Enrollment Form
Liver (LIHC)

Instructions: *The Enrollment Form should be completed for each TCGA qualified case, upon qualification notice from the BCR. All information provided on this form should include activity from the date of initial diagnosis to the most recent date of contact with the patient ("Date of Initial Pathologic Diagnosis" and "Date of Last Contact" on this form).*

Questions regarding this form should be directed to the Tissue Source Site's primary Clinical Outreach Contact at the BCR.

Please note the following definitions for the "Unknown" and "Not Evaluated" answer options on this form.

Unknown: This answer option should only be selected if the TSS does not know this information after all efforts to obtain the data have been exhausted. If this answer option is selected for a question that is part of the TCGA required data set, the TSS must complete a discrepancy note providing a reason why the answer is unknown.

Not Evaluated: This answer option should only be selected by the TSS if it is known that the information being requested cannot be obtained. This could be because the test in question was never performed on the patient or the TSS knows that the information requested was never disclosed.

Tissue Source Site (TSS): _____TSS Identifier: _____ TSS Unique Patient Identifier: _____

Completed By *(Interviewer Name in OpenClinica)*: _____Completed Date: _____

General Information

#	Data Element	Entry Alternatives	Working Instructions
1*	Has this TSS received permission from the NCI to provide time intervals as a substitute for requested dates on this form?	☐ Yes ☐ No	If the answer to this question is yes, time intervals must be provided instead of dates, as indicated throughout this form. Provided time intervals must begin with the date of initial pathologic diagnosis (e.g. biopsy or resection). Only provide interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.
2	Is this a prospective tissue collection?	☐ Yes ☐ No	Indicate whether the TSS providing tissue is contracted for prospective tissue collection. If the submitted tissue was collected for the specific purpose of TCGA, the tissue has been collected prospectively. 3088492
3	Is this a retrospective tissue collection?	☐ Yes ☐ No	Indicate whether the TSS providing tissue is contracted for retrospective tissue collection. If the submitted tissue was collected prior to the date the TCGA contract was executed, the tissue has been collected retrospectively. 3088528
Patient Information			
4	Date of Birth	___ ___ ___ ___ ___ ___ ___ ___ *Month* *Day* *Year*	Provide the date the patient was born. 2896950 (Month), 2896952 (Day), 2896954 (Year)
5	Number of Days from Definitive Surgical Procedure to Date of Birth	_____	Provide the number of days from the date of definitive surgical procedure for the submitted specimen to the patient's date of birth. 4461930 Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.
6*	Gender	☐ Female ☐ Male	Provide the patient's gender using the defined categories. 2200604

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#	Data Element	Entry Alternatives	Working Instructions
7	Height *(at time of diagnosis)*	_____(cm)	Provide the patient's height (in centimeters) at the time the patient was diagnosed with the malignancy being submitted for TCGA. 649
8	Weight *(at time of diagnosis)*	_____(kg)	Provide the patient's weight (in kilograms) at the time the patient was diagnosed with the malignancy being submitted for TCGA. 651
9	Race	☐ American Indian or Alaska Native *A person having origins in any of the original peoples of North and South America (including Central America), and who maintains tribal affiliation or community attachment.* ☐ Asian *A person having origins in any of the original peoples of the far East, Southeast Asia, or in the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam.* ☐ White *A person having origins in any of the original peoples of the far Europe, the Middle East, or North Africa.* ☐ Black or African American *A person having origins in any of any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black or African American."* ☐ Native Hawaiian or other Pacific Islander: *A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.* ☐ Not Evaluated ☐ Unknown	Provide the patient's race using the defined categories. 2192199
10	Ethnicity	☐ Not Hispanic or Latino: *A person not meeting the definition of Hispanic or Latino.* ☐ Hispanic or Latino: *A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race.* ☐ Not Evaluated ☐ Unknown	Provide the patient's ethnicity using the defined categories. 2192217
11*	History of Prior Malignancy	☐ Yes ☐ No	Indicate whether the patient was, at any time in their life, diagnosed with a malignancy prior to the diagnosis of the specimen submitted for TCGA. If the patient has had a prior malignancy, an additional form (the "Other Malignancy Form") must be completed for each prior malignancy. If the OMF was completed and submitted with the Initial Case Quality Control Form, the OMF does not need to be submitted a second time. 3382736 If this question cannot be answered because the answer is unknown, the case will be excluded from TCGA. If the patient has a history of multiple diagnoses of basal or squamous cell skin cancer, complete an OMF for the first diagnosis for each of these types.
12*	History of Neo-adjuvant (Pre-Operative) Treatment for Sample Submitted for TCGA	☐ Yes ☐ No	Indicate whether the patient received neo-adjuvant treatment (radiation, pharmaceutical, or both) prior to the collection of the sample submitted for TCGA. 3382737 Systemic therapy and certain localized therapies (those administered to the same site as the TCGA submitted sample) given prior to the collection of the sample submitted for TCGA is exclusionary.
13	Tumor Status *(at time of last contact or death)*	☐ Tumor free ☐ With tumor ☐ Unknown	Indicate whether the patient was tumor/disease free at the date of last contact or death. 2759550
14*	Vital Status *(at date of last contact)*	☐ Living ☐ Deceased	Indicate whether the patient was living or deceased at the date of last contact. 5

