrosis	○ 0% ○ 1%-25% ○ 26%-50% ○ 51%-75% ○ 76%-100% ○ Unknown

Describe nodule 3

Size of nodule 3 (cm)	
Was there tumor invasion into vascular structures?	○ No ○ Micro Invasion = micrometer tumor invasion into the portal or hepatic vein ○ Macro Invasion = millimeter tumor invasion into the portal or hepatic vein ○ Unknown/not assessed
Tumor Grade	○ G1 = well-differentiated ○ G2 = moderately differentiated ○ G3 = poorly differentiated ○ Unknown/not assessed
What level of mitosis was observed on microscopic analysis?	○ < 10 HPF ○ > = 10 HPF ○ Unknown
Proportion of Tumor Necrosis	○ 0% ○ 1%-25% ○ 26%-50% ○ 51%-75% ○ 76%-100% ○ Unknown

Describe nodule 4.

Size of nodule 4 (cm)

Was there tumor invasion into vascular structures?

- ○ No
- ○ Micro Invasion = micrometer tumor invasion into the portal or hepatic vein
- ○ Macro Invasion = millimeter tumor invasion into the portal or hepatic vein
- ○ Unknown/not assessed

Tumor Grade

- ○ G1 = well-differentiated
- ○ G2 = moderately differentiated
- ○ G3 = poorly differentiated
- ○ Unknown/not assessed

What level of mitosis was observed on microscopic analysis?

- ○ < 10 HPF
- ○ > = 10 HPF
- ○ Unknown

Proportion of Tumor Necrosis

- ○ 0%
- ○ 1%-25%
- ○ 26%-50%
- ○ 51%-75%
- ○ 76%-100%
- ○ Unknown

Describe nodule 5.

Size of nodule 5 (cm)

Was there tumor invasion into vascular structures?	○ No ○ Micro Invasion = micrometer tumor invasion into the portal or hepatic vein ○ Macro Invasion = millimeter tumor invasion into the portal or hepatic vein ○ Unknown/not assessed
Tumor Grade	○ G1 = well-differentiated ○ G2 = moderately differentiated ○ G3 = poorly differentiated ○ Unknown/not assessed
What level of mitosis was observed on microscopic analysis?	○ < 10 HPF ○ > = 10 HPF ○ Unknown
Proportion of Tumor Necrosis	○ 0% ○ 1%-25% ○ 26%-50% ○ 51%-75% ○ 76%-100% ○ Unknown

Describe nodule 6.

Size of nodule 6 (cm)	
Was there tumor invasion into vascular structures?	○ No ○ Micro Invasion = micrometer tumor invasion into the portal or hepatic vein ○ Macro Invasion = millimeter tumor invasion into the portal or hepatic vein ○ Unknown/not assessed

Tumor Grade	○ G1 = well-differentiated ○ G2 = moderately differentiated ○ G3 = poorly differentiated ○ Unknown/not assessed
What level of mitosis was observed on microscopic analysis?	○ < 10 HPF ○ > = 10 HPF ○ Unknown
Proportion of Tumor Necrosis	○ 0% ○ 1%-25% ○ 26%-50% ○ 51%-75% ○ 76%-100% ○ Unknown
The following questions refer to the aggregate assessment of the cancer.	
Based on the number and size of HCC nodules, and the presence or absence of vascular invasion, choose the tumor stage:	○ T0: Not Found ○ T1: one nodule < 1.9cm ○ T2: one nodule 2.0-5.0cm OR 2-3 nodules all < 3.0cm ○ T3: one nodule >5.0cm OR 2-3 nodules at least one > 3.0 cm ○ T4a: 4 or more nodules, any size ○ T4b: T2, T3 or T4a plus gross intrahepatic portal or hepatic vein involvement ○ TX: Not assessed
Was there evidence of HCC found in the regional lymph nodes?	○ N0 : no regional (porta hepatitis) nodes involved ○ N1: regional (porta hepatitis) nodes involved ○ NX: not assessed.

Cancer spread beyond the liver	○ M0: no metastatic disease including extrahepatic portal or hepatic vein involvement ○ M1 metastatic disease including extrahepatic portal or hepatic vein involvement ○ MX not assessed

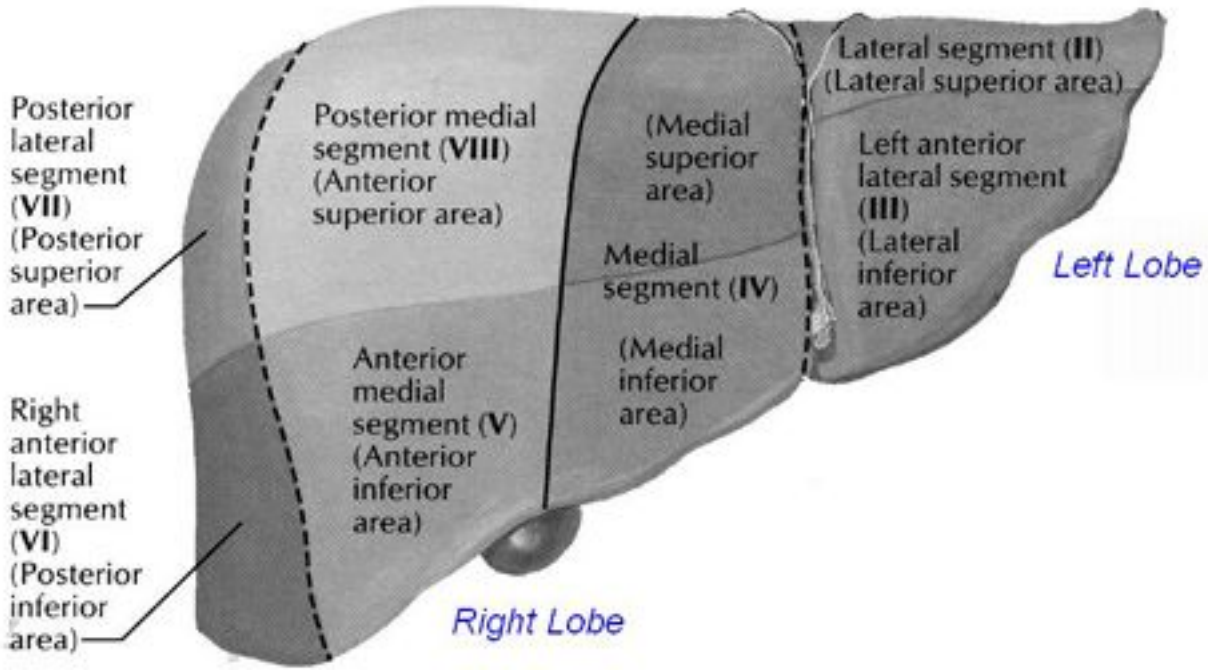
save reset cancel print

A2ALL
Adult to Adult Living Donor Liver Transplantation Cohort Study

HCC Explant Tumor Location

Number of tumors noted on HCC Explant Form = . Please describe their locations below. ☐

PARIETAL SURFACE



Segment II Lateral Segment (Lateral Superior Area)

Tumor 1 ☐

Tumor 2 ☐

Segment III Left Anterior Lateral Segment (Lateral Inferior Area)

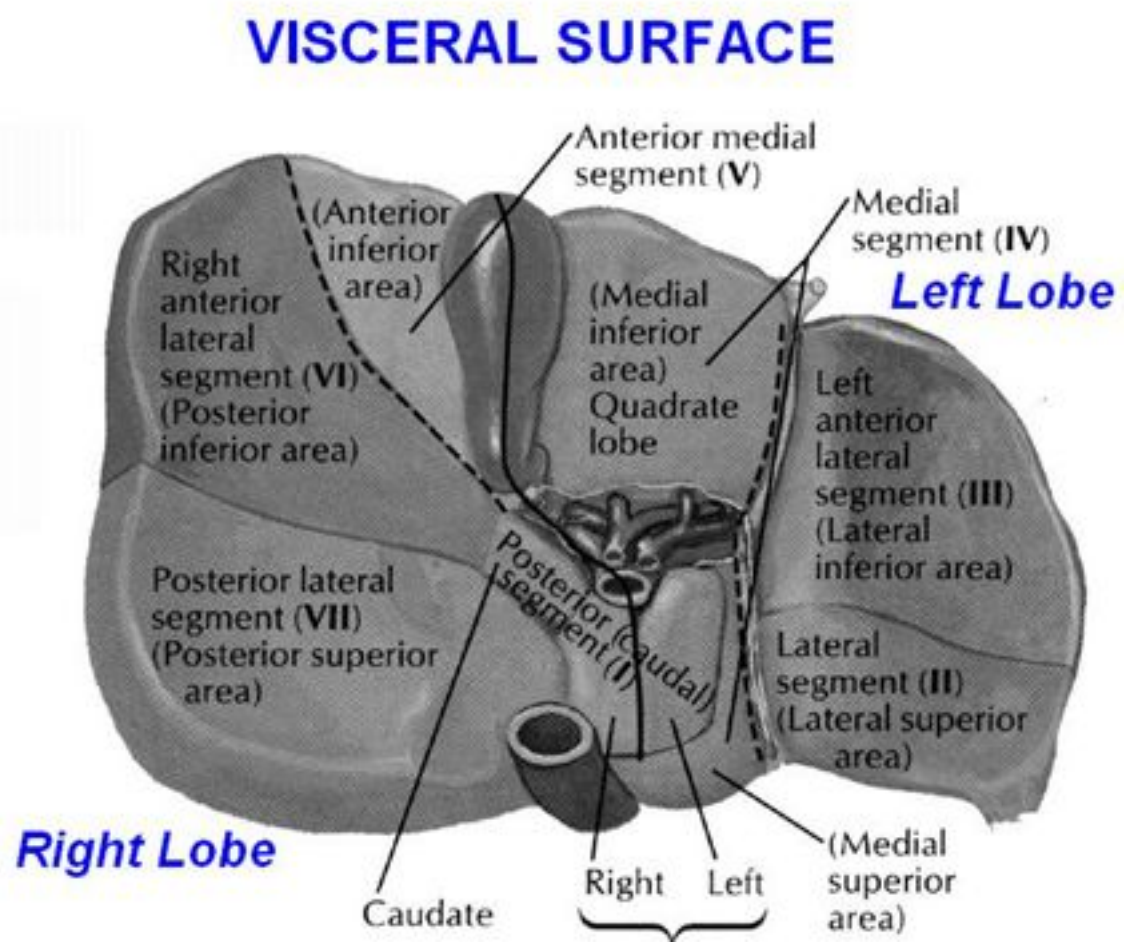
Tumor 1 ☐

Tumor 2 ☐

Tumor 3 ☐	Tumor 3 ☐
Tumor 4 ☐	Tumor 4 ☐
Tumor 5 ☐	Tumor 5 ☐
Tumor 6 ☐	Tumor 6 ☐
Tumor 7 ☐	Tumor 7 ☐
Tumor 8 ☐	Tumor 8 ☐
Tumor 9 ☐	Tumor 9 ☐
Tumor 10 ☐	Tumor 10 ☐
Tumor 11 ☐	Tumor 11 ☐
Tumor 12 ☐	Tumor 12 ☐
Segment IV - Medial Superior Area Tumor 1 ☐	**Segment IV - Medial Inferior Area** Tumor 1 ☐
Tumor 2 ☐	Tumor 2 ☐
Tumor 3 ☐	Tumor 3 ☐
Tumor 4 ☐	Tumor 4 ☐
Tumor 5 ☐	Tumor 5 ☐
Tumor 6 ☐	Tumor 6 ☐
Tumor 7 ☐	Tumor 7 ☐
Tumor 8 ☐	Tumor 8 ☐
Tumor 9 ☐	Tumor 9 ☐

Tumor 10 ☐	Tumor 10 ☐
Tumor 11 ☐	Tumor 11 ☐
Tumor 12 ☐	Tumor 12 ☐
Segment V (Anterior Inferior Area) Tumor 1 ☐	**Segment VI - Right Anterior Lateral Segment (Posterior Inferior Area)** Tumor 1 ☐
Tumor 2 ☐	Tumor 2 ☐
Tumor 3 ☐	Tumor 3 ☐
Tumor 4 ☐	Tumor 4 ☐
Tumor 5 ☐	Tumor 5 ☐
Tumor 6 ☐	Tumor 6 ☐
Tumor 7 ☐	Tumor 7 ☐
Tumor 8 ☐	Tumor 8 ☐
Tumor 9 ☐	Tumor 9 ☐
Tumor 10 ☐	Tumor 10 ☐
Tumor 11 ☐	Tumor 11 ☐
Tumor 12 ☐	Tumor 12 ☐

Segment VII - Posterior Lateral Segment (Posterior Superior Area)	**Segment VIII - Posterior Medial Segment (Anterior Superior Area)**
Tumor 1 ☐	Tumor 1 ☐
Tumor 2 ☐	Tumor 2 ☐
Tumor 3 ☐	Tumor 3 ☐
Tumor 4 ☐	Tumor 4 ☐
Tumor 5 ☐	Tumor 5 ☐
Tumor 6 ☐	Tumor 6 ☐
Tumor 7 ☐	Tumor 7 ☐
Tumor 8 ☐	Tumor 8 ☐
Tumor 9 ☐	Tumor 9 ☐
Tumor 10 ☐	Tumor 10 ☐
Tumor 11 ☐	Tumor 11 ☐
Tumor 12 ☐	Tumor 12 ☐



Segment 1 Posterior (Caudal) Segment Tumor 1	☐	**Segment II - Lateral (Lateral Superior Area)** Tumor 1	☐
Tumor 2	☐	Tumor 2	☐
Tumor 3	☐	Tumor 3	☐
Tumor 4	☐	Tumor 4	☐
Tumor 5	☐	Tumor 5	☐
Tumor 6	☐	Tumor 6	☐
Tumor 7	☐	Tumor 7	☐
Tumor 8	☐	Tumor 8	☐

Tumor 9	☐	Tumor 9	☐
Tumor 10	☐	Tumor 10	☐
Tumor 11	☐	Tumor 11	☐
Tumor 12	☐	Tumor 12	☐
Segment III - Left Anterior Lateral (Lateral Inferior Area)		**Segment IV - Quadrate Lobe (Medial Inferior Area)**	
Tumor 1	☐	Tumor 1	☐
Tumor 2	☐	Tumor 2	☐
Tumor 3	☐	Tumor 3	☐
Tumor 4	☐	Tumor 4	☐
Tumor 5	☐	Tumor 5	☐
Tumor 6	☐	Tumor 6	☐
Tumor 7	☐	Tumor 7	☐
Tumor 8	☐	Tumor 8	☐
Tumor 9	☐	Tumor 9	☐
Tumor 10	☐	Tumor 10	☐
Tumor 11	☐	Tumor 11	☐
Tumor 12	☐	Tumor 12	☐

Segment V - Anterior Medial (Anterior Inferior Area)		**Segment VI - Right Anterior Lateral (Posterior Inferior Area)**	
Tumor 1	☐	Tumor 1	☐
Tumor 2	☐	Tumor 2	☐
Tumor 3	☐	Tumor 3	☐
Tumor 4	☐	Tumor 4	☐
Tumor 5	☐	Tumor 5	☐
Tumor 6	☐	Tumor 6	☐
Tumor 7	☐	Tumor 7	☐
Tumor 8	☐	Tumor 8	☐
Tumor 9	☐	Tumor 9	☐
Tumor 10	☐	Tumor 10	☐
Tumor 11	☐	Tumor 11	☐
Tumor 12	☐	Tumor 12	☐

Segment VII - Posterior Lateral (Posterior Superior Area)	
Tumor 1	☐
Tumor 2	☐
Tumor 3	☐
Tumor 4	☐
Tumor 5	☐
Tumor 6	☐

Tumor 7	☐
Tumor 8	☐
Tumor 9	☐
Tumor 10	☐
Tumor 11	☐
Tumor 12	☐

save reset cancel print

Donor Assessment at 1 Week Post-Donation

Samples to be Collected:

*15 ml of whole blood, spun, and serum aliquotted into ten 0.4ml samples (to be frozen and batch-shipped to McKesson BioSample Repository)

