Cholangiocarcinoma (CHOL)

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.

TSS Unique Patient Identifier:

Working Instructions

TSS Identifier

Comj	Completed By (Interviewer Name in OpenClinica):		Completed Date:	
Gene	eral 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 (i.e. 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	

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Tissue Source Site (TSS).

#	Data Element	End y Aiternauv	62	Working mistractions
4*	Date of Birth		 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. $\underline{2200604}$
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

Entry Altornatives

#	Data Element	Entry Alternatives	Working Instructions
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 ☐ Asian ☐ White ☐ Black or African American ☐ Native Hawaiian or other Pacific Islander: ☐ Not Evaluated ☐ Unknown	Provide the patient's race using the defined categories. 2192199 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: Not provided or available. Unknown: Could not be determined or unsure.
10	Ethnicity	□ Not Hispanic or Latino □ Hispanic or Latino □ Not Evaluated □ Unknown	Provide the patient's ethnicity using the defined categories. 2192217 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: Not provided or available. Unknown: Could not be determined or unsure
11*	History of Other 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*	Neo-adjuvant (pre- operative) therapy	☐ 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. Pharmaceutical treatment includes chemotherapy, immunotherapy, hormonal therapy, and targeted molecular therapy.
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. $\underline{2759550}$
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
15*	Date of Last Contact		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)

#	Data Element	Entry Alternatives	Working Instructions
16	Number of Days from Date of Definitive Surgical Procedure to Date of Last Contact		Do not answer if patient is deceased. 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		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	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient's first degree relatives (i.e. parents, siblings, or children) had a history of cancer. 2691192 Note: First degree relatives only (i.e. parents, siblings or children)
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	First Degree Relative Cancer History	Relative Cancer Type Mother Father Grandmother Grandfather Sister Brother Child Cancer Type	Provide any first degree blood relatives with a known history of cancer. 2783641 Provide the cancer diagnosis of any known relatives with a history of cancer. 3813653
22*	Patient History of Primary Risk Factors For Hepatocellular Carcinoma (Check all that apply)	□ No History of Primary Risk Factors □ Primary sclerosing cholangitis □ Cirrhosis □ Hepatitis C □ Hepatitis B □ Diabetes mellitus □ Choledochal cyst □ Caroli disease (type V choledochal cyst) □ Non-Alcoholic Fatty Liver Disease □ Hepatolithiasis □ Smoking □ Crohn's disease □ Ulcerative colitis □ Liver fluke infestation □ Thorotrast contrast exposure □ Unknown □ Other, please specify	Indicate whether the patient had a history of primary risk factors for hepatocellular carcinoma. 3171846
23*	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
24*	Adjuvant (Post- Operative) Radiation Therapy	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient had adjuvant/ post-operative radiation therapy <u>for the tumor submitted for TCGA</u> . 2005312 If the patient did have adjuvant radiation, the Radiation Supplemental Form should be completed.

#	Data Element	Entry Alternatives	Working Instructions
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. Note: Pharmaceutical treatment includes chemotherapy, immunotherapy, hormonal therapy, and targeted molecular therapy.
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> . 3172120 If the patient did have ablation/embolization treatment for this new tumor event, the Ablation/Embolization Supplemental Form should be completed.

Patho	athologic/Prognostic Information			
#	Data Element	Entry Alternatives	Working Instructions	
27*	Primary Site of Disease	☐ Bile Duct	Using the patient's pathology/laboratory report, select the anatomic site of disease of the tumor submitted for TCGA. 3427536	
28*	Histologic Subtype	☐ Intrahepatic cholangiocarcinoma☐ Perihilar cholangiocarcinoma☐ Distal cholangiocarcinoma	Using the patient's pathology/laboratory report, select the histology and/or subtype of the tumor submitted for TCGA. 3081934 Intrahepatic: if the lesion arises within the hepatic parenchyma and does not extend beyond the secondary hilar branches of the biliary tree. Perihilar: if the lesion develops anywhere from the secondary hilar branches of the biliary tree to above the site of cystic duct origin. Distal: if the lesion develops anywhere between the cystic duct origin and the ampulla of Vater (without involvement of the ampulla).	
29*	Definitive Surgical/ Diagnostic Procedure Performed	☐ Simple Segmental Resection ☐ Multiple Segmental Resections ☐ Lobectomy ☐ Extended Lobectomy ☐ Whipple operation ☐ Bile Duct Resection with Anastomosis or Hepaticojejunostomy ☐ Other, please specify	Provide the surgical procedure used to find the definitive diagnosis of the tumor submitted for TCGA. If multiple procedures were performed, only provide the procedure that confirmed the final diagnosis. 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		Provide the date the patient was initially pathologically diagnosed with 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	

