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.

Completed Date:

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

Completed By (Interviewer Name in OpenClinica):

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

Enrollment Form Liver (LIHC)

#	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.
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. <u>651</u>
9	Race	 American Indian or Alaska Native A person having origins in any of the original peoples of	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. <u>3382736</u> 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. <u>3382737</u> 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

Enrollment Form Liver (LIHC)

#	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). <u>2897020</u> (Month), <u>2897022</u> (Day), <u>2897024</u> (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. <u>4461931</u> Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested
17	Date of Death		dates on this form.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. <u>4461932</u> 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.
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. <u>3171640</u>
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. <u>3171846</u>
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. <u>4395982</u>
24*	Adjuvant (Post- Operative) Radiation Therapy	□ Yes □ No □ Unknown	Indicate whether the patient had adjuvant/ post- operative radiation therapy <i>for the tumor submitted for</i> <u>TCGA</u> . <u>2005312</u> 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 <u>for the tumor</u> <u>submitted for TCGA</u> . <u>3397567</u> If the patient did have adjuvant pharmaceutical therapy, the Pharmaceutical Supplemental Form should be completed.

Enrollment Form Liver (LIHC)

#	Data Element	Entry Alternatives	Working Instructions
26*	Adjuvant (Post- Operative) Ablation or Embolization Therapy	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient had adjuvant/ post- operative ablation or embolization therapy <u>for the</u> <u>tumor submitted for TCGA</u> . <u>3172120</u> If the patient did have ablation/embolization treatment for this new tumor event, the Ablation/Embolization Supplemental Form should be completed.
Path	nologic/Prognostic Infor	mation	
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. <u>2735776</u>
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. <u>3081934</u>
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. <u>3131309</u>
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. <u>3121814</u>
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. <u>3167965</u> (Month), <u>3167977</u> (Day), <u>3167978</u> (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. <u>4461953</u> 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. <u>2785839</u>
34	Residual Tumor	□ RX □ R0 □ R1 □ R2	Using the patient's operative report, indicate whether there was residual tumor after the surgical procedure. <u>2608702</u>
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. <u>2722309</u>
36*	Pathologic T Stage	TX T2b T0 T3 T1 T3a T2 T3b T2a 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). <u>3045435</u>
37*	Pathologic N Stage	□ NX □ N1a □ N0 □ N1b □ N1 □ 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

Enrollment Form Liver (LIHC)

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

Enrollment Form Liver (LIHC)

#	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. <u>2655822</u>	
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: <u>2634934</u> Upper Level: <u>2183392</u>	
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. <u>3182621</u>	
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. <u>3173974</u>	
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	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. <u>3128033</u>	
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. <u>3104044</u> (Month), <u>3104042</u> (Day), <u>3104046</u> (Year)	

Enrollment Form Liver (LIHC)

#	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. <u>4461933</u> 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. <u>3168022</u> (Month), <u>3168021</u> (Day), <u>3168037</u> (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. <u>4461934</u> 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. <u>3427611</u>
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. <u>3427612</u> (Month), <u>3427613</u> (Day), <u>3427614</u> (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. <u>4461935</u> 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. <u>3104061</u>
70	Additional treatment for New Tumor Event: <i>Radiation Therapy</i>	□ Yes □ No □ Unknown	Indicate whether the patient received radiation treatment for this new tumor event. <u>3427615</u>
71	Additional treatment for New Tumor Event: Pharmaceutical Therapy	☐ Yes □ No □ Unknown	Indicate whether the patient received pharmaceutical treatment for this new tumor event. <u>3427616</u>
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. <u>3173961</u>

Principal Investigator or Designee Signature

___/ ____/ ____ ____ Date