*Keris: McGill Pain Survey ONLY

Visit Missed	☐
Date of this assessment:	MM/DD/YYYY

What is the donor's current status?
- ○ Alive
- ○ Dead
- ○ Unknown

(If dead)

What was the patient's date of death? MM/DD/YYYY

Was the liver functioning at the time of death?
- ○ Yes
- ○ No
- ○ Unknown

Select the primary cause of death from the list:

Select the secondary cause of death from the list:

	Select the tertiary cause of death from the list:

(If status is "unknown")

Date of last contact:

MM/DD/YYYY

Donor weight this assessment:	○ Kilograms ○ Pounds
Record the serum alanine aminotransferase (ALT) value at this assessment: *IU/L*	Not Done ☐
Record the serum aspartate transaminase (AST) value at this assessment: *IU/L*	Not Done ☐
Record the serum alkaline phosphatase (ALK) value at this assessment: *U/L*	Not Done ☐
Record the total serum bilirubin value at this assessment: *mg/dl*	Not Done ☐
Blood Urea Nitrogen (BUN) value at this assessment: *mg/dl*	Not Done ☐
Record the serum creatinine value at this assessment: *mg/dl*	Not Done ☐

Record the total serum albumin value at this assessment: *g/dl*	Not Done ☐
Record the INR value at this assessment:	Not Done ☐
Record the PT/ PTT value at this assessment:	Not Done ☐
White Blood Count value at this assessment: *x10^3/mm^3*	Not Done ☐
Record the ferritin level at this assessment *ng/ml*	Not Done ☐
Record the hemoglobin (Hgb) value at this assessment: *g/dl*	Not Done ☐
Record the platelet count at this assessment: *x10^3/mm^3*	Not Done ☐
Has the patient been hospitalized since the last assessment? ○ Yes ○ No *(If "Yes" fill out a Hospitalization Form for each hospitalization.)*	How many times has the patient been hospitalized since the last assessment? *(If "Yes" to hospitalizations)* *Leave blank for "None"*
Has the patient experienced a complication since the last assessment? ○ Yes ○ No *(If "Yes", and the complication(s) is included in the study, fill out a DNR Morbidity/Comp Severity Form)*	How many complications has the patient had since the last assessment? *(If "Yes" to complications)* *Leave blank for "None"*

Has the patient experienced an SAE since the last assessment? ○ Yes ○ No *(If "Yes", fill out an SAE Form.)*	How many adverse events has the patient had since the last assessment? [ ] *(If "Yes" to adverse events)* *Leave blank for "None"*

Donor medical condition at this assessment	○ Patient in ICU ○ Hospitalized, not in ICU ○ In Rehab Facility ○ Not Hospitalized
Donor on ventilator at this assessment?	○ Yes ○ No ○ Unknown
Donor functional status at this assessment	○ Normal, no complaints or evidence of disease ○ Able to perform normal activity; minor signs and symptoms of disease ○ Able to perform normal activity with effort; some signs and symptoms of disease ○ Cares for self, unable to perform normal activity or to do active work ○ Requires occasional assistance but is able to care for most of own needs ○ Requires considerable assistance and frequent medical care ○ Requires special care and assistance; disabled ○ Hospitalization indicated, although death not imminent; severely disabled ○ Hospitalization necessary; active supportive treatment required, very sick ○ Fatal processes progressing rapidly; moribund ○ Dead
Donor employment status at this assessment:	○ Working full time ○ Working part time by choice ○ Working part time due to disease ○ Working part time reason unknown ○ Not working by choice ○ Not working due to disease ○ Not working, unable to find employment ○ Not working, reason unknown ○ Retired

	○ Employment status unknown
Primary payment source (may reflect recipient's coverage):	○ Medicare ○ Medicaid ○ US State/Gov't Agency ○ Private Insurance ○ HMO/PPO ○ Self ○ Donation ○ Free Care ○ Dept. Veterans' Affairs ○ Pending ○ Foreign Gov't ○ Unknown ○ Other (specify)
Specify "other" primary payment source:	
Indicate what the patient indicates are typical drug use patterns. Patient reports no pain drug use during this interval.	☐
Plain Tylenol - Use	
NSAID (Motrin, Aleve, ibuprofen etc) - Use	
Aspirin - Use	
Tylenol w/ Codeine - Use	
Darvocet - Use	
Vicodin - Use	
Percocet - Use	
Percodan - Use	
Dilaudid - Use	
Oxycontin - Use	
MS Contin - Use	
Methadone - Use	
Other (specify)	Use

Is the patient a subject in another research study?	○ Yes, new to this assessment interval. ○ Yes, previously reported. ○ No ○ Unknown	If "yes", what is the name of the study?

save reset cancel print

RCP Condition @ 1 Week Post-Transplant

Samples to be Collected:

*15ml whole blood, spun, and serum aliquotted into ten 0.4ml samples (to be frozen and batch-shipped to McKesson BioSample Repository)

*Labs

Visit Missed ☐

Date of this assessment: _____ MM/DD/YYYY

What is the recipient's current status?
- ○ Alive
- ○ Dead
- ○ Unknown

(If dead)

What was the patient's date of death? _____ MM/DD/YYYY

Was the liver functioning at the time of death?
- ○ Yes
- ○ No
- ○ Unknown

Select the primary cause of death from the list: _____

Select the secondary cause of death from the list: _____

Select the tertiary cause of death from the list:

(If status is "Unknown")

Date of last contact:

MM/DD/YYYY

(If patient is still alive)

What is the status of the liver graft?

- ○ Functional
- ○ Failed
- ○ Unknown
- ○ Index graft failure information previously reported

(If the graft failed)

Date of graft failure:

MM/DD/YYYY

(If the graft failed)

What was the primary reason for graft failure?

- ○ Primary Graft Failure
- ○ Vascular Thrombosis
- ○ Biliary Tract Complication
- ○ Hepatitis: DeNovo
- ○ Hepatitis: Recurrent
- ○ Recurrent Disease: Non-Hepatitis
- ○ Rejection: Acute
- ○ Infection
- ○ Rejection Chronic
- ○ Other (specify)

Specify "other" primary reason for graft failure

What was the secondary reason for graft failure?

- ○ Primary Graft Failure
- ○ Vascular Thrombosis
- ○ Biliary Tract Complication
- ○ Hepatitis: DeNovo
- ○ Hepatitis: Recurrent
- ○ Recurrent Disease: Non-Hepatitis
- ○ Rejection: Acute
- ○ Infection

	○ Rejection Chronic ○ Other (specify)
Specify "other" secondary reason for graft failure	
(If the graft failed) Was the patient relisted for transplant?	○ Yes ○ No ○ Unknown
(If relisted) What was the date of re-listing? MM/DD/YYYY	
(if the graft failed) Did the subject recieve another liver transplant?	○ Yes ○ No ○ Unknown

What was the immunosuppression regimen in place during this assessment? (Check all that apply)

Prednisone (or oral equivalent)	☐
Methylprednisolone (or IV equivalent)	☐
Cyclosporine (Neoral, Gengraf or any other forumulation)	☐
Tacrolimus (Prograf)	☐
Rapamycin	☐
Certican (RAD)	☐
Azathioprine (Imuran or generic)	☐
Mycophenolate mofetil (Cellcept or generic)	☐
Enteric-coated mycophenolic acid (Myfortic or generic)	☐
Other immunosuppression ☐	Specify "other" immunsuppression
Antibody used? ○ Yes ○ No	
	ATGAM ☐
	OKT3 ☐
	Thymoglobulin ☐

Zenapax	☐
Simulect	☐
Campath	☐
Other antibody therapy used?	☐
Specify "other" antibody therapy used:	

Did the patient have a rejection episode that was confirmed by biopsy since the last assessment? ○ Yes ○ No *(If "Yes", fill out a Rejection Episode and Treatment form for each biopsy-proven episode)*	*(If "Yes" to Rejection Episodes)* How many biopsy-proven rejection episodes has the patient had since the last assessment? *Leave blank for "None"*
Has the patient been hospitalized since the last assessment? ○ Yes ○ No *(If "Yes" fill out a Hospitalization Form for each hospitalization.)*	*(If "Yes" to Hospitalizations)* How many hospitalizations has the patient had since the last assessment? *Leave blank for "None"*
Has the patient experienced a study-tracked complication since the last assessment? ○ Yes ○ No *(If "Yes", and the complication(s) is included in the study, fill out a RCP Morbidity/Comp Severity Form)*	*(If "Yes" to Complications/Morbidities)* How many study-tracked complications has the patient had since the last assessment? *Leave blank for "None"*
Has the patient experienced a serious adverse event since the last assessment? ○ Yes ○ No *(If "Yes", fill out an SAE/AE Report Form)*	*(If "Yes" to Adverse Events)* How many adverse events has the patient had since the last assessment? *Leave blank for "None"*

Recipient medical condition at this assessment	○ Patient in ICU ○ Hospitalized, not in ICU ○ In Rehab Facility ○ Not Hospitalized
Recipient on ventilator at this assessment?	○ Yes ○ No
Recipient functional status at this assessment	○ Normal, no complaints or evidence of disease ○ Able to perform normal activity; minor signs and symptoms of disease ○ Able to perform normal activity with effort; some signs and symptoms of disease ○ Cares for self, unable to perform normal activity or to do active work ○ Requires occasional assistance but is able to care for most of own needs ○ Requires considerable assistance and frequent medical care ○ Requires special care and assistance; disabled ○ Hospitalization indicated, although death not imminent; severely disabled ○ Hospitalization necessary; active supportive treatment required, very sick ○ Fatal processes progressing rapidly; moribund ○ Dead
Recipient employment status at this assessment:	○ Working full time ○ Working part time by choice ○ Working part time due to disease ○ Working part time reason unknown ○ Not working by choice ○ Not working due to disease ○ Not working, unable to find employment ○ Not working, reason unknown ○ Retired ○ Employment status unknown

Primary source of payment:

- ○ Medicare
- ○ Medicaid
- ○ US State/Gov't Agency
- ○ Private Insurance
- ○ HMO/PPO
- ○ Self
- ○ Donation
- ○ Free Care
- ○ Dept. Veterans' Affairs
- ○ Pending
- ○ Foreign Gov't
- ○ Unknown
- ○ Other (specify)

Specify "other" primary source of payment: [ ]

Recipient weight at this assessment [ ]

- ○ Kilograms
- ○ Pounds

Recipient systolic blood pressure at this assessment: [ ]

mm/Hg

Recipient diastolic blood pressure at this assessment: [ ]

mm/Hg

Recipient diabetes mellitus at this assessment?

- ○ No
- ○ Yes, Insulin Dependent
- ○ Yes, Non-insulin Dependent
- ○ Yes, Type Unknown
- ○ Other

(if patient has diabetes)

Diabetes Treatment

- ○ Insulin
- ○ Oral Agent
- ○ Both Insulin and Oral Agent
- ○ No medications

Recipient dialysis at this assessment?

- ○ No
- ○ Hemodialysis/CVVHD
- ○ Peritoneal Dialysis
- ○ Dialysis-Unknown type
- ○ Unknown

Record the serum creatinine value at this assessment: _____ *mg/dl*	Not Done ☐
Record the total serum albumin value at this assessment: _____ *g/dl*	Not Done ☐
Record the total serum bilirubin value at this assessment: _____ *mg/dl*	Not Done ☐
Record the INR value at this assessment: _____	Not Done ☐
Record the PT value at this assessment: _____	Not Done ☐
Record the serum aspartate transaminase (AST) value at this assessment: _____ *IU/L*	Not Done ☐
Record the serum alanine aminotransferase (ALT) value at this assessment: _____ *IU/L*	Not Done ☐
Record the serum alkaline phosphatase (ALK) value at this assessment: _____ *IU/L*	Not Done ☐
Record the AFP value at this assessment: _____ *ng/ml*	Not Done ☐
Record the serum sodium level at this assessment _____ *mEq/L*	Not Done ☐

Is the subject currently a partipant in another research study?	○ Yes, new to this assessment interval. ○ Yes, previously reported. ○ No ○ Unknown	If the subject is a participant in another research study, what is the name of that study?

save reset cancel print

A2ALL
Adult to Adult Living Donor Liver Transplantation Cohort Study

HCV Post-TXP Week 1 Assessment

Please Note: If HCV recurrence was discovered during this assessment, the protocol calls for a biopsy prior to intiation of HCV treatment. If this has occurred, you must fill out an HCV Post-Txp Biopsy Pathology Report.

Date of this assessment: _____ MM/DD/YYYY

Record the date of the RNA test: _____ MM/DD/YYYY

Record the quantitative HCV value at this assessment _____

Units for HCV quantification
- ○ Copies/ml
- ○ Equiv/ml
- ○ IU/ml
- ○ Unknown

Was ongoing HCV treatment being given as of last assessment?
- ○ Yes
- ○ No

Did the patient receive anti-viral treatment during the interval between the last assessment and this one?
- ○ Yes
- ○ No

(if "Yes" to HCV treatment)
What type of HCV treatment(s) did the patient receive during the interval between the last assessment and this one? *Check all that apply*

- ☐ Standard Interferon
- ☐ PEG Interferon
- ☐ Consensus Interferon
- ☐ Ribavirin

Other HCV treatment ☐	Specify "other treatment".
Record the date of initiation of post-transplant HCV treatment: MM/DD/YYYY	Not applicable, HCV treatment continuing from previous assessment period. ☐
Was ongoing treatment with interferon being given at the last post-transplant assessment? ○ Yes ○ No	If subject was receiving interferon at the last assessment, record the date of completion of interferon treatment: MM/DD/YYYY
	Not applicable, interferon treatment continuing. ☐
Was ongoing treatment with ribavirin being given at the last post-transplant assessment? ○ Yes ○ No	If subject was receiving ribavirin at the last assessment, record the date of completion of ribavirin treatment: MM/DD/YYYY

Not applicable, ribavirin treatment continuing.	☐

save reset cancel print

A2ALL
Adult to Adult Living Donor Liver Transplantation Cohort Study

HCV Post-TXP Biopsy Pathology Report

Samples to be Collected:

2 liver Bx samples stored in 2ml vials and preserved in RNA-Later

1 liver Bx sample stored in 2ml vial and preserved in formalin.

All samples to be batch-shipped to McKesson BioSample Repository.

Date of biopsy: _____ MM/DD/YYYY	Date of review: _____ MM/DD/YYYY
Name of pathologist reading biopsy _____	
Reason for biopsy: ○ Protocol ○ Pre-HCV treatment ○ Rule-out rejection/ abnormal LFT	*(if a protocol biopsy)* Post-transplant interval: ○ 3 months ○ 1 year ○ 2 years ○ 3 years ○ 4 years ○ 5 years

Indicate the presence of the following

Acute rejection	☐
Biliary obstruction	☐
CMV hepatitis	☐
Is this biopsy compatible with HCV recurrence?	○ Yes ○ No

Knodell Score for Periportal +/- Bridging Necrosis	○ **0** None ○ **1** Mild piecemeal necrosis ○ **3** Moderate piecemeal necrosis (less than 50% of the circumference of most portal tracts) ○ **4** Marked piecemeal necrosis (more than 50% of the circumference of most portal tracts) ○ **5** Moderate piecemeal necrosis PLUS bridging necrosis ○ **6** Marked piecemeal necrosis PLUS bridging necrosis ○ **10** Multilobular necrosis ○ Not Available	
Knodell Score for Lobular Inflammation and Focal Necrosis	○ **0** None ○ **1** Mild * ○ **3** Moderate (involvement of 1/3 to 2/3 of lobules or nodules) ○ **4** Marked (involvement of >2/3 of lobules or nodules) ○ Not Available	* (Mild = acidophilic bodies, ballooning degeneration and/ or scattered foci of hepatocellular necrosis in >1/3 of lobules or nodules)
Knodell Score for Portal Inflammation	○ **0** No portal inflammation ○ **1** Mild (sprinkling of inflammatory cells in <1/3 of portal tracts) ○ **3** Moderate (increased inflammatory cells in 1/3 to 2/3 of portal tracts) ○ **4** Marked (dense packing of inflammatory cells in >2/3 of portal tracts) ○ Not Available	

Ishak Score for Fibrosis	○ **0** No fibrosis ○ **1** Fibrous expansion of some portal areas, with or without short fibrous septa ○ **2** Fibrous expansion of most portal areas, with or without short fibrous septa ○ **3** Fibrous expansion of most portal areas, with occasional portal to portal (p-p) bridging ○ **4** Fibrous expansion of portal areas, with marked briding ((p-p) as well as portal to central (p-c) ○ **5** Marked bridging (p-p and/or p-c) with occasional nodules (incomplete cirrhosis) ○ **6** Cirrhosis; probable or definite ○ Not available

save reset cancel print

RCP Condition @ 2 Weeks Post-Transplant

Samples to be Collected:

*15ml whole blood, spun, and serum aliquotted into ten 0.4ml samples (to be frozen and batch-shipped to McKesson BioSample Repository)

*Labs

Visit Missed ☐

Date of this assessment: MM/DD/YYYY

What is the recipient's current status?
- ○ Alive
- ○ Dead
- ○ Unknown

(If dead)

What was the patient's date of death? MM/DD/YYYY

Was the liver functioning at the time of death?
- ○ Yes
- ○ No
- ○ Unknown

Select the primary cause of death from the list:

Select the secondary cause of death from the list:

Select the tertiary cause of death from the list:

(If status is "Unknown")

Date of last contact:

MM/DD/YYYY

(If patient is still alive)

What is the status of the liver graft?

