### Initial Case Quality Control Form Liver (LIHC)

Instr	Instructions: This form should be completed for all cases submitted for TCGA, prior to the shipment of samples to the BCR.						
	Questions regarding this form should be directed to the Tissue Source Site's primary Clinical Outreach Contact at the BCR.						
repor	ted by the TSS through histop	ges that the Biospecimen Core Resource (BCR) may confirm that the diagnosis of the frozen athology examination in the BCR laboratory. If the BCR identifies a possible discrepancy, th mal report in confidential email format for the quality assurance program of the TSS to add	e TSS authorizes the BCR to report these patient				
Tissue	Source Site (TSS):	TSS ID:TSS Unique Patient ID: Interviewer Name:	Interview Date / / /				
		om the NCI to provide time intervals as a substitute for requested dates on this form? $\Box$ Y	Zes □ No				
		gin with the date of initial pathologic diagnosis.					
Tumo	or Information: The following	g sections are to be provided by a Pathologist					
#	Question	Entry Alternatives	Working Instructions				
1	Histologic Subtype of Tumor Submitted for TCGA	<ul> <li>Hepatocellular carcinoma</li> <li>Fibrolamellar hepatocellular carcinoma</li> <li>Hepatocholangiocarcinoma (mixed)</li> </ul>	Indicate the confirmed diagnosis of the tumor submitted for TCGA. 3081934				
2	Tumor Type	<ul> <li>Primary (primary untreated malignant biospecimen)</li> <li>Indicate the type of tumor submitted for TCGA.</li> <li>3288124 This is a biospecimen that has not been treated with chemothera or radiation prior to resection.</li> </ul>					
3	Anatomic Organ Sub- Division of Frozen Biospecimen	□ Liver	Indicate the anatomic site of the frozen tumor biospecimen submitted for TCGA. 2008006				
Date	of Cancer Sample Procure	ment					
4	Month of Cancer Sample Procurement		Provide the month of the procedure performed to obtain the malignant tissue submitted for TCGA. <u>3008197</u>				
5	Day of Cancer Sample Procurement	01       02       03       04       05       06       07       08       09       10       11       12         13       14       15       16       17       18       19       20       21       22       23       24         25       26       27       28       29       30       31       31	Provide the day of the procedure performed to obtain the malignant tissue submitted for TCGA. <u>3008195</u>				
6	Year of Cancer Sample Procurement		Provide the year of the procedure performed to obtain the malignant tissue submitted for TCGA. 3008199				
7	Method of Cancer Sample Procurement	<ul> <li>Surgical resection</li> <li>Transplant</li> <li>Laparoscopic biopsy</li> <li>Other method (please specify)</li> </ul>	Indicate the procedure performed to obtain the malignant tissue submitted for TCGA. <u>3103514</u>				
8	Other Method of Cancer Sample Procurement		If the procedure performed to obtain the malignant tissue is not included in the provided list, specify the procedure. <u>2006730</u>				
9	Country Where Cancer Sample was Procured		Provide the country where the tissue submitted for TCGA was procured. 3203072				

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#	Question	Entry Alternatives	Working Instructions
10	Race	<ul> <li>American Indian or Alaska Native         <ul> <li>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.</li> </ul> </li> <li>Asian         <ul> <li>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.</li> <li>White                  <ul></ul></li></ul></li></ul>	Provide the patient's race using the defined categories. 2192199
11	Ethnicity	<ul> <li>Onknown: count not be determined of disarc.</li> <li>Not Hispanic or Latino         <ul> <li>A person not meeting the definition of Hispanic or Latino.</li> <li>Hispanic or Latino                 A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race.</li> <li>Not Evaluated                 Not provided or available.</li> <li>Unknown                 Could not be determined or unsure.</li> </ul> </li> </ul>	Provide the patient's ethnicity using the defined categories. 2192217
12	Vessel Used	CryovialCassetteOther, specifyBiospecimen Storage BagCryomold	Indicate the type of vessel used to ship the tissue to the Biospecimen Core Resource (BCR) for TCGA. <u>3081940</u>
13	Other Vessel Used		If the vessel used to ship the tissue to the BCR is not included in the provided list, specify the vessel used. 3288137
14	Is tumor sample being submitted for macrodissection?	□ Yes □ No	Indicate whether the tumor sample submitted to the BCR is intended to undergo macrodissection after the BCR receives the sample. 3288488
15	Was sample prescreened at site?	□ Yes □ No	Indicate whether the sample submitted to the BCR was prescreened at the TSS. <u>3081942</u>
Tum	or Slides Submitted		
<u>16</u>	Types of Slides Submitted	<ul> <li>Physical Top Slide</li> <li>Digital Top Slide Image</li> <li>Physical FFPE Slide</li> <li>Digital FFPE Slide Image</li> </ul>	Indicate the type(s) of slide(s) submitted to the BCR. <u>TBD</u> Top Slide Definition: Slide cut directly from frozen biospecimen = mirror image of inked surface
<u>17</u>	Slide/Digital Image ID #		Provide the slide ID for each slide (physical and digital image) submitted to the BCR. 2321277

