Tissue Source Site (TSS) Name: _		TSS Ide	entifier:	TSS Unique Patient #:	
Completed	Completed By: Completion Date (MM/DD/YYYY):				
Form Notes: 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.					
Question #	Data Element Label	Data Entry Alternatives		CDE ID With 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		Please note that time intervals must be recorded in place of dates where designated throughout this form if you have selected "yes" in the box to the left.  Note 1: Provided time intervals must begin with the date of initial pathologic diagnosis. (i.e., biopsy or resection)  Note 2: 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	Histological Subtype	Colon Adenocarcinoma Colon Mucinous Adenocarcinoma Rectal Adenocarcinoma Rectal Mucinous Adenocarcinoma		3081934 Indicate the histologic subtype for the colon/rectum tumor sample being submitted to TCGA.  Note: Mixed Subtypes Are Excluded For This Tumor Type. All other subtypes not listed are excluded from this study.	
3	Tumor Type	Primary		3288124 Confirm that the tumor being submitted to TCGA is a primary untreated malignant biospecimen.	
4	Anatomic Site of Frozen Biospecimen	Colon Subsites    Cecum	Rectal Subsites  Sigmoid Colon Rectum Rectosigmoid Junction	3081961 Indicate the anatomic site of the frozen tumor submitted for TCGA.	
Date of Cance	r Sample Procurement				
5	Month of Cancer Sample Procurement	□□ (MM)		3008197 Provide the month of the procedure performed to obtain the malignant tissue submitted for TCGA.	
6	Day of Cancer Sample Procurement	□□ (DD)		3008195 Provide the day of the procedure performed to obtain the malignant tissue submitted for TCGA.	
7	Year of Cancer Sample Procurement	(YYYY)		3008199 Provide the year of the procedure performed to obtain the malignant tissue submitted for TCGA.	
8	Number of Days from Date of Initial Pathologic Diagnosis to Date of Cancer Sample Procurement			3288495 Provide the number of days from the date the patient was initially diagnosed pathologically with the disease described on this form to the date of the procedure that produced the malignant sample submitted for TCGA.  Note: 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.	
9	Method of Cancer Sample Procurement	Right Hemicolectomy  Transverse Colectomy  Left Hemicolectomy  Sigmoid Colectomy  Total Colectomy  Pan-Procto Colectomy  Anterior Resection of Rectum  Abdomino-Perineal Resection  Endo-Rectal Tumor Resection  Other (please specify)		3103514 Indicate the procedure performed to obtain the malignant tissue submitted for TCGA.	
10	Other Method of Cancer Sample Procurement			2006730 If the procedure performed to obtain the malignant tissue is not included in the provided list, specify the procedure.	
11	Country Where Cancer Sample Was Procured			3203072 Provide the country where the tissue submitted for TCGA was procured.	

Question #	Data Element Label	Data Entry Alternatives	CDE ID With Working Instructions
		☐ American Indian or Alaska Native:	2192199
		A person having origins in any of the original peoples of	Provide the patient's race using the defined categories.
		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.	
4.0	Race	☐ White:	
12		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 Reported: <i>Not provided or available.</i>	
		☐ Unknown: Could not be determined or unsure.	
		□ Not Hispanic or Latino:	2192217
		A person not meeting the definition of Hispanic or Latino.	Provide the patient's ethnicity using the defined
		Hispanic or Latino:	categories.
13	Ethnicity	A person of Mexican, Puerto Rican, Cuban, Central or South	
	Lumercy	American or other Spanish culture or origin, regardless of	
		race.	
		□ Not Evaluated: Not provided or available.	
		☐ Unknown: Could not be determined or unsure.	
		Cryovial Cassotto	
		- Cassette	2004040
	Vessel Used	Cryomold	3081940
14			Indicate the type of vessel used to ship the tissue to the
		Biospecimen Storage Bag	Biospecimen Core Resource (BCR) for TCGA.