- ○ Functional
- ○ Failed
- ○ Unknown
- ○ Index graft failure information previously reported

(If the graft failed)

Date of graft failure:

MM/DD/YYYY

(If the graft failed)

What was the primary reason for graft failure?

- ○ Primary Graft Failure
- ○ Vascular Thrombosis
- ○ Biliary Tract Complication
- ○ Hepatitis: DeNovo
- ○ Hepatitis: Recurrent
- ○ Recurrent Disease: Non-Hepatitis
- ○ Rejection: Acute
- ○ Infection
- ○ Rejection Chronic
- ○ Other (specify)

Specify "other" primary reason for graft failure

What was the secondary reason for graft failure?

- ○ Primary Graft Failure
- ○ Vascular Thrombosis
- ○ Biliary Tract Complication
- ○ Hepatitis: DeNovo
- ○ Hepatitis: Recurrent
- ○ Recurrent Disease: Non-Hepatitis
- ○ Rejection: Acute
- ○ Infection

	○ Rejection Chronic ○ Other (specify)
Specify "other" secondary reason for graft failure	
(If the graft failed) Was the patient relisted for transplant?	○ Yes ○ No ○ Unknown
(If relisted) What was the date of re-listing? MM/DD/YYYY	
(if the graft failed) Did the subject recieve another liver transplant?	○ Yes ○ No ○ Unknown

What was the immunosuppression regimen in place during this assessment? (Check all that apply)

Prednisone (or oral equivalent)	☐
Methylprednisolone (or IV equivalent)	☐
Cyclosporine (Neoral, Gengraf or any other forumulation)	☐
Tacrolimus (Prograf)	☐
Rapamycin	☐
Certican (RAD)	☐
Azathioprine (Imuran or generic)	☐
Mycophenolate mofetil (Cellcept or generic)	☐
Enteric-coated mycophenolic acid (Myfortic or generic)	☐
Other immunosuppression	☐
Specify "other" immunsuppression	
Antibody used?	○ Yes ○ No
ATGAM	☐
OKT3	☐
Thymoglobulin	☐

Zenapax	☐
Simulect	☐
Campath	☐
Other antibody therapy used?	☐
Specify "other" antibody therapy used:	

Did the patient have a rejection episode that was confirmed by biopsy since the last assessment? ○ Yes ○ No *(If "Yes", fill out a Rejection Episode and Treatment form for each biopsy-proven episode)*	*(If "Yes" to Rejection Episodes)* How many biopsy-proven rejection episodes has the patient had since the last assessment? *Leave blank for "None"*
Has the patient been hospitalized since the last assessment? ○ Yes ○ No *(If "Yes" fill out a Hospitalization Form for each hospitalization.)*	*(If "Yes" to Hospitalizations)* How many hospitalizations has the patient had since the last assessment? *Leave blank for "None"*
Has the patient experienced a study-tracked complication since the last assessment? ○ Yes ○ No *(If "Yes", and the complication(s) is included in the study, fill out a RCP Morbidity/Comp Severity Form)*	*(If "Yes" to Complications/Morbidities)* How many study-tracked complications has the patient had since the last assessment? *Leave blank for "None"*
Has the patient experienced a serious adverse event since the last assessment? ○ Yes ○ No *(If "Yes", fill out an SAE/AE Report Form)*	*(If "Yes" to Adverse Events)* How many adverse events has the patient had since the last assessment? *Leave blank for "None"*

Recipient medical condition at this assessment	○ Patient in ICU ○ Hospitalized, not in ICU ○ In Rehab Facility ○ Not Hospitalized
Recipient on ventilator at this assessment?	○ Yes ○ No
Recipient functional status at this assessment	○ Normal, no complaints or evidence of disease ○ Able to perform normal activity; minor signs and symptoms of disease ○ Able to perform normal activity with effort; some signs and symptoms of disease ○ Cares for self, unable to perform normal activity or to do active work ○ Requires occasional assistance but is able to care for most of own needs ○ Requires considerable assistance and frequent medical care ○ Requires special care and assistance; disabled ○ Hospitalization indicated, although death not imminent; severely disabled ○ Hospitalization necessary; active supportive treatment required, very sick ○ Fatal processes progressing rapidly; moribund ○ Dead
Recipient employment status at this assessment:	○ Working full time ○ Working part time by choice ○ Working part time due to disease ○ Working part time reason unknown ○ Not working by choice ○ Not working due to disease ○ Not working, unable to find employment ○ Not working, reason unknown ○ Retired ○ Employment status unknown

Primary source of payment:

- ○ Medicare
- ○ Medicaid
- ○ US State/Gov't Agency
- ○ Private Insurance
- ○ HMO/PPO
- ○ Self
- ○ Donation
- ○ Free Care
- ○ Dept. Veterans' Affairs
- ○ Pending
- ○ Foreign Gov't
- ○ Unknown
- ○ Other (specify)

Specify "other" primary source of payment: [ ]

Recipient weight at this assessment [ ]

- ○ Kilograms
- ○ Pounds

Recipient systolic blood pressure at this assessment: [ ]

mm/Hg

Recipient diastolic blood pressure at this assessment: [ ]

mm/Hg

Recipient diabetes mellitus at this assessment?

- ○ No
- ○ Yes, Insulin Dependent
- ○ Yes, Non-insulin Dependent
- ○ Yes, Type Unknown
- ○ Other

(if patient has diabetes)

Diabetes Treatment

- ○ Insulin
- ○ Oral Agent
- ○ Both Insulin and Oral Agent
- ○ No medications

Recipient dialysis at this assessment?

- ○ No
- ○ Hemodialysis/CVVHD
- ○ Peritoneal Dialysis
- ○ Dialysis-Unknown type
- ○ Unknown

Record the serum creatinine value at this assessment: *mg/dl*	Not Done ☐
Record the total serum albumin value at this assessment: *g/dl*	Not Done ☐
Record the total serum bilirubin value at this assessment: *mg/dl*	Not Done ☐
Record the INR value at this assessment:	Not Done ☐
Record the PT/ PTT value at this assessment:	Not Done ☐
Record the serum aspartate transaminase (AST) value at this assessment: *IU/L*	Not Done ☐
Record the serum alanine aminotransferase (ALT) value at this assessment: *IU/L*	Not Done ☐
Record the serum alkaline phosphatase (ALK) value at this assessment: *IU/L*	Not Done ☐
Record the AFP value at this assessment: *ng/ml*	Not Done ☐
Record the serum sodium level at this assessment *mEq/L*	Not Done ☐

Is the subject currently a partipant in another research study?	○ Yes, new to this assessment interval. ○ Yes, previously reported. ○ No ○ Unknown	If the subject is a participant in another research study, what is the name of that study?

save reset cancel print

Donor Assessment at 1 Month Post-Donation

Samples to be Collected:

*15 ml of whole blood, spun, and serum aliquotted into ten 0.4ml samples (to be frozen and batch-shipped to McKesson BioSample Repository)

*Keris: McGill Pain Survey ONLY

Visit Missed	☐
Date of this assessment:	MM/DD/YYYY

What is the donor's current status?
- ○ Alive
- ○ Dead
- ○ Unknown

(If dead)

What was the patient's date of death?

MM/DD/YYYY

Was the liver functioning at the time of death?
- ○ Yes
- ○ No
- ○ Unknown

Select the primary cause of death from the list:

Select the secondary cause of death from the list:

Select the tertiary cause of death from the list:	

(If status is "unknown")

Date of last contact:

MM/DD/YYYY

Donor weight this assessment:		○ Kilograms ○ Pounds
Record the serum alanine aminotransferase (ALT) value at this assessment: *IU/L*		Not Done ☐
Record the serum aspartate transaminase (AST) value at this assessment: *IU/L*		Not Done ☐
Record the serum alkaline phosphatase (ALK) value at this assessment: *U/L*		Not Done ☐
Record the total serum bilirubin value at this assessment: *mg/dl*		Not Done ☐
Blood Urea Nitrogen (BUN) value at this assessment: *mg/dl*		Not Done ☐
Record the serum creatinine value at this assessment: *mg/dl*		Not Done ☐

Record the total serum albumin value at this assessment: *g/dl*	Not Done ☐
Record the INR value at this assessment:	Not Done ☐
Record the PT/ PTT value at this assessment:	Not Done ☐
White Blood Count value at this assessment: *x10^3/mm^3*	Not Done ☐
Record the ferritin level at this assessment *ng/ml*	Not Done ☐
Record the hemoglobin (Hgb) value at this assessment: *g/dl*	Not Done ☐
Record the platelet count at this assessment: *x10^3/mm^3*	Not Done ☐
Has the patient been hospitalized since the last assessment? ○ Yes ○ No *(If "Yes" fill out a Hospitalization Form for each hospitalization.)*	How many times has the patient been hospitalized since the last assessment? *(If "Yes" to hospitalizations)* *Leave blank for "None"*
Has the patient experienced a complication since the last assessment? ○ Yes ○ No *(If "Yes", and the complication(s) is included in the study, fill out a DNR Morbidity/Comp Severity Form)*	How many complications has the patient had since the last assessment? *(If "Yes" to complications)* *Leave blank for "None"*

Has the patient experienced an SAE since the last assessment? ○ Yes ○ No *(If "Yes", fill out an SAE Form.)*	How many adverse events has the patient had since the last assessment? [ ] *(If "Yes" to adverse events)* *Leave blank for "None"*

Donor medical condition at this assessment	○ Patient in ICU ○ Hospitalized, not in ICU ○ In Rehab Facility ○ Not Hospitalized
Donor on ventilator at this assessment?	○ Yes ○ No ○ Unknown
Donor functional status at this assessment	○ Normal, no complaints or evidence of disease ○ Able to perform normal activity; minor signs and symptoms of disease ○ Able to perform normal activity with effort; some signs and symptoms of disease ○ Cares for self, unable to perform normal activity or to do active work ○ Requires occasional assistance but is able to care for most of own needs ○ Requires considerable assistance and frequent medical care ○ Requires special care and assistance; disabled ○ Hospitalization indicated, although death not imminent; severely disabled ○ Hospitalization necessary; active supportive treatment required, very sick ○ Fatal processes progressing rapidly; moribund ○ Dead
Donor employment status at this assessment:	○ Working full time ○ Working part time by choice ○ Working part time due to disease ○ Working part time reason unknown ○ Not working by choice ○ Not working due to disease ○ Not working, unable to find employment ○ Not working, reason unknown ○ Retired

	○ Employment status unknown
Primary payment source (may reflect recipient's coverage):	○ Medicare ○ Medicaid ○ US State/Gov't Agency ○ Private Insurance ○ HMO/PPO ○ Self ○ Donation ○ Free Care ○ Dept. Veterans' Affairs ○ Pending ○ Foreign Gov't ○ Unknown ○ Other (specify)
Specify "other" primary payment source:	
Indicate what the patient indicates are typical drug use patterns. Patient reports no pain drug use during this interval.	☐
Plain Tylenol - Use	
NSAID (Motrin, Aleve, ibuprofen etc) - Use	
Aspirin - Use	
Tylenol w/ Codeine - Use	
Darvocet - Use	
Vicodin - Use	
Percocet - Use	
Percodan - Use	
Dilaudid - Use	
Oxycontin - Use	
MS Contin - Use	
Methadone - Use	
Other (specify)	Use

Is the patient a subject in another research study?	○ Yes, new to this assessment interval. ○ Yes, previously reported. ○ No ○ Unknown	If "yes", what is the name of the study?

save reset cancel print

RCP Condition @ 1 Month Post-Transplant

Samples to be Collected:

*15ml whole blood, spun, and serum aliquotted into ten 0.4ml samples (to be frozen and batch-shipped to McKesson BioSample Repository)

*Labs

Visit Missed	☐
Date of this assessment:	MM/DD/YYYY
What is the recipient's current status?	○ Alive ○ Dead ○ Unknown
(If dead) What was the patient's date of death?	MM/DD/YYYY
Was the liver functioning at the time of death?	○ Yes ○ No ○ Unknown
Select the primary cause of death from the list:	
Select the secondary cause of death from the list:	

Select the tertiary cause of death from the list:

(If status is "Unknown")

Date of last contact:

MM/DD/YYYY

(If patient is still alive)

What is the status of the liver graft?

- ○ Functional
- ○ Failed
- ○ Unknown
- ○ Index graft failure information previously reported

(If the graft failed)

Date of graft failure:

MM/DD/YYYY

(If the graft failed)

What was the primary reason for graft failure?

- ○ Primary Graft Failure
- ○ Vascular Thrombosis
- ○ Biliary Tract Complication
- ○ Hepatitis: DeNovo
- ○ Hepatitis: Recurrent
- ○ Recurrent Disease: Non-Hepatitis
- ○ Rejection: Acute
- ○ Infection
- ○ Rejection Chronic
- ○ Other (specify)

Specify "other" primary reason for graft failure

What was the secondary reason for graft failure?