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#	Question	Entry Alternatives	Working Instructions		
Tumor Information If the TSS is submitting multiple pieces of the same primary tumor for this case; complete the following information for each piece of tumor sent to the BCR.					
<u>18</u>	Tumor Identifier		Provide the TSS unique tumor ID. If multiple pieces of tumor are submitted, each tumor needs a unique ID. <u>3288096</u>		
<u>19</u>	Weight of Frozen Tumor	(mg) (0.2cm <sup>3</sup> (0.6cm * 0.6cm * 0.6cm) = ~200mg	Provide the weight of the tumor sample submitted for TCGA. <u>3081946</u> Weight can be estimated based on the size of the tumor <u>submitted</u> .		
<u>20</u>	Tumor Nuclei %	(%)	Provide the percent of tumor nuclei for the sample submitted for TCGA. 2841225 Check with the BCR to confirm the current acceptable TCGA metrics.		
22	Necrosis %	(%)	Provide the percent of necrosis for the sample submitted for TCGA. <u>2841237</u> Check with the BCR to confirm the current acceptable TCGA metrics.		
Norm	al Information A normal co	ontrol must be present to qualify.			
23	Type(s) of Normal Control Check all that apply	<ul> <li>Whole Blood</li> <li>Buffy Coat</li> <li>Lymphocytes</li> <li>Extracted DNA from Blood</li> <li>Non-Neoplastic Control Tissue*</li> </ul>	Indicate the type of normal control submitted for this case. <u>3081936</u> *Non-neoplastic Control Tissue may only be submitted with NCI approval.		
Norm	nal Control: Whole Blood				
24	Method of Normal Sample Procurement	D Blood Draw	Indicate the procedure performed to obtain the normal control sample submitted for TCGA. <u>3288147</u>		
25	Month of Normal Sample Procurement		Provide the month of the procedure performed to obtain the normal control submitted for TCGA. <u>3288195</u>		
26	Day of Normal Sample Procurement	01       02       03       04       05       06       07       08       09       10       11       12         13       14       15       16       17       18       19       20       21       22       23       24         25       26       27       28       29       30       31	Provide the day of the procedure performed to obtain the normal control submitted for TCGA. <u>3288196</u>		
27	Year of Normal Sample Procurement		Provide the year of the procedure performed to obtain the normal control submitted for TCGA. <u>3288197</u>		
<u>28</u>	Normal Identifier		Provide the TSS unique normal ID. If multiple normal control samples are submitted, each normal control needs a unique ID. <u>3288138</u>		
Norm	nal Control: Buffy Coat/ Lyr	nphocytes			
29	Normal Control Type	<ul> <li>Buffy Coat</li> <li>Lymphocytes</li> </ul>	Indicate the type of normal control submitted for TCGA. 3081936		
30	Method of Normal Sample Procurement	D Blood Draw	Indicate the procedure performed to obtain the normal control sample submitted for TCGA. <u>3288147</u>		