		Other vessel (please specify helew)	
		Other vessel (please specify below)	2222427
	Other Vessel Used		3288137
15			If the vessel used to ship tissue to the Biospecimen Core
			Resource (BCR) is not included in the provided list, specify
			the other type of vessel used.
	Is Tumor Sample being		3288488
16	Submitted for Laser	☐ Yes	
16	Cryo Enrichment (LCE)	□	Indicate if the tumor sample being submitted is to be
	Processing?	□ No	processed using Laser Cryo Enrichment (LCE).
		П	3081942
17	Was sample	☐ Yes	Indicate whether the sample submitted to the BCR was
1,	prescreened at site?	│ □ No	prescreened at the TSS.
		<b>—</b> 110	
			3288096
			Provide the TSS unique tumor ID. If multiple pieces of
18	Tumor Identifier		tumor are submitted, each tumor needs a unique ID.
10	Tamer raemine.		Note: If submitting multiple pieces of the same primary
			tumor for this case, complete the tumor information for
	<u> </u>		each piece of tumor sent to the BCR.
			3081946
40	Weight of Frozen		Provide the weight of the tumor sample submitted for
19	Tumor		TCGA.
	Talliol		Note: (0.2cm³ (0.6cm x 0.6cm x 0.6cm) = ~200mg
	Turner Nuclei 9/		2841225
			Provide the percent of tumor nuclei for the sample
20	Tumor Nuclei %		submitted for TCGA.
			Note: Check with the BCR to confirm the current
		1	acceptable TCGA metrics.
			2841237
24	Tumor Nocrocia 9/		
21	Tumor Necrosis %		2841237

Question #	Data Element Label	Data Entry Alternatives		CDE ID With Working Instructions
22	Will Top Slide be submitted to the BCR?	Yes No		3081944 Indicate whether a physical top slide for the sample submitted to the BCR will be shipped with the tissue sample.  Note: Top slide definition: Slide cut directly from frozen biospecimen = mirror image of inked surface.
23	Will Digital Slide Image be submitted to the BCR?	Yes No		3081948 Indicate whether a digital slide image for the sample submitted to the BCR will be shipped with the tissue sample.  Note: Physical top slides are preferred.
24	Top Slide / Digital Slide Image ID #		_	2321277 Provide the slide ID for the physical top slide OR the digital slide image being sent to the BCR.
Normal Inform	mation	Instructions: A normal contro	Il must be present to qualify.	
25	Type of Normal Control	□ Whole Blood □ Normal Tissue	Lymphocytes (Buffy Coat)  Extracted DNA from Blood	3081936 Indicate the type of normal control submitted for this case. Note: Whole blood is preferred. Normal tissue is only allowable with NCI approval.
26	Normal Identifier		_	3288138 Provide the TSS unique normal ID. If multiple normal control samples are submitted, each normal control needs a unique ID.
27	Method of Normal Sample Procurement	Blood Draw Total Colectomy Sigmoid Colectomy Left Hemicolectomy Right Hemicolectomy Transverse Colectomy	Pan-Procto Colectomy Endo-Rectal Tumor Resection Anterior Resection of Rectum Abdomino-Perineal Resection Other (please specify)	3288147 Indicate the procedure performed to obtain the normal sample submitted for TCGA.
28	Other Method of Normal Sample Procurement		_	3288151 If the procedure performed to obtain the normal sample is not included in the provided list, specify the procedure.
Date of Norm	al Sample Procurement			
29	Month of Normal Sample Procurement	□□ (MM)		3288195 Provide the month of the procedure performed to obtain the normal control sample for TCGA.
30	Day of Normal Sample Procurement	□□ (DD)		3288196 Provide the day of the procedure performed to obtain the normal control sample for TCGA.
31	Year of Normal Sample Procurement	(YYYY)		3288197 Provide the year of the procedure performed to obtain the normal control sample for TCGA.
32	Number of Days from Date of Initial Pathologic diagnosis to Date of Normal Sample Procurement		_	3288496 Provide the number of days from the date the patient was initially diagnosed pathologically with the disease described on this form to the date of the procedure that produced the normal control sample submitted for TCGA.  Note: 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.