- ○ Primary Graft Failure
- ○ Vascular Thrombosis
- ○ Biliary Tract Complication
- ○ Hepatitis: DeNovo
- ○ Hepatitis: Recurrent
- ○ Recurrent Disease: Non-Hepatitis
- ○ Rejection: Acute
- ○ Infection

	○ Rejection Chronic ○ Other (specify)
Specify "other" secondary reason for graft failure	
(If the graft failed) Was the patient relisted for transplant?	○ Yes ○ No ○ Unknown
(If relisted) What was the date of re-listing? MM/DD/YYYY	
(if the graft failed) Did the subject recieve another liver transplant?	○ Yes ○ No ○ Unknown

What was the immunosuppression regimen in place during this assessment? (Check all that apply)

Prednisone (or oral equivalent)	☐
Methylprednisolone (or IV equivalent)	☐
Cyclosporine (Neoral, Gengraf or any other forumulation)	☐
Tacrolimus (Prograf)	☐
Rapamycin	☐
Certican (RAD)	☐
Azathioprine (Imuran or generic)	☐
Mycophenolate mofetil (Cellcept or generic)	☐
Enteric-coated mycophenolic acid (Myfortic or generic)	☐
Other immunosuppression ☐	Specify "other" immunsuppression
Antibody used? ○ Yes ○ No	
	ATGAM ☐
	OKT3 ☐
	Thymoglobulin ☐

Zenapax	☐
Simulect	☐
Campath	☐
Other antibody therapy used?	☐
Specify "other" antibody therapy used:	

Did the patient have a rejection episode that was confirmed by biopsy since the last assessment? ○ Yes ○ No *(If "Yes", fill out a Rejection Episode and Treatment form for each biopsy-proven episode)*	*(If "Yes" to Rejection Episodes)* How many biopsy-proven rejection episodes has the patient had since the last assessment? *Leave blank for "None"*
Has the patient been hospitalized since the last assessment? ○ Yes ○ No *(If "Yes" fill out a Hospitalization Form for each hospitalization.)*	*(If "Yes" to Hospitalizations)* How many hospitalizations has the patient had since the last assessment? *Leave blank for "None"*
Has the patient experienced a study-tracked complication since the last assessment? ○ Yes ○ No *(If "Yes", and the complication(s) is included in the study, fill out a RCP Morbidity/Comp Severity Form)*	*(If "Yes" to Complications/Morbidities)* How many study-tracked complications has the patient had since the last assessment? *Leave blank for "None"*
Has the patient experienced a serious adverse event since the last assessment? ○ Yes ○ No *(If "Yes", fill out an SAE/AE Report Form)*	*(If "Yes" to Adverse Events)* How many adverse events has the patient had since the last assessment? *Leave blank for "None"*

Recipient medical condition at this assessment	○ Patient in ICU ○ Hospitalized, not in ICU ○ In Rehab Facility ○ Not Hospitalized
Recipient on ventilator at this assessment?	○ Yes ○ No
Recipient functional status at this assessment	○ Normal, no complaints or evidence of disease ○ Able to perform normal activity; minor signs and symptoms of disease ○ Able to perform normal activity with effort; some signs and symptoms of disease ○ Cares for self, unable to perform normal activity or to do active work ○ Requires occasional assistance but is able to care for most of own needs ○ Requires considerable assistance and frequent medical care ○ Requires special care and assistance; disabled ○ Hospitalization indicated, although death not imminent; severely disabled ○ Hospitalization necessary; active supportive treatment required, very sick ○ Fatal processes progressing rapidly; moribund ○ Dead
Recipient employment status at this assessment:	○ Working full time ○ Working part time by choice ○ Working part time due to disease ○ Working part time reason unknown ○ Not working by choice ○ Not working due to disease ○ Not working, unable to find employment ○ Not working, reason unknown ○ Retired ○ Employment status unknown

Primary source of payment:

- ○ Medicare
- ○ Medicaid
- ○ US State/Gov't Agency
- ○ Private Insurance
- ○ HMO/PPO
- ○ Self
- ○ Donation
- ○ Free Care
- ○ Dept. Veterans' Affairs
- ○ Pending
- ○ Foreign Gov't
- ○ Unknown
- ○ Other (specify)

Specify "other" primary source of payment: [ ]

Recipient weight at this assessment [ ]

- ○ Kilograms
- ○ Pounds

Recipient systolic blood pressure at this assessment: [ ]

mm/Hg

Recipient diastolic blood pressure at this assessment: [ ]

mm/Hg

Recipient diabetes mellitus at this assessment?

- ○ No
- ○ Yes, Insulin Dependent
- ○ Yes, Non-insulin Dependent
- ○ Yes, Type Unknown
- ○ Other

(if patient has diabetes)

Diabetes Treatment

- ○ Insulin
- ○ Oral Agent
- ○ Both Insulin and Oral Agent
- ○ No medications

Recipient dialysis at this assessment?

- ○ No
- ○ Hemodialysis/CVVHD
- ○ Peritoneal Dialysis
- ○ Dialysis-Unknown type
- ○ Unknown

Record the serum creatinine value at this assessment: _____ *mg/dl*	Not Done ☐
Record the total serum albumin value at this assessment: _____ *g/dl*	Not Done ☐
Record the total serum bilirubin value at this assessment: _____ *mg/dl*	Not Done ☐
Record the INR value at this assessment: _____	Not Done ☐
Record the PT/ PTT value at this assessment: _____	Not Done ☐
Record the serum aspartate transaminase (AST) value at this assessment: _____ *IU/L*	Not Done ☐
Record the serum alanine aminotransferase (ALT) value at this assessment: _____ *IU/L*	Not Done ☐
Record the serum alkaline phosphatase (ALK) value at this assessment: _____ *IU/L*	Not Done ☐
Record the AFP value at this assessment: _____ *ng/ml*	Not Done ☐
Record the serum sodium level at this assessment _____ *mEq/L*	Not Done ☐

Is the subject currently a partipant in another research study?	○ Yes, new to this assessment interval. ○ Yes, previously reported. ○ No ○ Unknown	If the subject is a participant in another research study, what is the name of that study?

save reset cancel print

A2ALL
Adult to Adult Living Donor Liver Transplantation Cohort Study

HCV Post-TXP Month 1 Assessment

Please Note: If HCV recurrence was discovered during this assessment, the protocol calls for a biopsy prior to intiation of HCV treatment. If this has occurred, you must fill out an HCV Post-Txp Biopsy Pathology Report.

Date of this assessment: _____ MM/DD/YYYY

Record the date of the RNA test: _____ MM/DD/YYYY

Record the quantitative HCV value at this assessment _____

Units for HCV quantification
- ○ Copies/ml
- ○ Equiv/ml
- ○ IU/ml
- ○ Unknown

Was ongoing HCV treatment being given as of last assessment?
- ○ Yes
- ○ No

Did the patient receive anti-viral treatment during the interval between the last assessment and this one?
- ○ Yes
- ○ No

(if "Yes" to HCV treatment)
What type of HCV treatment(s) did the patient receive during the interval between the last assessment and this one? *Check all that apply*

- Standard Interferon ☐
- PEG Interferon ☐
- Consensus Interferon ☐
- Ribavirin ☐

Other HCV treatment ☐	Specify "other treatment".
Record the date of initiation of post-transplant HCV treatment: MM/DD/YYYY	Not applicable, HCV treatment continuing from previous assessment period. ☐
Was ongoing treatment with interferon being given at the last post-transplant assessment? ○ Yes ○ No	If subject was receiving interferon at the last assessment, record the date of completion of interferon treatment: MM/DD/YYYY
	Not applicable, interferon treatment continuing. ☐
Was ongoing treatment with ribavirin being given at the last post-transplant assessment? ○ Yes ○ No	If subject was receiving ribavirin at the last assessment, record the date of completion of ribavirin treatment: MM/DD/YYYY

Not applicable, ribavirin treatment continuing.	☐

save reset cancel print

A2ALL
Adult to Adult Living Donor Liver Transplantation Cohort Study

HCV Biopsy Pathology Report

Samples to be Collected:

2 liver Bx samples stored in 2ml vials and preserved in RNA-Later

1 liver Bx sample stored in 2ml vial and preserved in formalin.

All samples to be batch-shipped to McKesson BioSample Repository.

Date of biopsy: _____ MM/DD/YYYY	Date of review: _____ MM/DD/YYYY
Name of pathologist reading biopsy	_____
Reason for biopsy: ○ Protocol ○ Pre-HCV treatment ○ Rule-out rejection/ abnormal LFT	*(if a protocol biopsy)* Post-transplant interval: ○ 3 months ○ 1 year ○ 2 years ○ 3 years ○ 4 years ○ 5 years

Indicate the presence of the following

Acute rejection	☐
Biliary obstruction	☐
CMV hepatitis	☐
Is this biopsy compatible with HCV recurrence?	○ Yes ○ No

Knodell Score for Periportal +/- Bridging Necrosis	○ **0** None ○ **1** Mild piecemeal necrosis ○ **3** Moderate piecemeal necrosis (less than 50% of the circumference of most portal tracts) ○ **4** Marked piecemeal necrosis (more than 50% of the circumference of most portal tracts) ○ **5** Moderate piecemeal necrosis PLUS bridging necrosis ○ **6** Marked piecemeal necrosis PLUS bridging necrosis ○ **10** Multilobular necrosis ○ Not Available	
Knodell Score for Lobular Inflammation and Focal Necrosis	○ **0** None ○ **1** Mild * ○ **3** Moderate (involvement of 1/3 to 2/3 of lobules or nodules) ○ **4** Marked (involvement of >2/3 of lobules or nodules) ○ Not Available	* (Mild = acidophilic bodies, ballooning degeneration and/ or scattered foci of hepatocellular necrosis in >1/3 of lobules or nodules)
Knodell Score for Portal Inflammation	○ **0** No portal inflammation ○ **1** Mild (sprinkling of inflammatory cells in <1/3 of portal tracts) ○ **3** Moderate (increased inflammatory cells in 1/3 to 2/3 of portal tracts) ○ **4** Marked (dense packing of inflammatory cells in >2/3 of portal tracts) ○ Not Available	

Ishak Score for Fibrosis	○ **0** No fibrosis ○ **1** Fibrous expansion of some portal areas, with or without short fibrous septa ○ **2** Fibrous expansion of most portal areas, with or without short fibrous septa ○ **3** Fibrous expansion of most portal areas, with occasional portal to portal (p-p) bridging ○ **4** Fibrous expansion of portal areas, with marked briding ((p-p) as well as portal to central (p-c) ○ **5** Marked bridging (p-p and/or p-c) with occasional nodules (incomplete cirrhosis) ○ **6** Cirrhosis; probable or definite ○ Not available

save reset cancel print

Donor Assessment at 3 Months Post-Donation

Samples to be Collected:

*15 ml of whole blood, spun, and serum aliquotted into ten 0.4ml samples (to be frozen and batch-shipped to McKesson BioSample Repository)

*MRI (at 91 days) post-donation for regeneration study

*Keris: All Keris QOL assessments

Visit Missed	☐
Date of this assessment:	MM/DD/YYYY

What is the donor's current status?
- ○ Alive
- ○ Dead
- ○ Unknown

(If dead)

What was the patient's date of death?

MM/DD/YYYY

Was the liver functioning at the time of death?
- ○ Yes
- ○ No
- ○ Unknown

Select the primary cause of death from the list:

Select the secondary cause of death from the list:

	Select the tertiary cause of death from the list:

(If status is "unknown")

Date of last contact:

MM/DD/YYYY

Donor weight this assessment:		○ Kilograms ○ Pounds
Record the serum alanine aminotransferase (ALT) value at this assessment:	*IU/L*	Not Done ☐
Record the serum aspartate transaminase (AST) value at this assessment:	*IU/L*	Not Done ☐
Record the serum alkaline phosphatase (ALK) value at this assessment:	*U/L*	Not Done ☐
Record the total serum bilirubin value at this assessment:	*mg/dl*	Not Done ☐
Blood Urea Nitrogen (BUN) value at this assessment:	*mg/dl*	Not Done ☐
Record the serum creatinine value at this assessment:	*mg/dl*	Not Done ☐

Record the total serum albumin value at this assessment: _____ *g/dl*	Not Done ☐
Record the INR value at this assessment: _____	Not Done ☐
Record the PT/ PTT value at this assessment: _____	Not Done ☐
White Blood Count value at this assessment: _____ *x10^3/mm^3*	Not Done ☐
Record the ferritin level at this assessment _____ *ng/ml*	Not Done ☐
Record the hemoglobin (Hgb) value at this assessment: _____ *g/dl*	Not Done ☐
Record the platelet count at this assessment: _____ *x10^3/mm^3*	Not Done ☐
Record the liver volume at 3 months post-donation: _____ *cc*	Not Done ☐
Has the patient been hospitalized since the last assessment? ○ Yes ○ No *(If "Yes" fill out a Hospitalization Form for each hospitalization.)*	How many times has the patient been hospitalized since the last assessment? _____ *(If "Yes" to hospitalizations)* *Leave blank for "None"*

Has the patient experienced a complication since the last assessment? ○ Yes ○ No *(If "Yes", and the complication(s) is included in the study, fill out a DNR Morbidity/Comp Severity Form.)*	How many complications has the patient had since the last assessment? [ ] *(If "Yes" to complications)* *Leave blank for "None"*
Has the patient experienced an SAE since the last assessment? ○ Yes ○ No *(If "Yes", fill out an SAE Form.)*	How many adverse events has the patient had since the last assessment? [ ] *(If "Yes" to adverse events)* *Leave blank for "None"*

Donor medical condition at this assessment	○ Patient in ICU ○ Hospitalized, not in ICU ○ In Rehab Facility ○ Not Hospitalized
Donor on ventilator at this assessment?	○ Yes ○ No ○ Unknown
Donor functional status at this assessment	○ Normal, no complaints or evidence of disease ○ Able to perform normal activity; minor signs and symptoms of disease ○ Able to perform normal activity with effort; some signs and symptoms of disease ○ Cares for self, unable to perform normal activity or to do active work ○ Requires occasional assistance but is able to care for most of own needs ○ Requires considerable assistance and frequent medical care ○ Requires special care and assistance; disabled ○ Hospitalization indicated, although death not imminent; severely disabled ○ Hospitalization necessary; active supportive treatment required, very sick ○ Fatal processes progressing rapidly; moribund ○ Dead

Donor employment status at this assessment:	○ Working full time ○ Working part time by choice ○ Working part time due to disease ○ Working part time reason unknown ○ Not working by choice ○ Not working due to disease ○ Not working, unable to find employment ○ Not working, reason unknown ○ Retired ○ Employment status unknown
Primary payment source (may reflect recipient's coverage):	○ Medicare ○ Medicaid ○ US State/Gov't Agency ○ Private Insurance ○ HMO/PPO ○ Self ○ Donation ○ Free Care ○ Dept. Veterans' Affairs ○ Pending ○ Foreign Gov't ○ Unknown ○ Other (specify)
Specify "other" primary payment source:	
Indicate what the patient indicates are typical drug use patterns. Patient reports no pain drug use during this interval.	☐
Plain Tylenol - Use	
NSAID (Motrin, Aleve, ibuprofen etc) - Use	
Aspirin - Use	
Tylenol w/ Codeine - Use	
Darvocet - Use	
Vicodin - Use	

Percocet - Use	
Percodan - Use	
Dilaudid - Use	
Oxycontin - Use	
MS Contin - Use	
Methadone - Use	

Other (specify)		Use	

Is the patient a subject in another research study?	○ Yes, new to this assessment interval. ○ Yes, previously reported. ○ No ○ Unknown	If "yes", what is the name of the study?

save reset cancel print

RCP Condition @ 3 Months Post-Transplant

Samples to be Collected:

*15ml whole blood, spun, and serum aliquotted into ten 0.4ml samples (to be frozen and batch-shipped to McKesson BioSample Repository)

*Labs

*Keris QOL Assessment (SF-36)

*MRI @ 91 days post-TXP for Regeneration study

*Prednisone Dose in mg

Visit Missed	☐
Date of this assessment:	MM/DD/YYYY
What is the recipient's current status?	○ Alive ○ Dead ○ Unknown
(If dead) What was the patient's date of death?	MM/DD/YYYY
Was the liver functioning at the time of death?	○ Yes ○ No ○ Unknown
Select the primary cause of death from the list:	

Select the secondary cause of death from the list:

Select the tertiary cause of death from the list:

(If status is "Unknown")

Date of last contact:

MM/DD/YYYY

(If patient is still alive)

What is the status of the liver graft?

- ○ Functional
- ○ Failed
- ○ Unknown
- ○ Index graft failure information previously reported

(If the graft failed)

Date of graft failure:

MM/DD/YYYY

(If the graft failed)

What was the primary reason for graft failure?