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#	Data Element	Entry Alternatives	Working Instructions Please select the AJCC edition used to answer the following
35*	AJCC Cancer Staging Edition	□ 1 st Edition (1978-1983) □ 2 nd Edition (1984-1988) □ 3 rd Edition (1989-1992) □ 4 th Edition (1993-1997) □ 5 th Edition (1998-2002) □ 6 th Edition (2003-2009)	questions. 2722309
36*	Pathologic T Stage	☐ 7 th Edition (2010-present) ☐ 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). 3045435
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
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 III □ Stage IIA □ Stage IIIA □ Stage IIIB □ Stage III □ Stage IIIC □ Stage IIA □ Stage IV □ Stage IIB □ 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	Is there perineural invasion?	☐ Yes ☐ No ☐ Unknown	Using the patient's pathology/laboratory report, indicate whether the patient had perineural invasion. 64181
42	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 ☐ Not Applicable Patient Does Not Have Cirrhosis ☐ Unknown	Using the patient's pathology/laboratory report, indicate the Child-Pugh classification. 2931791
Resu	ılts of laboratory testing (qı	estions 46-57) should be for tests ordered immedic	ately pre-operatively or at time of tissue procurement.
43	CA 19-9 Level (0-55 U/mL)	U/mL	Provide the patient's pre-operative CA 19-9 level or the level at the time the tumor submitted for TCGA was diagnosed. 65302
44	Normal Range for CA 19-9 Level (Normal Range for the Hospital)	U/mL (Lower Level) -	Provide the normal range for the alpha-fetoprotein level at the institute/ laboratory where the patient was tested. Lower Level: 3915551 Upper Level: 3915552
45	Alpha-Fetoprotein (AFP) Level (0-10 million ng/mL)	,,ng/mL	Provide the patient's pre-operative AFP level or the level at the time the tumor submitted for TCGA was diagnosed. 2932074

#	Data Element	Entry Alternatives	Working Instructions
46	AFP Level (Normal Range for the Hospital)	,,(Lower Level) - ,,ng/mL (Upper Level)	Provide the normal range for AFP level at the institute/laboratory where the patient was tested. Lower Level: 3171861 Upper Level: 2932064
47	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
48	Platelet Count (Normal Range for the Hospital)	,(Lower Level) - , (Upper Level)	Provide the normal range for the platelet count at the institute/laboratory where the patient was tested. Lower Level: 2003885 Upper Level: 2596499
49	Prothrombin Time INR (Serum Level, pre-resection)	(seconds)	Provide the patient's pre-operative prothrombin time INR or the level at the time the tumor submitted for TCGA was diagnosed. 2459694
50	Prothrombin Time INR (Normal Range for the Hospital)	(Lower Level) - (Upper Level)	Provide the normal range for the prothrombin time INR at the institute/laboratory where the patient was tested. Lower Level: 2799755 Upper Level: 3171875
51	Albumin (Serum Level, pre-resection)	mg/dL	Provide the patient's pre-operative albumin level or the level at the time the tumor submitted for TCGA was diagnosed. 58274
52	Albumin (Normal Range for the Hospital)	(Lower Level) - (Upper Level) mg/dL	Provide the normal range for the albumin level at the institute/laboratory where the patient was tested. Lower Level: 2004085 Upper Level: 2004086
53	Total Bilirubin (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. 2003891
54	Total Bilirubin (Normal Range for the Hospital)	(Lower Level) - (Upper 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: 2004060
55	Creatinine (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
56	Creatinine (Normal Range for the Hospital)	(Lower Level) – (Upper Level) 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
57	ISHAK Fibrosis Score	 □ 0 - No Fibrosis □ 1,2 - Portal Fibrosis □ 3,4 - 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
58	Evidence of PSC in Adjacent Tissue	 □ Ductopenia □ Ductal or ductular proliferation □ Concentric fibrosis of intrahepatic duct □ None □ Not Evaluated □ Unknown 	Indicate whether the patient had evidence of PSC in adjacent tissue. 3916091

#	Data Element	Entry Alternatives	Working Instructions
59	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.

#	Data Element	Entry Alternatives	Working Instructions
60*	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
		L Olikilowii	If the patient did not have a new tumor event or if this is unknown, the remaining questions can be skipped.
61	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 as the tumor submitted to TCGA. 3119721
62	Anatomic Site of New Tumor Event	☐ Peritoneum ☐ Perihilar lymph node ☐ Distant lymph node ☐ Lung ☐ Bone ☐ Liver ☐ Brain ☐ Unknown ☐ Other, specify	Indicate the site of this new tumor event. 3108271
<u>63</u>	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
<u>64</u>	Date of New Tumor Event		If the patient had a new tumor event, provide the date of diagnosis for this new tumor event. 3104044 (Month), 3104042 (Day), 3104046 (Year)
<u>65</u>	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.
<u>66</u>	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
<u>67</u>	Date of Liver Transplant		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)

#	Data Element	Entry Alternatives	Working Instructions
<u>68</u>	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.
<u>69</u>	Additional treatment for New Tumor Event: Surgery	☐ Yes ☐ No ☐ Unknown	Using the patient's medical records, indicate whether the patient had surgery for the new tumor event in question. 3427611
<u>70</u>	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)
<u>71</u>	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.
<u>72</u>	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
<u>73</u>	Additional treatment for New Tumor Event: Radiation Therapy	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient received radiation treatment for this new tumor event. $\underline{3427615}$
74	Additional treatment for New Tumor Event: Pharmaceutical Therapy	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient received pharmaceutical treatment for this new tumor event. 3427616 Note: Pharmaceutical treatment includes chemotherapy, immunotherapy, hormonal therapy, and targeted molecular therapy.
<u>75</u>	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

Principal Investigator or Designee Signature

Print Name

Date (Month/Day/Year)