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#	Data Element	Entry Alternatives	Working Instructions
15	Date of Last Contact	___ ___ ___ ___ ___ ___ ___ ___ *Month* *Day* *Year*	If the patient is living, provide the date of last contact with the patient (as reported by the patient, medical provider, family member, or caregiver). 2897020 (Month), 2897022 (Day), 2897024 (Year) Do not answer if patient is deceased.
16	Number of Days from Date of Definitive Surgical Procedure to Date of Last Contact	_____	Provide the number of days from the date of definitive surgical procedure for the submitted specimen to the date of last contact. 4461931 Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.
17	Date of Death	___ ___ ___ ___ ___ ___ ___ ___ *Month* *Day* *Year*	If the patient is deceased, provide the date of death. 2897026 (Month), 2897028 (Day), 2897030 (Year)
18	Number of Days from Date of Definitive Surgical Procedure to Date of Death	_____	Provide the number of days from the date of definitive surgical procedure for the submitted specimen to the date of death. 4461932 Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.
19	Family History of Cancer *(First Degree Relatives Only)*	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient's first degree relatives (i.e. parents, siblings or children) had a history of cancer. 2691192
20	Number of First Degree Relatives Who Have Had Cancer	_____	If any of the patient's first degree relatives had a history of cancer, provide the number of relatives. 3171640
21*	Patient History of Primary Risk Factors For Hepatocellular Carcinoma *(Check all that apply)*	☐ No History of Primary Risk Factors ☐ Alcohol Consumption ☐ Hepatitis B ☐ Hepatitis C ☐ Hemochromatosis ☐ Non-Alcoholic Fatty Liver Disease ☐ Alpha 1-Antitrypsin Disease ☐ Unknown ☐ Other, specify	Indicate whether the patient had a history of primary risk factors for hepatocellular carcinoma. 3171846
22	Other risk factors for Hepatocellular carcinoma	_____	If the patient had a history of risk factors for hepatocellular carcinoma and it is not included in the provided list, describe the risk factor. 3171859
23*	Viral Hepatitis Serologies *(check all that apply)*	☐ Hepatitis C Antibody ☐ Hepatitis C Virus RNA ☐ HCV Genotype ☐ Hepatitis B Surface Antigen ☐ HBV Surface Antibody ☐ HBV Core Antibody ☐ HBV DNA ☐ HBV Genotype ☐ Unknown	Please provide the serology/serologies that were used to determine the positive or negative test results for hepatitis, regardless of whether the patient was positive for hepatitis. 4395982
24*	Adjuvant (Post-Operative) Radiation Therapy	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient had adjuvant/ post-operative radiation therapy *for the tumor submitted for TCGA*. 2005312 If the patient did have adjuvant radiation, the Radiation Supplemental Form should be completed.
25*	Adjuvant (Post-Operative) Pharmaceutical Therapy	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient had adjuvant/ post-operative pharmaceutical therapy *for the tumor submitted for TCGA*. 3397567 If the patient did have adjuvant pharmaceutical therapy, the Pharmaceutical Supplemental Form should be completed.