- ○ Primary Graft Failure
- ○ Vascular Thrombosis
- ○ Biliary Tract Complication
- ○ Hepatitis: DeNovo
- ○ Hepatitis: Recurrent
- ○ Recurrent Disease: Non-Hepatitis
- ○ Rejection: Acute
- ○ Infection
- ○ Rejection Chronic
- ○ Other (specify)

Specify "other" primary reason for graft failure

What was the secondary reason for graft failure?	○ Primary Graft Failure ○ Vascular Thrombosis ○ Biliary Tract Complication ○ Hepatitis: DeNovo ○ Hepatitis: Recurrent ○ Recurrent Disease: Non-Hepatitis ○ Rejection: Acute ○ Infection ○ Rejection Chronic ○ Other (specify)
Specify "other" secondary reason for graft failure	
(If the graft failed) Was the patient relisted for transplant?	○ Yes ○ No ○ Unknown
(If relisted) What was the date of re-listing? MM/DD/YYYY	
(if the graft failed) Did the subject recieve another liver transplant?	○ Yes ○ No ○ Unknown

What was the immunosuppression regimen in place during this assessment? (Check all that apply)

Prednisone (or oral equivalent)	☐
Methylprednisolone (or IV equivalent)	☐
Cyclosporine (Neoral, Gengraf or any other forumulation)	☐
Tacrolimus (Prograf)	☐
Rapamycin	☐
Certican (RAD)	☐
Azathioprine (Imuran or generic)	☐
Mycophenolate mofetil (Cellcept or generic)	☐
Enteric-coated mycophenolic acid (Myfortic or generic)	☐

Other immunosuppression ☐	Specify "other" immunsuppression
Antibody used? ○ Yes ○ No	
	ATGAM ☐
	OKT3 ☐
	Thymoglobulin ☐
	Zenapax ☐
	Simulect ☐
	Campath ☐
	Other antibody therapy used? ☐
	Specify "other" antibody therapy used:

Prednisone dose at 3 months, in mg. If none, enter "0". For an every other day regimen, divide the bi-daily dose by half and enter that amount. mg

Did the patient have a rejection episode that was confirmed by biopsy since the last assessment? ○ Yes ○ No *(If "Yes", fill out a Rejection Episode and Treatment form for each biopsy-proven episode)*	*(If "Yes" to Rejection Episodes)* How many biopsy-proven rejection episodes has the patient had since the last assessment? *Leave blank for "None"*
Has the patient been hospitalized since the last assessment? ○ Yes ○ No *(If "Yes" fill out a Hospitalization Form for each hospitalization.)*	*(If "Yes" to Hospitializations)* How many hospitalizations has the patient had since the last assessment? *Leave blank for "None"*

Has the patient experienced a study-tracked complication since the last assessment? ○ Yes ○ No *(If "Yes", and the complication(s) is included in the study, fill out a RCP Morbidity/Comp Severity Form)*	*(If "Yes" to Complications/Morbidities)* How many study-tracked complications has the patient had since the last assessment? [ ] *Leave blank for "None"*
Has the patient experienced a serious adverse event since the last assessment? ○ Yes ○ No *(If "Yes", fill out an SAE/AE Report Form)*	*(If "Yes" to Adverse Events)* How many adverse events has the patient had since the last assessment? [ ] *Leave blank for "None"*

Recipient medical condition at this assessment	○ Patient in ICU ○ Hospitalized, not in ICU ○ In Rehab Facility ○ Not Hospitalized
Recipient on ventilator at this assessment?	○ Yes ○ No
Recipient functional status at this assessment	○ Normal, no complaints or evidence of disease ○ Able to perform normal activity; minor signs and symptoms of disease ○ Able to perform normal activity with effort; some signs and symptoms of disease ○ Cares for self, unable to perform normal activity or to do active work ○ Requires occasional assistance but is able to care for most of own needs ○ Requires considerable assistance and frequent medical care ○ Requires special care and assistance; disabled ○ Hospitalization indicated, although death not imminent; severely disabled ○ Hospitalization necessary; active supportive treatment required, very sick ○ Fatal processes progressing rapidly; moribund ○ Dead

Recipient employment status at this assessment:	○ Working full time ○ Working part time by choice ○ Working part time due to disease ○ Working part time reason unknown ○ Not working by choice ○ Not working due to disease ○ Not working, unable to find employment ○ Not working, reason unknown ○ Retired ○ Employment status unknown
Primary source of payment:	○ Medicare ○ Medicaid ○ US State/Gov't Agency ○ Private Insurance ○ HMO/PPO ○ Self ○ Donation ○ Free Care ○ Dept. Veterans' Affairs ○ Pending ○ Foreign Gov't ○ Unknown ○ Other (specify)
Specify "other" primary source of payment:	
Recipient weight at this assessment	○ Kilograms ○ Pounds
Recipient systolic blood pressure at this assessment:	*mm/Hg*
Recipient diastolic blood pressure at this assessment:	*mm/Hg*
Date of MRI done to assess post-txp liver volume: MM/DD/YYYY	Not Done ☐

	Liver Volume: ☐ cc
Recipient diabetes mellitus at this assessment? ○ No ○ Yes, Insulin Dependent ○ Yes, Non-insulin Dependent ○ Yes, Type Unknown ○ Other	*(if patient has diabetes)* Diabetes Treatment ○ Insulin ○ Oral Agent ○ Both Insulin and Oral Agent ○ No medications
Recipient dialysis at this assessment?	○ No ○ Hemodialysis/CVVHD ○ Peritoneal Dialysis ○ Dialysis-Unknown type ○ Unknown
Record the serum creatinine value at this assessment: ☐ *mg/dl*	Not Done ☐
Record the total serum albumin value at this assessment: ☐ *g/dl*	Not Done ☐
Record the total serum bilirubin value at this assessment: ☐ *mg/dl*	Not Done ☐
Record the INR value at this assessment: ☐	Not Done ☐
Record the PT/ PTT value at this assessment: ☐	Not Done ☐
Record the serum aspartate transaminase (AST) value at this assessment: ☐ *IU/L*	Not Done ☐

Record the serum alanine aminotransferase (ALT) value at this assessment: _____ *IU/L*	Not Done ☐
Record the serum alkaline phosphatase (ALK) value at this assessment: _____ *IU/L*	Not Done ☐
Record the AFP value at this assessment: _____ *ng/ml*	Not Done ☐
Record the serum sodium level at this assessment _____ *mEq/L*	Not Done ☐
Is the subject currently a partipant in another research study? ○ Yes, new to this assessment interval. ○ Yes, previously reported. ○ No ○ Unknown	If the subject is a participant in another research study, what is the name of that study? _____

save reset cancel print

A2ALL
Adult to Adult Living Donor Liver Transplantation Cohort Study

HCV Post-TXP 3 Month Assessment

Please Note: A protocol Liver Biopsy is required at Month 3. Please fill out an HCV Post-Txp Biopsy Pathology Report

If HCV recurrence was discovered during this assessment, the protocol calls for a biopsy prior to intiation of HCV treatment. If this has occurred, you must fill out an HCV Post-Txp Biopsy Pathology Report.

Was the protocol biopsy performed?
- ○ Yes
- ○ No

If the protocol Bx was not done, indicate why:

Date of this assessment: MM/DD/YYYY

Record the date of the RNA test: MM/DD/YYYY

Record the quantitative HCV value at this assessment

Units for HCV quantification
- ○ Copies/ml
- ○ Equiv/ml
- ○ IU/ml
- ○ Unknown

Was ongoing HCV treatment being given as of last assessment?	○ Yes ○ No
Did the patient receive anti-viral treatment during the interval between the last assessment and this one?	○ Yes ○ No

(if "Yes" to HCV treatment)
What type of HCV treatment(s) did the patient receive during the interval between the last assessment and this one? *Check all that apply*

Standard Interferon	☐
PEG Interferon	☐
Consensus Interferon	☐
Ribavirin	☐

Other HCV treatment	☐	Specify "other treatment".	
Record the date of initiation of post-transplant HCV treatment: MM/DD/YYYY		Not applicable, HCV treatment continuing from previous assessment period.	☐
Was ongoing treatment with interferon being given at the last post-transplant assessment?	○ Yes ○ No	If subject was receiving interferon at the last assessment, record the date of completion of interferon treatment: MM/DD/YYYY	
		Not applicable, interferon treatment continuing.	☐

Was ongoing treatment with ribavirin being given at the last post-transplant assessment? ○ Yes ○ No	If subject was receiving ribavirin at the last assessment, record the date of completion of ribavirin treatment: _____ MM/DD/YYYY
	Not applicable, ribavirin treatment continuing. ☐

save reset cancel print

HCV Bx Path Report

Samples to be Collected:

2 liver Bx samples stored in 2ml vials and preserved in RNA-Later

1 liver Bx sample stored in 2ml vial and preserved in formalin.

All samples to be batch-shipped to McKesson BioSample Repository.

Date of biopsy: _____ MM/DD/YYYY	Date of review: _____ MM/DD/YYYY
Name of pathologist reading biopsy	_____
Reason for biopsy: ○ Protocol ○ Pre-HCV treatment ○ Rule-out rejection/ abnormal LFT	*(if a protocol biopsy)* Post-transplant interval: ○ 3 months ○ 1 year ○ 2 years ○ 3 years ○ 4 years ○ 5 years
Indicate the presence of the following	
Acute rejection	☐
Biliary obstruction	☐
CMV hepatitis	☐
Is this biopsy compatible with HCV recurrence?	○ Yes ○ No

Knodell Score for Periportal +/- Bridging Necrosis	○ **0** None ○ **1** Mild piecemeal necrosis ○ **3** Moderate piecemeal necrosis (less than 50% of the circumference of most portal tracts) ○ **4** Marked piecemeal necrosis (more than 50% of the circumference of most portal tracts) ○ **5** Moderate piecemeal necrosis PLUS bridging necrosis ○ **6** Marked piecemeal necrosis PLUS bridging necrosis ○ **10** Multilobular necrosis ○ Not Available	
Knodell Score for Lobular Inflammation and Focal Necrosis	○ **0** None ○ **1** Mild * ○ **3** Moderate (involvement of 1/3 to 2/3 of lobules or nodules) ○ **4** Marked (involvement of >2/3 of lobules or nodules) ○ Not Available	* (Mild = acidophilic bodies, ballooning degeneration and/ or scattered foci of hepatocellular necrosis in >1/3 of lobules or nodules)
Knodell Score for Portal Inflammation	○ **0** No portal inflammation ○ **1** Mild (sprinkling of inflammatory cells in <1/3 of portal tracts) ○ **3** Moderate (increased inflammatory cells in 1/3 to 2/3 of portal tracts) ○ **4** Marked (dense packing of inflammatory cells in >2/3 of portal tracts) ○ Not Available	

Ishak Score for Fibrosis	○ **0** No fibrosis ○ **1** Fibrous expansion of some portal areas, with or without short fibrous septa ○ **2** Fibrous expansion of most portal areas, with or without short fibrous septa ○ **3** Fibrous expansion of most portal areas, with occasional portal to portal (p-p) bridging ○ **4** Fibrous expansion of portal areas, with marked briding ((p-p) as well as portal to central (p-c) ○ **5** Marked bridging (p-p and/or p-c) with occasional nodules (incomplete cirrhosis) ○ **6** Cirrhosis; probable or definite ○ Not available

save reset cancel print

RCP Condition @ 6 Months Post-Transplant

Samples to be Collected:

*15ml whole blood, spun, and serum aliquotted into ten 0.4ml samples (to be frozen and batch-shipped to McKesson BioSample Repository)

*Labs

*Keris QOL Assessment (SF-36)

Visit Missed	☐
Date of this assessment:	MM/DD/YYYY

What is the recipient's current status?
- ○ Alive
- ○ Dead
- ○ Unknown

(If dead)

What was the patient's date of death?

MM/DD/YYYY

Was the liver functioning at the time of death?
- ○ Yes
- ○ No
- ○ Unknown

Select the primary cause of death from the list:

Select the secondary cause of death from the list:

Select the tertiary cause of death from the list:

(If status is "Unknown")

Date of last contact:

MM/DD/YYYY

(If patient is still alive)

What is the status of the liver graft?

- ○ Functional
- ○ Failed
- ○ Unknown
- ○ Index graft failure information previously reported

(If the graft failed)

Date of graft failure:

MM/DD/YYYY

(If the graft failed)

What was the primary reason for graft failure?

- ○ Primary Graft Failure
- ○ Vascular Thrombosis
- ○ Biliary Tract Complication
- ○ Hepatitis: DeNovo
- ○ Hepatitis: Recurrent
- ○ Recurrent Disease: Non-Hepatitis
- ○ Rejection: Acute
- ○ Infection
- ○ Rejection Chronic
- ○ Other (specify)

Specify "other" primary reason for graft failure

What was the secondary reason for graft failure?

- ○ Primary Graft Failure
- ○ Vascular Thrombosis
- ○ Biliary Tract Complication
- ○ Hepatitis: DeNovo
- ○ Hepatitis: Recurrent
- ○ Recurrent Disease: Non-Hepatitis
- ○ Rejection: Acute
- ○ Infection

○ Rejection Chronic
○ Other (specify)

Specify "other" secondary reason for graft failure

(If the graft failed)

Was the patient relisted for transplant?
○ Yes
○ No
○ Unknown

(If relisted)

What was the date of re-listing?

MM/DD/YYYY

(if the graft failed)

Did the subject recieve another liver transplant?
○ Yes
○ No
○ Unknown

What was the immunosuppression regimen in place during this assessment? (Check all that apply)

- ☐ Prednisone (or oral equivalent)
- ☐ Methylprednisolone (or IV equivalent)
- ☐ Cyclosporine (Neoral, Gengraf or any other forumulation)
- ☐ Tacrolimus (Prograf)
- ☐ Rapamycin
- ☐ Certican (RAD)
- ☐ Azathioprine (Imuran or generic)
- ☐ Mycophenolate mofetil (Cellcept or generic)
- ☐ Enteric-coated mycophenolic acid (Myfortic or generic)
- ☐ Other immunosuppression

Specify "other" immunsuppression

Antibody used?
○ Yes
○ No

- ☐ ATGAM
- ☐ OKT3
- ☐ Thymoglobulin

Zenapax	☐
Simulect	☐
Campath	☐
Other antibody therapy used?	☐
Specify "other" antibody therapy used:	

Did the patient have a rejection episode that was confirmed by biopsy since the last assessment? ○ Yes ○ No *(If "Yes", fill out a Rejection Episode and Treatment form for each biopsy-proven episode)*	*(If "Yes" to Rejection Episodes)* How many biopsy-proven rejection episodes has the patient had since the last assessment? *Leave blank for "None"*
Has the patient been hospitalized since the last assessment? ○ Yes ○ No *(If "Yes" fill out a Hospitalization Form for each hospitalization.)*	*(If "Yes" to Hospitalizations)* How many hospitalizations has the patient had since the last assessment? *Leave blank for "None"*
Has the patient experienced a study-tracked complication since the last assessment? ○ Yes ○ No *(If "Yes", and the complication(s) is included in the study, fill out a RCP Morbidity/Comp Severity Form)*	*(If "Yes" to Complications/Morbidities)* How many study-tracked complications has the patient had since the last assessment? *Leave blank for "None"*
Has the patient experienced a serious adverse event since the last assessment? ○ Yes ○ No *(If "Yes", fill out an SAE/AE Report Form)*	*(If "Yes" to Adverse Events)* How many adverse events has the patient had since the last assessment? *Leave blank for "None"*

Recipient medical condition at this assessment	○ Patient in ICU ○ Hospitalized, not in ICU ○ In Rehab Facility ○ Not Hospitalized
Recipient on ventilator at this assessment?	○ Yes ○ No
Recipient functional status at this assessment	○ Normal, no complaints or evidence of disease ○ Able to perform normal activity; minor signs and symptoms of disease ○ Able to perform normal activity with effort; some signs and symptoms of disease ○ Cares for self, unable to perform normal activity or to do active work ○ Requires occasional assistance but is able to care for most of own needs ○ Requires considerable assistance and frequent medical care ○ Requires special care and assistance; disabled ○ Hospitalization indicated, although death not imminent; severely disabled ○ Hospitalization necessary; active supportive treatment required, very sick ○ Fatal processes progressing rapidly; moribund ○ Dead
Recipient employment status at this assessment:	○ Working full time ○ Working part time by choice ○ Working part time due to disease ○ Working part time reason unknown ○ Not working by choice ○ Not working due to disease ○ Not working, unable to find employment ○ Not working, reason unknown ○ Retired ○ Employment status unknown

Primary source of payment:	○ Medicare ○ Medicaid ○ US State/Gov't Agency ○ Private Insurance ○ HMO/PPO ○ Self ○ Donation ○ Free Care ○ Dept. Veterans' Affairs ○ Pending ○ Foreign Gov't ○ Unknown ○ Other (specify)
Specify "other" primary source of payment:	
Recipient weight at this assessment	○ Kilograms ○ Pounds
Recipient systolic blood pressure at this assessment:	*mm/Hg*
Recipient diastolic blood pressure at this assessment:	*mm/Hg*
Recipient diabetes mellitus at this assessment?	○ No ○ Yes, Insulin Dependent ○ Yes, Non-insulin Dependent ○ Yes, Type Unknown ○ Other
(if patient has diabetes) Diabetes Treatment	○ Insulin ○ Oral Agent ○ Both Insulin and Oral Agent ○ No medications
Recipient dialysis at this assessment?	○ No ○ Hemodialysis/CVVHD ○ Peritoneal Dialysis ○ Dialysis-Unknown type ○ Unknown