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#	Question					E	ntry Alt	ernative	es					Working Instructions
31	Month of Normal Sample	• 01	02	□ 03	□ 04	05	06	□ 07	08	09	<b>□</b> 10	<b>□</b> 11	<b>1</b> 2	Provide the month of the procedure performed to obtain the normal control submitted for TCGA. <u>3288195</u>
32	Day of Normal Sample	□ 01 □ 13 □ 25	□ 02 □ 14 □ 26	□ 03 □ 15 □ 27	□ 04 □ 16 □ 28	□ 05 □ 17 □ 29	□ 06 □ 18 □ 30	□ 07 □ 19 □ 31	□ 08 □ 20	□ 09 □ 21	□ 10 □ 22	□ 11 □ 23	□ 12 □ 24	Provide the day of the procedure performed to obtain the normal control submitted for TCGA. <u>3288196</u>
33	Year of Normal Sample Procurement													Provide the year of the procedure performed to obtain the normal control submitted for TCGA. <u>3288197</u>
<u>34</u>	Normal Identifier													Provide the TSS unique normal ID. If multiple normal control samples are submitted, each normal control needs a unique ID. <u>3288138</u>
Norn	nal Control: Extracted DNA	from B	lood											
35	Method of Normal Sample Procurement	🗖 Blo	od Drav	V										Indicate the procedure performed to obtain the normal control sample submitted for TCGA. <u>3288147</u>
36	Month of Normal Sample Procurement	<b>D</b> 01	□ 02	□ 03	□ 04	<b>D</b> 05	06	□ 07	08	09	<b>□</b> 10	<b>□</b> 11	<b>□</b> 12	Provide the month of the procedure performed to obtain the normal control submitted for TCGA. <u>3288195</u>
37	Day of Normal Sample	□ 01 □ 13 □ 25	□ 02 □ 14 □ 26	□ 03 □ 15 □ 27	□ 04 □ 16 □ 28	□ 05 □ 17 □ 29	□ 06 □ 18 □ 30	□ 07 □ 19 □ 31	□ 08 □ 20	□ 09 □ 21	□ 10 □ 22	□ 11 □ 23	□ 12 □ 24	Provide the day of the procedure performed to obtain the normal control submitted for TCGA. <u>3288196</u>
38	Year of Normal Sample Procurement													Provide the year of the procedure performed to obtain the normal control submitted for TCGA. <u>3288197</u>
<u>39</u>	Normal Identifier													Provide the TSS unique normal ID. If multiple normal control samples are submitted, each normal control needs a unique ID. <u>3288138</u>
<u>40</u>	Extracted DNA Quantity								(µg)					Provide the quantity (μg) of the normal control sample sent to the BCR for TCGA. <u>3288185</u>
<u>41</u>	Extracted DNA Quantification Method													Provide the quantification method of the normal control sample sent to the BCR for TCGA. <u>3288186</u>
<u>42</u>	Extracted DNA Concentration								_(µg/µl	L)				Provide the concentration ( $\mu$ g/ $\mu$ L) of the normal control sample sent to the BCR for TCGA. 3288187
<u>43</u>	Extracted DNA Volume								(µL)					Provide the volume ( $\mu$ L) of the normal control sample sent to the BCR for TCGA. <u>3288188</u>
Normal Control: Non-Neoplastic Control Tissue														
44	Method of Normal Sample Procurement	🗖 Tra 🗖 Lap	rgical re ansplant baroscop ner Meth	; pic biop	sy	cify)								Indicate the procedure performed to obtain the normal control sample submitted for TCGA. <u>3288147</u>

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#	Question	Entry Alternatives	Working Instructions	
45	Other Method of Normal Sample Procurement		If the procedure performed to obtain the normal sample is not included in the provided list, specify the procedure. <u>3288151</u>	
46	Month of Normal Sample Procurement		Provide the month of the procedure performed to obtain the normal control submitted for TCGA. <u>3288195</u>	
47	LIGV OF NORMAL SAMPLE	01       02       03       04       05       06       07       08       09       10       11       12         13       14       15       16       17       18       19       20       21       22       23       24         25       26       27       28       29       30       31	Provide the day of the procedure performed to obtain the normal control submitted for TCGA. <u>3288196</u>	
48	Year of Normal Sample Procurement		Provide the year of the procedure performed to obtain the normal control submitted for TCGA. <u>3288197</u>	
<u>49</u>	Normal Identifier		Provide the TSS unique normal ID. If multiple normal control samples are submitted, each normal control needs a unique ID. <u>3288138</u>	
<u>50</u>	Anatomic Site of Non- Neoplastic Control Tissue	<ul> <li>Liver</li> <li>Other (please specify)</li> </ul>	If the normal control type is normal tissue, indicate the anatomic site of the non-neoplastic control tissue submitted for TCGA. <u>3081938</u>	
<u>51</u>	Other Site of Non- Neoplastic Control Tissue		If the normal control type is normal tissue and the anatomic site is not included in the provided list, specify the site of the non- neoplastic control. 3288189	
<u>52</u>	Proximity of Normal Tissue to Tumor	□ Distal (> 2cm) from the primary tumor	If the normal control type is normal tissue, confirm that the submitted normal tissue was at least 2cm away from the primary tumor. <u>3088708</u> Adjacent (≤ 2cm) Normal Tissue is not accepted for this tissue type. Unknown Normal Tissue is not acceptable for this tissue type.	
<u>53</u>	Normal Slide ID#		If the normal control type is normal tissue, provide the slide ID for the physical top slide OR the digital slide image of the normal control being sent to the BCR. 3288217	
Verification: By providing the below information, the Principal Investigator acknowledges that the information provided by the institution is true and correct and has been quality controlled.				