33	Extracted DNA Quantity		-	3288185 If the normal control type is extracted DNA from blood, provide the quantity (µg) of the normal control sample sent to the BCR for TCGA.
34	Extracted DNA Quantification Method		-	3288186 If the normal control type is extracted DNA from blood, provide the quantification method of the normal control sample sent to the BCR for TCGA.
35	Extracted DNA Concentration		_	3288187 If the normal control type is extracted DNA from blood, provide the concentration (µg/ µL) of the normal control sample sent to the BCR for TCGA.
36	Extracted DNA Volume		_	3288188 If the normal control type is extracted DNA from blood,

Question #	Data Element Label	Data Entry Alternatives		CDE ID With Working Instructions
				provide the volume ( $\mu$ L) of the normal control sample sent to the BCR for TCGA.
		Colon Subsites	Rectal Subsites	
37	Anatomic Site of Normal Tissue	□ Cecum □ Ascending Colon □ Sigmoid Colon □ Transverse □ Splenic Flexure □ Colon □ Hepatic □ Colon □ Other (please specify)	Sigmoid Colon Rectum Rectosigmoid Junction Other (please specify)	3081938 If the normal control type is normal tissue, indicate the anatomic site of the non-neoplastic control tissue submitted for TCGA. Note: Site matched is preferred.
38	Other Anatomic Site of Normal Tissue			3288189 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.
39	Proximity of Normal Tissue to Tumor	☐ Distal (≥ 2 cm) from the primary tumor		3088708 If normal tissue is being submitted, confirm that the normal tissue is ≥ 2.0cm from the primary tumor.  Note: Adjacent and/or tissue of unknown proximity are not accepted for this tissue type.
40	Normal Slide ID #			3288217 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.
Verification: E quality contro		on below, the Principal Investigator acknowled	ges that the information	n provided by the institution is true and correct and has been
41	Name of Pathologist			3288225 Provide the name of the Pathologist that reviewed and prescreened the top slide and provided the information for all previous sections.
42	Date of Pathologist Review			3288224 Provide the date of the pathology prescreening review performed by the TSS pathologist above.
43	Number of Days from Date of Initial Pathologic Diagnosis to Date of Pathological Review			3288497 Provide the number of days from the date the patient was initially diagnosed pathologically with the disease described on this form to the date of the pathological review performed as part of the submission process for TCGA.  Note: 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.
44	Percent Tumor Nuclei meets TCGA metrics?	Yes No		3288520 Confirm that the malignant sample submitted to the BCR meets the current tumor nuclei metrics for TCGA.  Note: Check with the BCR to confirm the current acceptable TCGA metrics.
45	Percent Tumor Necrosis meets TCGA metrics?	Yes No		3288524 Confirm that the malignant sample submitted to the BCR meets the current necrosis metrics for TCGA.  Note: Check with the BCR to confirm the current acceptable TCGA metrics.
46	De-Identified Pathology Report Submitted?	Yes No		3288292 Confirm that a de-identified pathology report will be sent to BCR prior to or with the shipment of the physical samples.
47	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	Yes (skip related question below).		3288300 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.  Note: The diagnosis is considered to be consistent if at least one of the following criteria are met:  1) Diagnosis on the CQCF is identical to the pathology report for the tumor being sent to the BCR.

Question #	Data Element Label	Data Entry Alternatives	CDE ID With Working Instructions	
	pathology report?		2) Diagnosis on the CQCF includes at least one of the subtypes listed on the pathology report and all subtypes on the pathology report are acceptable for TCGA.  3) Diagnosis on the CQCF is "histology, NOS" (i.e. Adenocarcinoma, NOS) and the pathology report lists a specific subtype within the same histological group.  4) 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.	