Record the serum creatinine value at this assessment: *mg/dl*	Not Done ☐
Record the total serum albumin value at this assessment: *g/dl*	Not Done ☐
Record the total serum bilirubin value at this assessment: *mg/dl*	Not Done ☐
Record the INR value at this assessment:	Not Done ☐
Record the PT/ PTT value at this assessment:	Not Done ☐
Record the serum aspartate transaminase (AST) value at this assessment: *IU/L*	Not Done ☐
Record the serum alanine aminotransferase (ALT) value at this assessment: *IU/L*	Not Done ☐
Record the serum alkaline phosphatase (ALK) value at this assessment: *IU/L*	Not Done ☐
Record the AFP value at this assessment: *ng/ml*	Not Done ☐
Record the serum sodium level at this assessment *mEq/L*	Not Done ☐

Is the subject currently a partipant in another research study?	○ Yes, new to this assessment interval. ○ Yes, previously reported. ○ No ○ Unknown	If the subject is a participant in another research study, what is the name of that study?

save reset cancel print

HCC Post-TXP 6 Month Assessment

Samples/Labs/Procedures for Subjects with HCC at Post-TXP Assessments

*HCC Imaging

Date of assessment:	MM/DD/YYYY
Did the patient receive adjunctive/preventive/pre-emptive chemotherapy without a diagnosis of recurrent HCC since the last post-txp assessment?	○ Yes ○ No
Did the patient develop HCC recurrence since the last post-transplant assessment? ○ Yes ○ No	*(If "yes" to HCC recurrence)* Date recurrence first diagnosed: MM/DD/YYYY
What diagnostic/imaging studies were used to diagnose the HCC recurrence? (check all that apply)	
Chest CT	☐
Bone scan	☐
Abdominal MRI/Contrast CT	☐
Other (specify):	

Where was the initial site of recurrence?	○ Intrahepatic ○ Extrahepatic ○ Both ○ Unknown ○ Other

Location of extrahepatic recurrence (check all that apply)

Bone	☐
Lung	☐
Abdominal wall or incision	☐
Other ☐	Other extrahepatic location:

Record the date and type of ablations the subject received since the last assessment, either as treatment for cancer recurrence or adjunctive therapy after transplant.

No ablations performed in this interval	☐		
Ablation 1 Date:	MM/DD/YYYY	Ablation 1 Type:	
Ablation 2 Date:	MM/DD/YYYY	Ablation 2 Type:	
Ablation 3 Date:	MM/DD/YYYY	Ablation 3 Type:	
Ablation 4 Date:	MM/DD/YYYY	Ablation 4 Type:	
Ablation 5 Date:	MM/DD/YYYY	Ablation 5 Type:	

Ablation 6 Date:	MM/DD/YYYY	Ablation 6 Type:	
Ablation 7 Date:	MM/DD/YYYY	Ablation 7 Type:	
Ablation 8 Date:	MM/DD/YYYY	Ablation 8 Type:	
Ablation 9 Date:	MM/DD/YYYY	Ablation 9 Type:	
Ablation 10 Date:	MM/DD/YYYY	Ablation 10 Type:	

If surgical resection(s) were performed, what type (s) were performed? (check all that apply)

Wedge	☐
Segment	☐
Lobe	☐
Non-anatomic	☐

Has the patient received systemic or local chemotherapy (other than ablative chemoinfusion) to treat known HCC recurrence since the last assessment?	○ Yes, Systemic ○ Yes, Local ○ Yes, Both ○ No ○ Unknown
Has the patient received radiation treatment for HCC recurrence since the last assessment?	○ Yes ○ No

save reset cancel print

Donor Assessment at 1 Year Post-Donation

Samples to be Collected:

*15 ml of whole blood, spun, and serum aliquotted into ten 0.4ml samples (to be frozen and batch-shipped to McKesson BioSample Repository)

*Keris: All Keris QOL assessments

Visit Missed	☐
Date of this assessment:	MM/DD/YYYY

What is the donor's current status?
- ○ Alive
- ○ Dead
- ○ Unknown

(If dead)

What was the patient's date of death?

MM/DD/YYYY

Was the liver functioning at the time of death?
- ○ Yes
- ○ No
- ○ Unknown

Select the primary cause of death from the list:

Select the secondary cause of death from the list:

Select the tertiary cause of death from the list:	

(If status is "unknown")

Date of last contact:

MM/DD/YYYY

Donor weight this assessment:		○ Kilograms ○ Pounds
Record the serum alanine aminotransferase (ALT) value at this assessment: *IU/L*		Not Done ☐
Record the serum aspartate transaminase (AST) value at this assessment: *IU/L*		Not Done ☐
Record the serum alkaline phosphatase (ALK) value at this assessment: *U/L*		Not Done ☐
Record the total serum bilirubin value at this assessment: *mg/dl*		Not Done ☐
Blood Urea Nitrogen (BUN) value at this assessment: *mg/dl*		Not Done ☐
Record the serum creatinine value at this assessment: *mg/dl*		Not Done ☐

Record the total serum albumin value at this assessment: *g/dl*	Not Done ☐
Record the INR value at this assessment:	Not Done ☐
Record the PT/ PTT value at this assessment:	Not Done ☐
White Blood Count value at this assessment: *x10^3/mm^3*	Not Done ☐
Record the ferritin level at this assessment *ng/ml*	Not Done ☐
Record the hemoglobin (Hgb) value at this assessment: *g/dl*	Not Done ☐
Record the platelet count at this assessment: *x10^3/mm^3*	Not Done ☐
Has the patient been hospitalized since the last assessment? ○ Yes ○ No *(If "Yes" fill out a Hospitalization Form for each hospitalization.)*	How many times has the patient been hospitalized since the last assessment? *(If "Yes" to hospitalizations)* *Leave blank for "None"*
Has the patient experienced a complication since the last assessment? ○ Yes ○ No *(If "Yes", and the complication(s) is included in the study, fill out a DNR Morbidity/Comp Severity Form.)*	How many complications has the patient had since the last assessment? *(If "Yes" to complications)* *Leave blank for "None"*

Has the patient experienced an SAE since the last assessment? ○ Yes ○ No *(If "Yes", fill out an SAE Form.)*	How many adverse events has the patient had since the last assessment? [ ] *(If "Yes" to adverse events)* *Leave blank for "None"*

Donor medical condition at this assessment	○ Patient in ICU ○ Hospitalized, not in ICU ○ In Rehab Facility ○ Not Hospitalized
Donor on ventilator at this assessment?	○ Yes ○ No ○ Unknown
Donor functional status at this assessment	○ Normal, no complaints or evidence of disease ○ Able to perform normal activity; minor signs and symptoms of disease ○ Able to perform normal activity with effort; some signs and symptoms of disease ○ Cares for self, unable to perform normal activity or to do active work ○ Requires occasional assistance but is able to care for most of own needs ○ Requires considerable assistance and frequent medical care ○ Requires special care and assistance; disabled ○ Hospitalization indicated, although death not imminent; severely disabled ○ Hospitalization necessary; active supportive treatment required, very sick ○ Fatal processes progressing rapidly; moribund ○ Dead
Donor employment status at this assessment:	○ Working full time ○ Working part time by choice ○ Working part time due to disease ○ Working part time reason unknown ○ Not working by choice ○ Not working due to disease ○ Not working, unable to find employment ○ Not working, reason unknown ○ Retired

	○ Employment status unknown
Primary payment source (may reflect recipient's coverage):	○ Medicare ○ Medicaid ○ US State/Gov't Agency ○ Private Insurance ○ HMO/PPO ○ Self ○ Donation ○ Free Care ○ Dept. Veterans' Affairs ○ Pending ○ Foreign Gov't ○ Unknown ○ Other (specify)
Specify "other" primary payment source:	
Indicate what the patient indicates are typical drug use patterns. Patient reports no pain drug use during this interval.	☐
Plain Tylenol - Use	
NSAID (Motrin, Aleve, ibuprofen etc) - Use	
Aspirin - Use	
Tylenol w/ Codeine - Use	
Darvocet - Use	
Vicodin - Use	
Percocet - Use	
Percodan - Use	
Dilaudid - Use	
Oxycontin - Use	
MS Contin - Use	
Methadone - Use	
Other (specify)	Use

Is the patient a subject in another research study?	○ Yes, new to this assessment interval. ○ Yes, previously reported. ○ No ○ Unknown	If "yes", what is the name of the study?

save reset cancel print

RCP Condition @ 1 Year Post-Transplant

Samples to be Collected:

*15ml whole blood, spun, and serum aliquotted into ten 0.4ml samples (to be frozen and batch-shipped to McKesson BioSample Repository)

*Labs

*Keris QOL Assessment (SF-36)

Visit Missed	☐
Date of this assessment:	MM/DD/YYYY

What is the recipient's current status?
- ○ Alive
- ○ Dead
- ○ Unknown

(If dead)

What was the patient's date of death?

MM/DD/YYYY

Was the liver functioning at the time of death?
- ○ Yes
- ○ No
- ○ Unknown

Select the primary cause of death from the list:

Select the secondary cause of death from the list:

Select the tertiary cause of death from the list:

(If status is "Unknown")

Date of last contact:

MM/DD/YYYY

(If patient is still alive)

What is the status of the liver graft?

- ○ Functional
- ○ Failed
- ○ Unknown
- ○ Index graft failure information previously reported

(If the graft failed)

Date of graft failure:

MM/DD/YYYY

(If the graft failed)

What was the primary reason for graft failure?

- ○ Primary Graft Failure
- ○ Vascular Thrombosis
- ○ Biliary Tract Complication
- ○ Hepatitis: DeNovo
- ○ Hepatitis: Recurrent
- ○ Recurrent Disease: Non-Hepatitis
- ○ Rejection: Acute
- ○ Infection
- ○ Rejection Chronic
- ○ Other (specify)

Specify "other" primary reason for graft failure

What was the secondary reason for graft failure?

- ○ Primary Graft Failure
- ○ Vascular Thrombosis
- ○ Biliary Tract Complication
- ○ Hepatitis: DeNovo
- ○ Hepatitis: Recurrent
- ○ Recurrent Disease: Non-Hepatitis
- ○ Rejection: Acute
- ○ Infection

	○ Rejection Chronic ○ Other (specify)
Specify "other" secondary reason for graft failure	
(If the graft failed) Was the patient relisted for transplant?	○ Yes ○ No ○ Unknown
(If relisted) What was the date of re-listing? MM/DD/YYYY	
(if the graft failed) Did the subject recieve another liver transplant?	○ Yes ○ No ○ Unknown

What was the immunosuppression regimen in place during this assessment? (Check all that apply)

Prednisone (or oral equivalent)	☐
Methylprednisolone (or IV equivalent)	☐
Cyclosporine (Neoral, Gengraf or any other forumulation)	☐
Tacrolimus (Prograf)	☐
Rapamycin	☐
Certican (RAD)	☐
Azathioprine (Imuran or generic)	☐
Mycophenolate mofetil (Cellcept or generic)	☐
Enteric-coated mycophenolic acid (Myfortic or generic)	☐
Other immunosuppression	☐
Specify "other" immunsuppression	
Antibody used?	○ Yes ○ No
ATGAM	☐
OKT3	☐
Thymoglobulin	☐

Zenapax	☐
Simulect	☐
Campath	☐
Other antibody therapy used?	☐
Specify "other" antibody therapy used:	

Did the patient have a rejection episode that was confirmed by biopsy since the last assessment? ○ Yes ○ No *(If "Yes", fill out a Rejection Episode and Treatment form for each biopsy-proven episode)*	*(If "Yes" to Rejection Episodes)* How many biopsy-proven rejection episodes has the patient had since the last assessment? *Leave blank for "None"*
Has the patient been hospitalized since the last assessment? ○ Yes ○ No *(If "Yes" fill out a Hospitalization Form for each hospitalization.)*	*(If "Yes" to Hospitalizations)* How many hospitalizations has the patient had since the last assessment? *Leave blank for "None"*
Has the patient experienced a study-tracked complication since the last assessment? ○ Yes ○ No *(If "Yes", and the complication(s) is included in the study, fill out a RCP Morbidity/Comp Severity Form)*	*(If "Yes" to Complications/Morbidities)* How many study-tracked complications has the patient had since the last assessment? *Leave blank for "None"*
Has the patient experienced a serious adverse event since the last assessment? ○ Yes ○ No *(If "Yes", fill out an SAE/AE Report Form)*	*(If "Yes" to Adverse Events)* How many adverse events has the patient had since the last assessment? *Leave blank for "None"*

Recipient medical condition at this assessment	○ Patient in ICU ○ Hospitalized, not in ICU ○ In Rehab Facility ○ Not Hospitalized
Recipient on ventilator at this assessment?	○ Yes ○ No
Recipient functional status at this assessment	○ Normal, no complaints or evidence of disease ○ Able to perform normal activity; minor signs and symptoms of disease ○ Able to perform normal activity with effort; some signs and symptoms of disease ○ Cares for self, unable to perform normal activity or to do active work ○ Requires occasional assistance but is able to care for most of own needs ○ Requires considerable assistance and frequent medical care ○ Requires special care and assistance; disabled ○ Hospitalization indicated, although death not imminent; severely disabled ○ Hospitalization necessary; active supportive treatment required, very sick ○ Fatal processes progressing rapidly; moribund ○ Dead
Recipient employment status at this assessment:	○ Working full time ○ Working part time by choice ○ Working part time due to disease ○ Working part time reason unknown ○ Not working by choice ○ Not working due to disease ○ Not working, unable to find employment ○ Not working, reason unknown ○ Retired ○ Employment status unknown

Primary source of payment:	○ Medicare ○ Medicaid ○ US State/Gov't Agency ○ Private Insurance ○ HMO/PPO ○ Self ○ Donation ○ Free Care ○ Dept. Veterans' Affairs ○ Pending ○ Foreign Gov't ○ Unknown ○ Other (specify)
Specify "other" primary source of payment:	
Recipient weight at this assessment	○ Kilograms ○ Pounds
Recipient systolic blood pressure at this assessment:	*mm/Hg*
Recipient diastolic blood pressure at this assessment:	*mm/Hg*
Recipient diabetes mellitus at this assessment?	○ No ○ Yes, Insulin Dependent ○ Yes, Non-insulin Dependent ○ Yes, Type Unknown ○ Other
(if patient has diabetes) Diabetes Treatment	○ Insulin ○ Oral Agent ○ Both Insulin and Oral Agent ○ No medications
Recipient dialysis at this assessment?	○ No ○ Hemodialysis/CVVHD ○ Peritoneal Dialysis ○ Dialysis-Unknown type ○ Unknown

Record the serum creatinine value at this assessment: *mg/dl*	Not Done ☐
Record the total serum albumin value at this assessment: *g/dl*	Not Done ☐
Record the total serum bilirubin value at this assessment: *mg/dl*	Not Done ☐
Record the INR value at this assessment:	Not Done ☐
Record the PT/ PTT value at this assessment:	Not Done ☐
Record the serum aspartate transaminase (AST) value at this assessment: *IU/L*	Not Done ☐
Record the serum alanine aminotransferase (ALT) value at this assessment: *IU/L*	Not Done ☐
Record the serum alkaline phosphatase (ALK) value at this assessment: *IU/L*	Not Done ☐
Record the AFP value at this assessment: *ng/ml*	Not Done ☐
Record the serum sodium level at this assessment *mEq/L*	Not Done ☐

Is the subject currently a partipant in another research study?	○ Yes, new to this assessment interval. ○ Yes, previously reported. ○ No ○ Unknown	If the subject is a participant in another research study, what is the name of that study?

save reset cancel print

A2ALL
Adult to Adult Living Donor Liver Transplantation Cohort Study

HCV Post-TXP 1 Year Assessment

Please Note: Please Note: A protocol Liver Biopsy is required at Year 1. Please fill out an HCV Post-Txp Biopsy Pathology Report

If HCV recurrence was discovered during this assessment, the protocol calls for a biopsy prior to intiation of HCV treatment. If this has occurred, you must fill out an HCV Post-Txp Biopsy Pathology Report.