#### **Pathology Review**

Tissue Source Site (TSS) acknowledges that the Biospecimen Core Resource (BCR) may confirm that the diagnosis of the frozen biospecimen is consistent with the primary diagnosis reported by the TSS through histopathology examination in the BCR laboratory. If the BCR identifies a possible discrepancy, the TSS authorizes the BCR to report these patient results to the TSS by means of a formal report in confidential email format for the quality assurance program of the TSS to address.

54	Name of Pathologist	Provide the name of the Pathologist that provided the information for all previous sections. <u>3288225</u>
55	Date of Pathologist Review	Provide the date of the pathology review performed by the TSS pathologist above. <u>3288224</u>

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#	Question	Entry Alternatives	Working Instructions
Prin	cipal Investigator/Authori	zed Designee Confirmation	
56	Percent Tumor Nuclei meets TCGA metrics?	□ Yes □ No	Confirm that the malignant sample submitted to the BCR meets the current tumor nuclei metrics for TCGA. <u>3288520</u> Check with the BCR to confirm the current acceptable TCGA metrics
57	Percent Necrosis meets TCGA metrics?	□ Yes □ No	Confirm that the malignant sample submitted to the BCR meets the current necrosis metrics for TCGA. <u>3288524</u> Check with the BCR to confirm the current acceptable TCGA metrics
58	De-Identified Pathology Report Submitted?	□ Yes □ No	Confirm that a de-identified pathology report will be sent to BCR prior to or with the shipment of the physical samples. <u>3288292</u>
59	Is the histologic diagnosis on the CQCF (as determined by the TSS pathology review of the TCGA frozen section top slide) consistent with the histology listed in the final diagnosis on the pathology report?	🗖 Yes 🗖 No	<ul> <li>Confirm that the diagnosis provided on this CQCF for the tumor sample being submitted to TCGA is consistent with the diagnosis found on the patient's pathology report for the tumor being sent to the BCR.</li> <li><u>3288300</u></li> <li>If "yes," skip related question below.</li> <li>The diagnosis is considered to be consistent if at least one of the following criteria are met: <ol> <li>Diagnosis on the CQCF is identical to the pathology report for the tumor being sent to the BCR.</li> <li>Diagnosis on the CQCF is identical to the pathology report for the tumor being sent to the BCR.</li> <li>Diagnosis on the CQCF includes as least one of the subtypes listed on the pathology report and all subtypes on the pathology report are acceptable for TCGA.</li> <li>Diagnosis on the CQCF is "histology, NOS" (i.e., Adenocarcinoma, NOS) and the pathologic group</li> <li>Diagnosis on the CQCF indicates "Mixed Subtype" and the pathology report lists two or more acceptable subtypes, provided that percent subtype(s) meet applicable TCGA disease-specific requirements.</li> </ol> </li> </ul>
60	If the diagnosis on this form is not consistent with the provided pathology report, indicate the reason for the inconsistency.	<ul> <li>Macrodissection performed at TSS to select for a region containing an acceptable TCGA diagnosis (see note at right)</li> <li>Pathology analysis at TSS determined a specific histological subtype different from original pathology report (see note at right)</li> <li>Pathology review of frozen section for TCGA determined histological subtype different from the pathology report (see note at right)</li> </ul>	If the diagnosis provided on this form is not consistent with the diagnosis found on the pathology report provided, specify a reason for this inconsistency. <u>3288315</u> If a TSS pathology review of the TCGA committed sample resulted in a different histological subtype than what is documented on the original pathology report, an amendment to the pathology report should be submitted when the sample is shipped to the BCR; or in the absence of an amended pathology report, the TSS must complete and submit an electronic copy of the "TCGA Pathologic Diagnosis Discrepancy Form". In the case of diagnosis modifications, institution protocol should be followed for proper quality assurance.
61	History of Other Malignancy	<ul> <li>None</li> <li>History of Prior Malignancy</li> <li>History of Synchronous/ Bilateral Malignancy</li> <li>Both History of Synchronous/ Bilateral and Prior Malignancy</li> </ul>	Indicate whether the patient has a history of malignancies. If the patient has any history, including synchronous or bilateral malignancies, please complete an "Other Malignancy Form" for each malignancy diagnosed prior to the procurement of the tissue submitted for TCGA. <u>3382736</u> If the patient has a history of multiple diagnoses of basal