48	If the diagnosis on this form is not consistent with the provided pathology report, indicate the reason for the inconsistency.	☐ Macrodissection performed at TSS to select for region containing an acceptable TCGA diagnosis ☐ Pathology analysis at TSS determined a specific histological subtype different from original pathology report (see note at right) ☐ Pathology review of frozen section for TCGA determined histological subtype different from the pathology report (see note at right)	3288315 If the diagnosis provided on this form is not consistent with the diagnosis found on the patient's pathology report for the tumor being submitted for TCGA, specify a reason for this inconsistency.  Note: If a TSS pathology review of the TCGA committed sample resulted in a different histological subtype than what is documented on the 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	
49	History of Neo- Adjuvant Treatment to Tumor Specimen Submitted for TCGA	□ No □ Radiation Prior to Sample Procurement □ Pharmaceutical Treatment Prior to Sample Procurement □ Both Pharmaceutical and Radiation Treatment Prior to Sample Procurement	3382737 Indicate whether the patient received therapy for this cancer prior to sample procurement of the tumor submitted for TCGA. If the patient did receive treatment for this cancer prior to procurement, the TSS should contact the BCR for further instructions.  Note: Systemic treatment and certain localized therapies (those administered to the same site as the TCGA submitted tissue) given prior to procurement of the sample submitted for TCGA are exclusionary.	
50	Has the Patient Had Any Prior Cancer Diagnosed?	<ul><li>□ No</li><li>□ History of Prior Malignancy</li><li>□ History of Synchronous / Bilateral Malignancy</li></ul>	Indicate whether the patient has a history of prior malignancies.  Note 1: If this question cannot be answered because the answer is unknown, the case will be excluded from TCGA.  Note 2: If the patient has any history of prior malignancies, 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. If the patient has a history of multiple diagnoses of basal and/or squamous cell skin cancers, complete an "Other Malignancy Form" for the first diagnosis for each of these types.	
51	Consent Status	Consented Deceased Exemption 4 Waiver	3288361 Indicate whether the patient was formally consented, consented by death, or if the case has an exemption or waiver for consent  Note: Either the Date of Consent or the Date of Death must be provided to qualify.	
Date of Consent				
52	Month of Consent	□□ (мм)	3081955 If the patient was formally consented, provide the month of consent.  Note: Do not answer this question if the patient consented by death only.	
53	Day of Consent	□□ (DD)	3081957 If the patient was formally consented, provide the day of consent.  Note: Do not answer this question if the patient consented by death only.	
54	Year of Consent		3081959	

Question #	Data Element Label	Data Entry Alternatives	CDE ID With Working Instructions		
			If the patient was formally consented, provide the year of		
			consent.		
			Note: Do not answer this question if the patient		
			consented by death only. 3288498		
			If the patient formally consented, provide the number of		
	Number of Days from		days from the date the patient was initially diagnosed		
	Date of Initial		pathologically with the disease described on this form to		
55	Pathologic diagnosis		the date of the patient's formal consent.		
	to Date of Consent		Note: 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.		
Date of Death	1 		T		
			2897026		
56	Month of Death		If the patient consented by death, provide the month of death.		
30	World of Death	ШШ (MM)	Note: If the patient formally consented, only supply the		
			date the patient consent.		
			2897028		
			If the patient consented by death, provide the day of		
57	Day of Death		death		
			Note: If the patient formally consented, only supply the		
			date the patient consent.		
			2897030		
58	Year of Death		If the patient consented by death, provide the year of death.		
36	real of Death		Note: If the patient formally consented, only supply the		
			date the patient consent.		
			3288499		
			If the patient consented by death, provide the number of		
	Number of Days from Date of Initial Pathologic diagnosis to Date of Death		days from the date the patient was initially diagnosed		
			pathologically with the disease described on this form to		
			the date of the patient's death.		
59			Note 1: 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.  Note 2: If the patient formally consented prior to death,		
			do not answer this question. Only answer the question		
			above that asks for the number of days between the date		
			of diagnosis and the date of the patient consent.		
Comments:					
Principal Investigator Name: Principal Investigator Signature:					
•					
		Date Signed (MM/DD/	/YYYY):		