Was the protocol biopsy performed? ○ Yes ○ No

If the protocol Bx was not done, indicate why:

Record the date of the RNA test: MM/DD/YYYY

Date of this assessment: MM/DD/YYYY

Record the quantitative HCV value at this assessment

Units for HCV quantification ○ Copies/ml ○ Equiv/ml ○ IU/ml ○ Unknown

Was ongoing HCV treatment being given as of last assessment? ○ Yes ○ No

Did the patient receive anti-viral treatment during the interval between the last assessment and this one?	○ Yes ○ No

(if "Yes" to HCV treatment)

What type of HCV treatment(s) did the patient receive during the interval between the last assessment and this one? *Check all that apply*

Standard Interferon	☐
PEG Interferon	☐
Consensus Interferon	☐
Ribavirin	☐

Other HCV treatment	☐	Specify "other treatment".	
Record the date of initiation of post-transplant HCV treatment: MM/DD/YYYY		Not applicable, HCV treatment continuing from previous assessment period.	☐
Was ongoing treatment with interferon being given at the last post-transplant assessment?	○ Yes ○ No	If subject was receiving interferon at the last assessment, record the date of completion of interferon treatment: MM/DD/YYYY	
		Not applicable, interferon treatment continuing.	☐
Was ongoing treatment with ribavirin being given at the last post-transplant assessment?	○ Yes ○ No	If subject was receiving ribavirin at the last assessment, record the date of completion of ribavirin treatment: MM/DD/YYYY	

Not applicable, ribavirin treatment continuing.	☐

save reset cancel print

HCV Bx Path Report

Samples to be Collected:

2 liver Bx samples stored in 2ml vials and preserved in RNA-Later

1 liver Bx sample stored in 2ml vial and preserved in formalin.

All samples to be batch-shipped to McKesson BioSample Repository.

Date of biopsy: _____ MM/DD/YYYY	Date of review: _____ MM/DD/YYYY
Name of pathologist reading biopsy	_____
Reason for biopsy: ○ Protocol ○ Pre-HCV treatment ○ Rule-out rejection/ abnormal LFT	*(if a protocol biopsy)* Post-transplant interval: ○ 3 months ○ 1 year ○ 2 years ○ 3 years ○ 4 years ○ 5 years
Indicate the presence of the following	
Acute rejection	☐
Biliary obstruction	☐
CMV hepatitis	☐
Is this biopsy compatible with HCV recurrence?	○ Yes ○ No

Knodell Score for Periportal +/- Bridging Necrosis	○ **0** None ○ **1** Mild piecemeal necrosis ○ **3** Moderate piecemeal necrosis (less than 50% of the circumference of most portal tracts) ○ **4** Marked piecemeal necrosis (more than 50% of the circumference of most portal tracts) ○ **5** Moderate piecemeal necrosis PLUS bridging necrosis ○ **6** Marked piecemeal necrosis PLUS bridging necrosis ○ **10** Multilobular necrosis ○ Not Available	
Knodell Score for Lobular Inflammation and Focal Necrosis	○ **0** None ○ **1** Mild * ○ **3** Moderate (involvement of 1/3 to 2/3 of lobules or nodules) ○ **4** Marked (involvement of >2/3 of lobules or nodules) ○ Not Available	* (Mild = acidophilic bodies, ballooning degeneration and/ or scattered foci of hepatocellular necrosis in >1/3 of lobules or nodules)
Knodell Score for Portal Inflammation	○ **0** No portal inflammation ○ **1** Mild (sprinkling of inflammatory cells in <1/3 of portal tracts) ○ **3** Moderate (increased inflammatory cells in 1/3 to 2/3 of portal tracts) ○ **4** Marked (dense packing of inflammatory cells in >2/3 of portal tracts) ○ Not Available	

Ishak Score for Fibrosis	○ **0** No fibrosis ○ **1** Fibrous expansion of some portal areas, with or without short fibrous septa ○ **2** Fibrous expansion of most portal areas, with or without short fibrous septa ○ **3** Fibrous expansion of most portal areas, with occasional portal to portal (p-p) bridging ○ **4** Fibrous expansion of portal areas, with marked briding ((p-p) as well as portal to central (p-c) ○ **5** Marked bridging (p-p and/or p-c) with occasional nodules (incomplete cirrhosis) ○ **6** Cirrhosis; probable or definite ○ Not available

save reset cancel print

HCC Post-TXP 1 Year Assessment

Samples/Labs/Procedures for Subjects with HCC at Post-TXP Assessments

*HCC Imaging

Date of assessment:	MM/DD/YYYY
Did the patient receive adjunctive/preventive/pre-emptive chemotherapy without a diagnosis of recurrent HCC since the last post-txp assessment?	○ Yes ○ No
Did the patient develop HCC recurrence since the last post-transplant assessment? ○ Yes ○ No	*(If "yes" to HCC recurrence)* Date recurrence first diagnosed: MM/DD/YYYY
What diagnostic/imaging studies were used to diagnose the HCC recurrence? (check all that apply)	
Chest CT	☐
Bone scan	☐
Abdominal MRI/Contrast CT	☐
Other (specify):	

Where was the initial site of recurrence?	○ Intrahepatic ○ Extrahepatic ○ Both ○ Unknown ○ Other

Location of extrahepatic recurrence (check all that apply)

Bone	☐
Lung	☐
Abdominal wall or incision	☐
Other ☐	Other extrahepatic location:

Record the date and type of ablations the subject received since the last assessment, either as treatment for cancer recurrence or adjunctive therapy after transplant.

No ablations performed in this interval	☐
Ablation 1 Date: MM/DD/YYYY	Ablation 1 Type:
Ablation 2 Date: MM/DD/YYYY	Ablation 2 Type:
Ablation 3 Date: MM/DD/YYYY	Ablation 3 Type:
Ablation 4 Date: MM/DD/YYYY	Ablation 4 Type:
Ablation 5 Date: MM/DD/YYYY	Ablation 5 Type:

Ablation 6 Date:	MM/DD/YYYY	Ablation 6 Type:	
Ablation 7 Date:	MM/DD/YYYY	Ablation 7 Type:	
Ablation 8 Date:	MM/DD/YYYY	Ablation 8 Type:	
Ablation 9 Date:	MM/DD/YYYY	Ablation 9 Type:	
Ablation 10 Date:	MM/DD/YYYY	Ablation 10 Type:	

If surgical resection(s) were performed, what type (s) were performed? (check all that apply)

- ☐ Wedge
- ☐ Segment
- ☐ Lobe
- ☐ Non-anatomic

Has the patient received systemic or local chemotherapy (other than ablative chemoinfusion) to treat known HCC recurrence since the last assessment?

- ○ Yes, Systemic
- ○ Yes, Local
- ○ Yes, Both
- ○ No
- ○ Unknown

Has the patient received radiation treatment for HCC recurrence since the last assessment?

- ○ Yes
- ○ No

save reset cancel print

HCC Post-TXP 18 Month Assessment

Samples/Labs/Procedures for Subjects with HCC at Post-TXP Assessments

*HCC Imaging

*18 months post-txp is a unique time point for subjects with HCC. In addition to imaging, collect blood for AFP.

Date of assessment:	MM/DD/YYYY
Did the patient receive adjunctive/preventive/pre-emptive chemotherapy without a diagnosis of recurrent HCC since the last post-txp assessment?	○ Yes ○ No
Did the patient develop HCC recurrence since the last post-transplant assessment? ○ Yes ○ No	*(If "yes" to HCC recurrence)* Date recurrence first diagnosed: MM/DD/YYYY
What diagnostic/imaging studies were used to diagnose the HCC recurrence? (check all that apply)	
Chest CT	☐
Bone scan	☐
Abdominal MRI/Contrast CT	☐
Other (specify):	

Where was the initial site of recurrence?	○ Intrahepatic ○ Extrahepatic ○ Both ○ Unknown ○ Other

Location of extrahepatic recurrence (check all that apply)

Bone	☐
Lung	☐
Abdominal wall or incision	☐
Other ☐	Other extrahepatic location:

Record the date and type of ablations the subject received since the last assessment, either as treatment for cancer recurrence or adjunctive therapy after transplant.

No ablations performed in this interval	☐
Ablation 1 Date: MM/DD/YYYY	Ablation 1 Type:
Ablation 2 Date: MM/DD/YYYY	Ablation 2 Type:
Ablation 3 Date: MM/DD/YYYY	Ablation 3 Type:
Ablation 4 Date: MM/DD/YYYY	Ablation 4 Type:
Ablation 5 Date: MM/DD/YYYY	Ablation 5 Type:

Ablation 6 Date:	MM/DD/YYYY	Ablation 6 Type:	
Ablation 7 Date:	MM/DD/YYYY	Ablation 7 Type:	
Ablation 8 Date:	MM/DD/YYYY	Ablation 8 Type:	
Ablation 9 Date:	MM/DD/YYYY	Ablation 9 Type:	
Ablation 10 Date:	MM/DD/YYYY	Ablation 10 Type:	

If surgical resection(s) were performed, what type (s) were performed? (check all that apply)

Wedge	☐
Segment	☐
Lobe	☐
Non-anatomic	☐

Has the patient received systemic or local chemotherapy (other than ablative chemoinfusion) to treat known HCC recurrence since the last assessment?	○ Yes, Systemic ○ Yes, Local ○ Yes, Both ○ No ○ Unknown
Has the patient received radiation treatment for HCC recurrence since the last assessment?	○ Yes ○ No

save reset cancel print

HCC Post-TXP 2 Year Assessment

Samples/Labs/Procedures for Subjects with HCC at Post-TXP Assessments

*HCC Imaging

Date of assessment:	MM/DD/YYYY
Did the patient receive adjunctive/preventive/pre-emptive chemotherapy without a diagnosis of recurrent HCC since the last post-txp assessment?	○ Yes ○ No
Did the patient develop HCC recurrence since the last post-transplant assessment? ○ Yes ○ No	*(If "yes" to HCC recurrence)* Date recurrence first diagnosed: MM/DD/YYYY
What diagnostic/imaging studies were used to diagnose the HCC recurrence? (check all that apply)	
Chest CT	☐
Bone scan	☐
Abdominal MRI/Contrast CT	☐
Other (specify):	

Where was the initial site of recurrence?	○ Intrahepatic ○ Extrahepatic ○ Both ○ Unknown ○ Other

Location of extrahepatic recurrence (check all that apply)

Bone	☐
Lung	☐
Abdominal wall or incision	☐
Other ☐	Other extrahepatic location:

Record the date and type of ablations the subject received since the last assessment, either as treatment for cancer recurrence or adjunctive therapy after transplant.

No ablations performed in this interval	☐
Ablation 1 Date: MM/DD/YYYY	Ablation 1 Type:
Ablation 2 Date: MM/DD/YYYY	Ablation 2 Type:
Ablation 3 Date: MM/DD/YYYY	Ablation 3 Type:
Ablation 4 Date: MM/DD/YYYY	Ablation 4 Type:
Ablation 5 Date: MM/DD/YYYY	Ablation 5 Type:

Ablation 6 Date:	MM/DD/YYYY	Ablation 6 Type:	
Ablation 7 Date:	MM/DD/YYYY	Ablation 7 Type:	
Ablation 8 Date:	MM/DD/YYYY	Ablation 8 Type:	
Ablation 9 Date:	MM/DD/YYYY	Ablation 9 Type:	
Ablation 10 Date:	MM/DD/YYYY	Ablation 10 Type:	

If surgical resection(s) were performed, what type (s) were performed? (check all that apply)

Wedge	☐
Segment	☐
Lobe	☐
Non-anatomic	☐

Has the patient received systemic or local chemotherapy (other than ablative chemoinfusion) to treat known HCC recurrence since the last assessment?	○ Yes, Systemic ○ Yes, Local ○ Yes, Both ○ No ○ Unknown
Has the patient received radiation treatment for HCC recurrence since the last assessment?	○ Yes ○ No

save reset cancel print

A2ALL
Adult to Adult Living Donor Liver Transplantation Cohort Study

Rejection Episodes and Treatment 1

Please Note: In the Cohort Study, rejection episodes should be confirmed by liver biopsy except if medically contraindicated. Samples of this biopsy should be collected.
*****2 liver Bx samples in 2ml container preserved in RNALater and batch-shipped to McKesson BioSample Repository**
*****1 liver Bx samples in 2ml container preserved in formalin and batch-shipped to McKesson BioSample Repository.**

Date of start of treatment for this rejection episode: _____ MM/DD/YYYY

Date of the biopsy that confirmed this rejection episode: _____ MM/DD/YYYY

Biopsy not done. ☐

REJECTION ACTIVITY INDEX (BANFF CRITERIA 1997)

Portal Inflammation Scoring Criteria
Score = 1: Mostly lymphocytic inflammation involving, but not noticeably explanding, a minority of triads.
Score = 2: Expansion of most or all of the triads, by a mixed infiltrate containing lymphocytes with occasional blasts, neutrophils and eosinophils.
Score = 3: Marked expansion of most or all of the triads by a mixed infiltrate containing numerous blasts and eosinophils with inflammatory spillover into the periportal parenchyma.

Portal Inflammation Score: ○ 1 ○ 2 ○ 3

Bile Duct Inflammation Damage Scoring Criteria

Score = 1: A minority of the ducts are cuffed and infiltrated by inflammatory cells and show only mild reactive changes such as increased nuclear:cytoplasmic ratio of the epithelial cells.
Score = 2: Most or all of the ducts infiltrated by inflammatory cells. More than an occasional duct shows degenerative changes such as nuclear pleomorphism, disordered polarity and cytoplasmic vacuolization of the epithelium
Score = 3: As above for 2, with most or all of the ducts showing degenerative changes or focal lumenal disruption.

Bile Duct Inflammation Damage Score:	○ 1	○ 2	○ 3

Venous Endothelial Inflammation Scoring Criteria

Score = 1: Subendothelial lymphocytic infiltration involving some, but not a majority of the portal and/or hepatic venules.
Score = 2: Subendothelial infiltration involving most or all of the portal and/or hepatic venules.
Score = 3: As above for 2, with moderate or severe perivenular inflammation that extends into the perivenular parenchyma and is associated with perivenular hepatocyte necrosis.

Venous Endothelial Inflammation Score:	○ 1	○ 2	○ 3

REJECTION SEVERITY (BANFF CRITERIA 1997)

Global Assessment Scoring Criteria for Acute Rejection

Indeterminate: Portal inflammatory infiltrate that fails to meet the criteria for the diagnosis of acute rejection.
Mild: Rejection infiltrate in a minority of the triads, that is generally mild, and confined within the portal spaces.
Moderate: Rejection infiltrate, expanding most or all of the triads.
Severe: As above for "moderate", with spillover into the periportal areas and moderate to severe perivenular inflammation that extends into the hepatic parenchyma and is associated with perivenular hepatocyte necrosis.