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#	Question	Entry Alternatives	Working Instructions
			orsquamous cell skin cancer, complete an OMF for the first diagnosis for each of these types.
62	History of Neoadjuvant Treatment <i>for Tumor</i> <i>Submitted for TCGA</i>	<ul> <li>None</li> <li>Radiation prior to sample procurement*</li> <li>Pharmaceutical treatment prior to sample procurement*</li> <li>Both pharmaceutical treatment and radiation prior to sample procurement*</li> </ul>	Indicate whether the patient received therapy for this cancer prior to the sample procurement of <i>the tumor submitted for</i> <i>TCGA</i> . If the patient did receive treatment for this cancer prior to procurement, the TSS should contact the BCR for further instruction. <u>3382737</u> *Systemic therapy and certain localized therapies (those administered to the same site as the TCGA submitted tissue) given prior to the procurement of the sample submitted for TCGA are exclusionary.
63	Consent Status	<ul> <li>□ Consented</li> <li>□ Exemption 4*</li> <li>□ Deceased</li> <li>□ Waiver*</li> </ul>	Indicate whether the patient was formally consented, consented by death, or if the case has an exemption or waiver for consent. 3288361 *Exemptions and waivers for consent must be approved by NCI.
Date	of Consent		
64	Month of Consent		If the patient was formally consented, provide the month of consent. <u>3081955</u>
65	Day of Consent	01       02       03       04       05       06       07       08       09       10       11       12         13       14       15       16       17       18       19       20       21       22       23       24         25       26       27       28       29       30       31	If the patient was formally consented, provide the day of consent. <u>3081957</u>
66	Year of Consent		If the patient was formally consented, provide the year of consent. <u>3081959</u>
Date	of Death Do not complete da	ate of death, if patient formally consented.	
67	Month of Death		If the patient consented by death, provide the month of death. <u>2897026</u>
68	Day of Death	01       02       03       04       05       06       07       08       09       10       11       12         13       14       15       16       17       18       19       20       21       22       23       24         25       26       27       28       29       30       31	If the patient consented by death, provide the day of death. <u>2897028</u>
69	Year of Death		If the patient consented by death, provide the year of death. $\underline{2897030}$
			//

Principal Investigator or Designee Signature

Print Name

Date

I acknowledge that the above information provided by my institution is true and correct and has been quality controlled.

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Time	Fime Intervals: The following questions are only to be answered if the Tissue Source Site is unable to provide the dates requested on this form.						
#	Question	Entry Alternatives	Working Instructions				
ii	Number of Days from Date of Diagnosis to Date of Cancer Sample Procurement	days	Provide the number of days from the date the patient was diagnosed with the disease described on this form to the date of the procedure that produced the malignant sample submitted for TCGA. 3288495				
iii	Number of Days from Date of Diagnosis to Normal Sample Procurement	days	Provide the number of days from the date the patient was diagnosed with the disease described on this form to the date of the procedure that produced the normal control sample submitted for TCGA. 3288496				
iv	Number of Days from Date of Diagnosis to Date of Pathological Review	days	Provide the number of days from the date the patient was diagnosed with the disease described on this form to the date of the pathological review performed as part of the submission process for TCGA. 3288497				
v	Number of Days from Date of Diagnosis to Date of Consent	days	If the patient formally consented, provide the number of days from the date the patient was diagnosed with the disease described on this form to the date of the patient's formal consent. 3288498				
vi	Number of Days from Date of Diagnosis to Date of Death	days	If the patient consented by death, provide the number of days from the date the patient was diagnosed with the disease described on this form to the date of the patient's death. <u>3288499</u> Do not complete days to death, if patient formally consented.				