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26*	Adjuvant (Post-Operative) Ablation or Embolization Therapy	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient had adjuvant/ post-operative ablation or embolization therapy *for the tumor submitted for TCGA*. 3172120 If the patient did have ablation/embolization treatment for this new tumor event, the Ablation/Embolization Supplemental Form should be completed.
Pathologic/Prognostic Information			
27*	Primary Site of Disease	☐ Liver	Using the patient's pathology/laboratory report, select the anatomic site of disease of the tumor submitted for TCGA. 2735776
28*	Histological Subtype	☐ Hepatocellular Carcinoma ☐ Fibrolamellar Carcinoma ☐ Hepatocholangiocarcinoma (Mixed)	Using the patient's pathology/laboratory report, select the histology and/or subtype of the tumor submitted for TCGA. 3081934
29	Definitive Surgical Procedure Performed	☐ Simple Segmental Resection ☐ Multiple Segmental Resections ☐ Lobectomy ☐ Extended Lobectomy ☐ Total Hepatectomy with Transplant ☐ Other, specify	Provide the surgical procedure used to find the definitive diagnosis of the tumor submitted for TCGA. 3131309
30	Other Definitive Surgical Procedure Performed	_____	If the surgical procedure used to find the definitive diagnosis for the tumor submitted for TCGA is not included on the provided list, describe the procedure. 3121814
31*	Date of Definitive Surgical Procedure	___ ___ ___ ___ ___ ___ ___ ___ *Month* *Day* *Year*	Provide the date of the surgical procedure that resulted in the definitive diagnosis of the malignancy submitted for TCGA. 3167965 (Month), 3167977 (Day), 3167978 (Year)
32	Age at Date of Definitive Surgical Procedure	_____	Provide the age of the patient in years, at the date the definitive surgical procedure for the submitted specimen was performed. 4461953 Only complete this question if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.
33*	Tumor Grade *(Select the Least Differentiated Grade Observed)*	☐ G1 Well differentiated ☐ G2 Moderately differentiated ☐ G3 Poorly differentiated ☐ G4 Undifferentiated	Using the patient's pathology/laboratory report, select the tumor grade. 2785839
34	Residual Tumor	☐ RX ☐ R0 ☐ R1 ☐ R2	Using the patient's operative report, indicate whether there was residual tumor after the surgical procedure. 2608702
35*	AJCC Cancer Staging Edition	☐ 1st Edition *(1978-1983)* ☐ 2nd Edition *(1984-1988)* ☐ 3rd Edition *(1989-1992)* ☐ 4th Edition *(1993-1997)* ☐ 5th Edition *(1998-2002)* ☐ 6th Edition *(2003-2009)* ☐ 7th Edition *(2010-present)*	Based on the date the patient was staged select the AJCC edition used to stage the patient. 2722309
36*	Pathologic T Stage	☐ TX ☐ T0 ☐ T1 ☐ T2 ☐ T2a ☐ T2b ☐ T3 ☐ T3a ☐ T3b ☐ T4	Using the patient's pathology/laboratory report, select the code for the pathologic T (primary tumor) defined by the American Joint Committee on Cancer (AJCC). 3045435
37*	Pathologic N Stage	☐ NX ☐ N0 ☐ N1 ☐ N1a ☐ N1b ☐ N2	Using the patient's pathology/laboratory report, select the code for the pathologic N (nodal) defined by the American Joint Committee on Cancer (AJCC). 3203106