What was the acute rejection severity as recorded in the pathology reading of the biopsy that confirmed the rejection episode?	○ Mild ○ Moderate ○ Severe ○ Rejection Severity Indeterminant ○ Not Stated/Not Done

Maintenance immunosuppression regimen that was in use immediately prior to treatment of this rejection episode (check all that apply).	
Prednisone (or oral equivalent)	☐
Methylprednisolone (or IV equivalent)	☐
Cyclosporine (neoral, Gengraf, or any other formulation)	☐
Tacrolimus (Prograf)	☐
Rapamycin	☐
Certican (RAD)	☐
Azathioprine (Imuran or generic)	☐
Mycophenolate mofetil (Cellcept or generic)	☐
Enteric-coated mycophenolic acid (Myfortic or generic)	☐
Other	☐
Specify "other":	

What medications were used to treat this rejection episode (check all that apply)?	
Recycling oral steroids	☐
IV steroids	☐

Was antibody used?	○ Yes ○ No	*If "yes" to use of antibody. Check all that apply.*
		ATGAM ☐
		OKT3 ☐
		Thymoglobulin ☐
		Zenapax ☐

Simulect	☐
Campath	☐
Other antibody therapy used?	☐
Specify "other" antibody therapy:	
Cyclosporine (Neoral, Gengraf, or any other formulation)	☐
Tacrolimus (Prograf)	☐
Rapamycin	☐
Certican (RAD)	☐
Azathioprine (Imuran or generic)	☐
Mycophenoloate mofetil (Cellcept or generic)	☐
Enteric-coated mycophenolic acid (Myfortic or generic)	☐
Switch maintenance immunosuppression	☐

save reset cancel print

V5_GEN_FORM

A2ALL
Adult to Adult Living Donor Liver Transplantation Cohort Study

Donor Hospitalizations 1

Date of Admission	MM/DD/YYYY
Date of Discharge	MM/DD/YYYY
Was this admission associated with a study-tracked post-donation complication?	○ Yes ○ No *If "yes", fill out a Donor Morbidity/Complication Severity page.*
Discharge Destination	○ Home ○ Hospital-affiliated transitional residence ○ Transfer to another hospital ○ Rehabilitation facility ○ Nursing Home ○ Other (specify) ○ N/A - patient died
Number of ICU days during this admission	*Enter "0" for none.*
Number of ICU days unknown.	☐
Type of hospital	○ A2ALL hospital ○ Non-A2ALL hospital

Type of hospital admission	○ Pre-donation Other ○ Liver Donation Operation ○ Post Donation Complication ○ Post Donation Other

For post-donation complication or post-donation other	
Primary Discharge Diagnosis	
Enter the numeric ICD-9 diagnosis code	

Start Time: 16:29:51Stop Time: 16:29:51Time To Generate: 0 seconds

save reset cancel print

A2ALL
Adult to Adult Living Donor Liver Transplantation Cohort Study

Recipient Hospitalizations 1

Date of Admission	MM/DD/YYYY
Date of Discharge	MM/DD/YYYY
Was this admission associated with a study-tracked post-txp complication?	○ Yes ○ No *If "yes", fill out RCP Morbidity/Complication Severity page.*
Discharge Destination	○ Home ○ Hospital-affiliated transitional residence ○ Transfer to another hospital ○ Rehabilitation facility ○ Nursing Home ○ Other (specify) ○ N/A - patient died
Number of ICU days	*Use 0 for none* Number of ICU days unknown. ☐
Type of hospital	○ A2ALL hospital ○ Non-A2ALL hospital
Type of hospital admission	

Discharge Diagnosis	
	Enter the discharge numeric ICD-9 diagnosis code.

save reset cancel print

V5_GEN_FORM

Donor Morbidity & Complication Severity 1

Choose the complication that you wish to document.

Each complication requires a separate form.

.

For definitions of these conditions, please refer to the Manual of Operations.

You must fill out a new form updating this complication's status at the following times:

1. when there is a change in status (condition changes to stable/controlled, worsens, resolves, or patient dies)

2. if unresolved, at each scheduled patient visit

Date of Assessment: _____

MM/DD/YYYY

Type of Assessment:

- ○ Regularly scheduled visit
- ○ Interventional visit
- ○ Emergent visit
- ○ Telephone contact
- ○ Subject is hospital in-patient

Liver-related Morbidity/Complications

- ○ Encephalopathy/hepatic coma
- ○ Ascites
- ○ Liver cirrhosis
- ○ Liver failure
- ○ Liver transplantation

Biliary Morbidity/Complications

- ○ Biliary stricture
- ○ Bile leak/biloma

Surgical Morbidity/Complications	○ Re-exploration during txp or donation hospitalization ○ Dehiscence ○ Neuropraxia
Bleeding Morbidity/Complications	○ Intra-abdominal bleeding ○ Upper GI bleed caused by ulcer ○ Upper GI bleed not caused by ulcer ○ Lower GI bleed caused by ulcer ○ Lower GI bleed not caused by ulcer
Vascular Morbidity/Complications	○ Deep vein thrombosis ○ Portal vein thrombosis ○ Inferior vena cava thrombosis ○ Hepatic artery thrombosis
GI Complications (except bleeding)	○ Prolonged ileus ○ Localized intra-abdominal abcess ○ Bowel obstruction ○ Hernia development ○ Peptic ulcer development ○ C-difficile colitis
Cardiac Morbidity/Complications	○ Myocardial infarction ○ Congestive heart failure ○ Cardio-pulmonary arrest
Respiratory Morbidity/Complications	○ Pneumothorax ○ Pleural effusion ○ Pulmonary edema ○ Respiratory arrest ○ Aspiration ○ Pulmonary embolism

Infections

- ○ Wound infection
- ○ Biliary tree infection
- ○ Blood infection
- ○ Liver infection/abcess
- ○ Pulmonary infection
- ○ Central nervous system infection
- ○ GI tract infection
- ○ Urinary tract infection
- ○ Other infection location (specify)

Specify other location of infection:

Psychological

- ○ General psychological difficulties requiring treatment
- ○ Depression
- ○ Suicide attempt

(if "yes" to prolonged ileus)

Duration of ileus (time from diagnosis to resumption of oral food intake)

in days

(If "yes" to duodenal ulcer development)

Did the patient have H. Pylori?

- ○ Yes
- ○ No
- ○ Unknown

(if "yes" to infection)

Type of infection:

- ○ Bacterial
- ○ Viral
- ○ Fungal
- ○ Protozoal

(if "yes" to bacterial infection)

Identify the type of bacterial infection:

- ○ Gram Positive
- ○ Gram Negative
- ○ Mixed
- ○ Other

Other bacterial infection (specify):

(if "yes" to viral infection)

Type of viral infection:

- ○ Cytomegalovirus (CMV)
- ○ Herpes
- ○ HIV
- ○ Epstein-Barr Virus (EBV)
- ○ Other (specify)

Other viral infection (specify):

(if "yes" to fungal infection)

Type of fungal infection:

- ○ Candida albicans
- ○ Non-candida
- ○ Fumogatus aspergellus
- ○ torulopsis globrata
- ○ Other (specify)

Other fungal infection (specify):

(if "yes" to protozoal infection)

Type of protozoal infection:

- ○ Pneumocystis Carinii (PCP)
- ○ Other (specify)

Other protozoal infection (specify):

RATE THE SEVERITY OF THIS COMPLICATION.

Date of Onset:

MM/DD/YYYY

At onset (if documenting onset on this form), or since the last assessment, was the patient hospitalized for treatment of this complication?

- ○ Yes
- ○ No

(If "yes" to hospitalization)

What was the date of hospital admission?

MM/DD/YYYY

Has the complication been resolved?

- ○ Yes
- ○ No
- ○ Not Applicable

Date of complication resolution:

MM/DD/YYYY

(If "no" or "N/A" to Resolution)

Did the complication get worse? (requiring frequent/varied/ continued intervention in an effort to control the complication or its sequelae)

- ○ Yes
- ○ No
- ○ Not Applicable

At onset (if documenting onset on this form), or since the last assessment, was it necessary to treat the complication with medications?

- ○ Yes
- ○ No

At onset (if documenting onset on this form), or since the last assessment, did the complication require a procedure or intervention?

- ○ Yes
- ○ No

Type of intervention or procedure:

- ○ Bedside therapeutic procedure (e.g. evacuation of pneumothorax, pleural effusion or monitoring lines)
- ○ Surgical Intervention
- ○ Endoscopic Intervention
- ○ Radiologic Intervention

At onset (if documenting onset on this form), or since the last assessment, did the patient receive a blood transfusion associated with this complication?

- ○ Yes
- ○ No

Number of units of blood transfused: _____

At onset (if documenting onset on this form), or since the last assessment, was the patient admitted to the ICU as a result of this complication?

- ○ Yes
- ○ No

At onset (if documenting onset on this form), or since the last assessment, was the patient required to stay in the hospital for more than 14 days as a result of this complication?

- ○ Yes
- ○ No

At onset (if documenting onset on this form), or since the last assessment, did the complication cause the patient to experience residual disability or disease?

- ○ Yes
- ○ No

At onset (if documenting onset on this form), or since the last assessment, did the complication result in liver complications that caused the patient to be listed as a candidate for liver transplant?	○ Yes ○ No	*(if "yes" to listed)* Date of Listing: MM/DD/YYYY

At onset (if documenting onset on this form), or since the last assessment, did the complication result in liver failure that led to transplantation?	○ Yes ○ No
At onset (if documenting onset on this form), or since the last assessment, did the patient die as a result of this complication?	○ Yes ○ No

Start Time: 16:19:18Stop Time: 16:19:19Time To Generate: 0 seconds

save reset cancel print

Recipient Morbidity & Complication Severity 1

Choose the complication that you wish to document.

Each complication requires a separate form.

.

For definitions of these conditions, please refer to the Manual of Operations.

You must fill out a new form updating this complication's status at the following times:

1. when there is a change in status (condition changes to stable/controlled, worsens, resolves, or patient dies)

2. if unresolved, at each scheduled patient visit

Date of Assessment: _____ *MM/DD/YYYY*

Type of Assessment:
- ○ Regularly scheduled visit
- ○ Interventional visit
- ○ Emergent visit
- ○ Telephone contact
- ○ Subject is hospital in-patient

Biliary Morbidity/Complications
- ○ Biliary stricture
- ○ Biloma/bile leak

Liver-related Complications/Morbidity
- ○ Encephalopathy/hepatic coma
- ○ Ascites
- ○ Liver cirrhosis

Surgical Morbidity/Complications
- ○ Re-exploration during txp or donation hospitalization
- ○ Dehiscence
- ○ Neuropraxia

Bleeding Morbidity/Complications	○ Intra-abdominal bleeding ○ Upper GI bleed caused by ulcer ○ Upper GI bleed not caused by ulcer ○ Lower GI bleed caused by ulcer ○ Lower GI bleed not caused by ulcer
Vascular Morbidity/Complications	○ Deep vein thrombosis ○ Portal vein thrombosis ○ Inferior vena cava thrombosis ○ Hepatic artery thrombosis
GI Complications (except bleeding)	○ Prolonged ileus ○ Localized intra-abdominal abcess ○ Bowel obstruction ○ Hernia development ○ C-difficile colitis
Cardiac Morbidity/Complications	○ Myocardial infarction ○ Congestive heart failure ○ Cardio-pulmonary arrest
Respiratory Morbidity/Complications	○ Pneumothorax ○ Pleural effusion ○ Pulmonary edema ○ Respiratory arrest ○ Aspiration ○ Pulmonary embolism
Infections	○ Wound infection ○ Biliary tree infection ○ Blood infection ○ Liver infection/abcess ○ Pulmonary infection ○ Central nervous system infection ○ GI tract infection ○ Urinary tract infection ○ Other infection location (specify)
Specify other location of infection:	

Psychological

- ○ General psychological difficulties requiring treatment
- ○ Depression
- ○ Suicide attempt

(if "yes" to prolonged ileus)

Duration of ileus (time from diagnosis to resumption of oral food intake)

in days

(if "yes" to infection)

Type of infection:

- ○ Bacterial
- ○ Viral
- ○ Fungal
- ○ Protozoal

(if "yes" to bacterial infection)

Type of bacterial infection:

- ○ Gram Positive
- ○ Gram Negative
- ○ Mixed
- ○ Other

Other bacterial infection (specify):

(if "yes" to viral infection)

Type of viral infection:

- ○ Cytomegalovirus (CMV)
- ○ Herpes
- ○ HIV
- ○ Epstein-Barr Virus (EBV)
- ○ Other (specify)

Other viral infection (specify):

(if "yes" to fungal infection)

Type of fungal infection:

- ○ Candida albicans
- ○ Non-candida
- ○ Fumogatus aspergellus
- ○ torulopsis globrata
- ○ Other (specify)

Other fungal infection (specify):

(if "yes" to protozoal infection)

Type of protozoal infection:

- ○ Pneumocystis Carinii (PCP)
- ○ Other (specify)

Other protozoal infection (specify):

RATE THE SEVERITY OF THIS COMPLICATION.

Date of Onset: MM/DD/YYYY

At onset (if documenting onset on this form), or since the last assessment, was the patient hospitalized? ○ Yes ○ No

If "yes" to hospitalization

What was the date of hospital admission? MM/DD/YYYY

Has the complication resolved? ○ Yes ○ No ○ Not Applicable

Date of complication resolution: MM/DD/YYYY

(If "no" or "N/A" to Resolution)

Did the complication get worse? (requiring frequent/varied/ continued intervention in an effort to control the complication or its sequelae) ○ Yes ○ No

At onset (if documenting onset on this form), or since the last assessment, was it necessary to treat the complication with medications? ○ Yes ○ No

At onset (if documenting onset on this form), or since the last assessment, did the complication require a procedure or intervention? ○ Yes ○ No

Type of intervention or procedure:

○ Bedside therapeutic procedure (e.g. evacuation of pneumothorax, pleural effusion or monitoring lines)

○ Surgical Intervention

○ Endoscopic Intervention

○ Radiologic Intervention

At onset (if documenting onset on this form), or since the last assessment, did the patient receive a blood transfusion associated with this complication? ○ Yes ○ No

Number of units of blood transfused:

At onset (if documenting onset on this form), or since the last assessment, was the patient admitted to the ICU as a result of this complication?
○ Yes
○ No

*(If "yes" to ICU Admission **AND** this is the transplant surgery hospitalization.)*
At onset (if documenting onset on this form), or since the last assessment, was the patient's stay in the ICU prolonged ≥5 days?
○ Yes
○ No

At onset (if documenting onset on this form), or since the last assessment, was the patient required to stay in the hospital for more than 4 weeks (if this is the initial transplant surgery hospitalization) or 14 days (if this is a subsequent post-transplant admission) total?
○ Yes
○ No

At onset (if documenting onset on this form), or since the last assessment, did the complication cause the patient to experience residual disability or disease?
○ Yes
○ No

At onset (if documenting onset on this form), or since the last assessment, did the complication result in liver complications that caused the patient to be listed as a candidate for another liver transplant?
○ Yes
○ No

(if "yes" to listed)
Date of re-listing: [ ]
MM/DD/YYYY

At onset (if documenting onset on this form), or since the last assessment, did the complication result in liver failure that led to re-transplantation?
○ Yes
○ No

At onset (if documenting onset on this form), or since the last assessment, did the patient die as a result of this complication?
○ Yes
○ No

save reset cancel print

V5_GEN_FORM

A2ALL
Adult to Adult Living Donor Liver Transplantation Cohort Study

AE/SAE Report

Update this report:

1. There is a change in the conditions of the event. or,

2. If you receive more information about the event. or,

3. If unresolved at a regularly scheduled assessment.

Fill out a separate SAE/AE form for each event

Date of this report:	MM/DD/YYYY
Start date of the event: MM/DD/YYYY	End date of the event: MM/DD/YYYY
ICD-9/10 code:	
Describe the adverse event.	
Severity of event	○ Mild ○ Moderate ○ Severe

Pattern of event	○ Single episode ○ Intermittent ○ Continuous

Relatedness of event to study procedure	○ Unrelated ○ Remote ○ Possible ○ Probable ○ Related	*(if event is related, possibly related, probably related or remotely related)* Which study procedure?	○ Liver biopsy ○ Phlebotomy ○ MRI, CT or Other imaging study ○ QOL assessment

Action(s) Taken (check all that apply)	
None	☐
Additional meds	☐
Additional therapy	☐
Additional lab tests	☐
Hospitalization required	☐
Prolonged hospitalization required	☐

Does this event qualify as a Severe Adverse Event (SAE)?	○ Yes ○ No	**If "yes" to SAE, check all that apply.** Death	☐
		Life-threatening	☐
		Inpatient/prolonged hospitalization	☐
		Congenital anomaly or birth defect	☐
		Persistent/significant disability or incapacity	☐

	Medically important condition ☐
Is this an expected SAE?	○ Yes ○ No
Has the principal investigator reviewed this report? ○ Yes ○ No	Date of PI review [ ] MM/DD/YYYY

Start Time: 16:22:49Stop Time: 16:22:50Time To Generate: 0 seconds

save reset cancel print