#	Data Element	Entry Alternatives	Working Instructions
38*	Pathologic M Stage	☐ MX ☐ M0 ☐ M1	Using the patient's pathology/laboratory report, select the code for the pathologic M (metastasis) defined by the American Joint Committee on Cancer (AJCC). 3045439
39*	Tumor Stage (Pathological and/or Clinical)	☐ Stage I ☐ Stage IA ☐ Stage IB ☐ Stage II ☐ Stage IIA ☐ Stage IIB ☐ Stage III ☐ Stage IIIA ☐ Stage IIIB ☐ Stage IIIC ☐ Stage IV ☐ Stage IVA ☐ Stage IVB	Using the patient's pathology/laboratory report, select the stage defined by the American Joint Committee on Cancer (AJCC). 3203222
40	Is There Vascular Invasion?	☐ Macro ☐ Micro ☐ None ☐ Unknown	Using the patient's pathology/laboratory report, indicate whether the patient had macro, micro, or no vascular invasion. 3168001
41	Child-Pugh Classification	☐ Grade A (5-6 points) *Well Compensated Disease* ☐ Grade B (7-9 points) *Significant Functional Compromise* ☐ Grade C (10-15 points) *Decompensated Disease* ☐ Unknown	Using the patient's pathology/laboratory report, indicate the Child-Pugh classification. 2931791
For the following questions, results of laboratory testing should be for tests ordered immediately pre-operatively or at time of tissue procurement.			
42	Alpha-Fetoprotein Level *(0-10 million ng/mL)*	___ ___ ,___ ___ ___ ,___ ___ ___ ng/mL	Provide the patient's pre-operative alpha-fetoprotein level or the level at the time the tumor submitted for TCGA was diagnosed. 2932074
43	Normal Range for the Alpha-Fetoprotein Level	___ ___ ,___ ___ ___ ,___ ___ ___ – ___ ___ ,___ ___ ___ ,___ ___ ___ ng/mL	Provide the normal range for the alpha-fetoprotein level at the institute/ laboratory where the patient was tested. Lower Level: 3171861 Upper Level: 2932064
44	Platelet Count *(Pre-resection)*	___ ___ ___ ,___ ___ ___	Provide the patient's pre-operative platelet count or the count at the time the tumor submitted for TCGA was diagnosed. 58304
45	Normal Range for the Platelet Count	___ ___ ___ ,___ ___ ___ – ___ ___ ___ ,___ ___ ___	Provide the normal range for the platelet count at the institute/ laboratory where the patient was tested. Lower Level: 2003885 Upper Level: 2596499
46	Prothrombin Time INR *(Serum Level, pre-resection)*	___ . ___ seconds	Provide the patient's pre-operative prothrombin time INR or the time at the time the tumor submitted for TCGA was diagnosed. 2459694
47	Normal Range for the Prothrombin Time INR	___ . ___ – ___ . ___ seconds	Provide the normal range for the prothrombin time INR at the institute/ laboratory where the patient was tested. Lower Level: 2799755 Upper Level: 3171875
48	Albumin Level *(Serum Level, pre-resection)*	___.___ g/dL	Provide the patient's pre-operative albumin level or the level at the time the tumor submitted for TCGA was diagnosed. 58274
49	Normal Range for the Albumin Level	___.___ – ___.___ g/dL	Provide the normal range for the albumin level at the institute/ laboratory where the patient was tested. Lower Level: 2004085 Upper Level: 2004086
50	Total Bilirubin Level *(Serum Level, pre-resection)*	___.___ mg/dL	Provide the patient's pre-operative bilirubin level or the level at the time the tumor submitted for TCGA was diagnosed. 2004060
51	Normal Range for the Total Bilirubin Level	___.___ – ___.___ mg/dL	Provide the normal range for the bilirubin level at the institute/ laboratory where the patient was tested. Lower Level: 2718241 Upper Level: 2003891

#	Data Element	Entry Alternatives	Working Instructions
52	Creatinine Level *(Serum Level, pre-resection)*	___.___ mg/dL	Provide the patient's pre-operative creatinine level or the level at the time the tumor submitted for TCGA was diagnosed. 2655822
53	Normal Range for the Creatinine Level *(Normal Range for the Hospital)*	___.___ – ___.___ mg/dL	Provide the normal range for the creatinine level at the institute/ laboratory where the patient was tested. Lower Level: 2634934 Upper Level: 2183392
54	ISHAK Fibrosis Score	☐ 0 – No Fibrosis ☐ 1 or 2 – Portal Fibrosis ☐ 3 or 4 – Fibrous Septa ☐ 5 – Nodular Formation and Incomplete Cirrhosis ☐ 6 – Established Cirrhosis ☐ Unknown	Using the patient's pathology/laboratory report, provide the patient's Ishak fibrosis score. 3182621
55	Evidence of Active Hepatic Inflammation in Adjacent Tissue	☐ Mild ☐ Severe ☐ None ☐ Unknown	Indicate whether the patient had evidence of active hepatic inflamed adjacent tissue. 3173974
56	Performance Status Scale: Eastern Cooperative Oncology Group (ECOG) *(To be taken prior to surgery/treatment)*	☐ 0 – Asymptomatic ☐ 1 – Symptomatic but fully ambulatory ☐ 2 – Symptomatic but in bed less than 50% of the day ☐ 3 – Symptomatic and in bed more than 50% of the day ☐ 4 – Bedridden ☐ Unknown	Provide the patient's ECOG performance status score. 88
New Tumor Event Information *Complete this section if the patient had a new tumor event. If the patient did not have a new tumor event (or if the TSS does not know) indicate this in the question below, and the remainder of this section can be skipped.*			
57*	New Tumor Event After Initial Treatment?	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient had a new tumor event (e.g. metastatic, recurrent, or new primary tumor) after initial treatment. 3121376 If the patient did not have a new tumor event or if this is unknown, the remaining questions can be skipped.
58	Type of New Tumor Event	☐ Locoregional *(contiguous w/ tumor bed)* ☐ Intrahepatic Recurrence *(new tumor distant from surgery site)* ☐ Extrahepatic Recurrence *(Please specify anatomic site)* ☐ New Primary Tumor *(Please specify anatomic site)*	Indicate whether the patient's new tumor event was a locoregional recurrence, a distant metastasis or a new primary tumor. A new primary tumor is a tumor with a different histology than the tumor submitted to TCGA. 3119721
59	Anatomic Site of New Tumor Event	☐ Lung ☐ Bone ☐ Liver ☐ Brain ☐ Unknown ☐ Other, specify	Indicate the site of this new tumor event. 3108271
60	Other Site of New Tumor Event	_____	If the site of the new tumor event is not included in the provided list, describe the site of this new tumor event. 3128033
61	Date of New Tumor Event	___ ___ *Month* ___ ___ *Day* ___ ___ ___ ___ *Year*	If the patient had a new tumor event, provide the date of diagnosis for this new tumor event. 3104044 (Month), 3104042 (Day), 3104046 (Year)

#	Data Element	Entry Alternatives	Working Instructions
62	Number of Days from Date of Definitive Surgical Procedure to Date of New Tumor Event After Initial Treatment	_____	Provide the number of days from the date of definitive surgical procedure for the submitted specimen to the date of new tumor event after initial treatment. 4461933 Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.
63	Was Liver Transplant Performed in Conjunction with New Tumor Event?	☐ Yes ☐ No ☐ Unknown	If the patient had a new tumor event, indicate whether a liver transplant was performed in conjunction with the new tumor event. 3168060
64	Date of Liver Transplant	___ ___ ___ ___ ___ ___ ___ ___ *Month* *Day* *Year*	If the patient had a liver transplant in conjunction with the new tumor event, provide the date of the liver transplant. 3168022 (Month), 3168021 (Day), 3168037 (Year)
65	Number of Days from Date of Definitive Surgical Procedure to Date of Liver Transplant	_____	Provide the number of days from the date of definitive surgical procedure for the submitted specimen to the date of Liver Transplant. 4461934 Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.
66	Additional Surgery for New Tumor Event:	☐ Yes ☐ No ☐ Unknown	Using the patient's medical records, indicate whether the patient had surgery for the new tumor event in question. 3427611
67	Date of Additional Surgery for New Tumor Event	___ ___ ___ ___ ___ ___ ___ ___ *Month* *Day* *Year*	If the patient had surgery for the new tumor event, provide the date this surgery was performed. 3427612 (Month), 3427613 (Day), 3427614 (Year)
68	Number of Days from Date of Definitive Surgical Procedure to Date of Additional Surgery for New Tumor Event	_____	Provide the number of days from the date of definitive surgical procedure for the submitted specimen to the date of Additional Surgery for New Tumor Event. 4461935 Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.
69	Residual Tumor *After surgery for New Tumor Event*	☐ RX: The presence of residual tumor or margin status cannot be assessed. ☐ R0: No residual tumor and negative microscopic margins in resected specimen. ☐ R1: Microscopic residual tumor. No gross residual disease but positive microscopic margins. ☐ R2: Macroscopic residual tumor. Grossly visible residual disease.	Using the patient's pathology/laboratory report, select the residual tumor status after the surgical resection for the new tumor event. 3104061
70	Additional treatment for New Tumor Event: *Radiation Therapy*	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient received radiation treatment for this new tumor event. 3427615
71	Additional treatment for New Tumor Event: *Pharmaceutical Therapy*	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient received pharmaceutical treatment for this new tumor event. 3427616
72	Additional treatment of New Tumor Event *Ablation/ Embolization Therapy*	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient received or is currently receiving ablation/embolization treatment for this new tumor event. 3173961